CMS Manual System

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Department of Health & Human Services (DHHS)

Centers for Medicare & Medicaid Services (CMS)

Transmittal 169- Advanced Copy

Date:

SUBJECT: Revision to State Operations Manual (SOM) Appendix PP for Phase 2, F-Tag Revisions, and Related Issues

I. SUMMARY OF CHANGES: The revisions to the Centers for Medicare & Medicaid Services (CMS) Requirements for Participation under the Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities Final Rule caused many of the prior regulatory citations to be re-designated. As such, CMS was required to re-number the F-Tags used to identify each regulatory part. Those new F-Tags are described here

NEW/REVISED MATERIAL - EFFECTIVE DATE: Month XX, 2017
IMPLEMENTATION: Month XX,, 2017

Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (*N/A if manual not updated.*)
(R = REVISED, N = NEW, D = DELETED) – (*Only One Per Row.*)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	Entire Appendix, New F-Tags

III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2016 operating budgets.

IV. ATTACHMENTS:

	Business Requirements
X	**Manual Instruction**
	Confidential Requirements
	One-Time Notification
	Recurring Update Notification

***Unless otherwise specified, the effective date is the date of service.**

Effective November 28, 2017

State Operations Manual

State Operations Manual
Appendix PP - Guidance to Surveyors for Long Term Care Facilities
Table of Contents

(Rev. XXX, XX-XX-17)

Transmittals for Appendix PP

INDEX

§483.5 Definitions
§483.10 Resident Rights
§483.12 Freedom from Abuse, Neglect, and Exploitation
§483.15 Admission Transfer and Discharge Rights
§483.20 Resident Assessment
§483.21 Comprehensive Person-Centered Care Planning
§483.24 Quality of Life
§483.25 Quality of Care
§483.30 Physician Services
§483.35 Nursing Services
§483.40 Behavioral health services
§483.45 Pharmacy Services
§483.55 Dental Services
§483.60 Food and Nutrition Services
§483.65 Specialized Rehabilitative Services
§483.70 Administration
§483.75 Quality Assurance and Performance Improvement
§483.80 Infection Control
§483.85 Compliance and Ethics Program
§483.90 Physical Environment
§483.95 Training Requirements

Effective November 28, 2017

NOTE: *In the regulation text that is noted under the following-Tags : F540, F584, F620-623, F625, F757, F774, F842, and F868, there were minor, technical inaccuracies (spelling, cross-references, etc.) in the 2016 Final Rule that updated the Requirements of Participation. In an effort to ensure clarity of understanding of the guidance, the instructions to surveyors, and the determining of compliance, we have made the appropriate correction in this guidance document. This document is not intended to replace, modify or otherwise amend the regulatory text. Such revisions, modifications or amendments can only be made through a Correction Notice or other rulemaking that would be published in the Federal Register.*

F540
§483.5 Definitions.
As used in this subpart, the following definitions apply:

Abuse. Abuse is the willful infliction of injury, unreasonable confinement, intimidation, or punishment with resulting physical harm, pain or mental anguish. Abuse also includes the deprivation by an individual, including a caretaker, of goods or services that are necessary to attain or maintain physical, mental, and psychosocial well-being. Instances of abuse of all residents, irrespective of any mental or physical condition, cause physical harm, pain or mental anguish. It includes verbal abuse, sexual abuse, physical abuse, and mental abuse including abuse facilitated or enabled through the use of technology. Willful, as used in this definition of abuse, means the individual must have acted deliberately, not that the individual must have intended to inflict injury or harm.

Adverse event. An adverse event is an untoward, undesirable, and usually unanticipated event that causes death or serious injury, or the risk thereof.

Common area. Common areas are areas in the facility where residents may gather together with other residents, visitors, and staff *or engage in individual pursuits, apart from their residential rooms. This includes but is not limited to living rooms, dining rooms,* activity rooms, *outdoor areas,* and meeting rooms where residents are located on a regular basis.

Composite distinct part.
(1) Definition. A composite distinct part is a distinct part consisting of two or more non-contiguous components that are not located within the same campus, as defined in §413.65(a)(2) of this chapter.
(2) Requirements. In addition to meeting the requirements of specified in the definition of "distinct part" of this section, a composite distinct part must meet all of the following requirements:
(i) A SNF or NF that is a composite of more than one location will be treated as a single distinct part of the institution of which it is a distinct part. As such, the composite distinct part will have only one provider agreement and only one provider number.
(ii) If two or more institutions (each with a distinct part SNF or NF) undergo a change of ownership, CMS must approve the existing SNFs or NFs as meeting the requirements before they are considered a composite distinct part of a single institution. In making such a determination, CMS considers whether its approval or disapproval of a composite distinct part promotes the effective and efficient use of

public monies without sacrificing the quality of care. If there is a change of ownership of a composite distinct part SNF or NF, the assignment of the provider agreement to the new owner will apply to all of the approved locations that comprise the composite distinct part SNF or NF.

(iii) To ensure quality of care and quality of life for all residents, the various components of a composite distinct part must meet all of the requirements for participation independently in each location.

(iv) To ensure quality of care and quality of life for all residents, the various components of a composite distinct part must meet all of the requirements for participation independently in each location.

(v) Use of composite distinct parts to segregate residents by payment source or on a basis other than care needs is prohibited.

Distinct part

(1) Definition. A distinct part SNF or NF is physically distinguishable from the larger institution or institutional complex that houses it, meets the requirements of this paragraph and of paragraph (2) of this definition, and meets the applicable statutory requirements for SNFs or NFs in sections 1819 or 1919 of the Act, respectively. A distinct part SNF or NF may be comprised of one or more buildings or designated parts of buildings (that is, wings, wards, or floors) that are: In the same physical area immediately adjacent to the institution's main buildings; other areas and structures that are not strictly contiguous to the main buildings but are located within close proximity of the main buildings; and any other areas that CMS determines on an individual basis, to be part of the institution's campus. A distinct part must include all of the beds within the designated area, and cannot consist of a random collection of individual rooms or beds that are scattered throughout the physical plant. The term "distinct part" also includes a composite distinct part that meets the additional requirements specified in the definition of "composite distinct part" of this section.

(2) Requirements. In addition to meeting the participation requirements for long-term care facilities set forth elsewhere in this subpart, a distinct part SNF or NF must meet all of the following requirements:

(i) The SNF or NF must be operated under common ownership and control (that is, common governance) by the institution of which it is a distinct part, as evidenced by the following:

(A) The SNF or NF is wholly owned by the institution of which it is a distinct part.

(B) The SNF or NF is subject to the by-laws and operating decisions of common governing body.

(C)The institution of which the SNF or NF is a distinct part has final responsibility for the distinct part's administrative decisions and personnel policies, and final approval for the distinct part's personnel actions.

(D) The SNF or NF functions as an integral and subordinate part of the institution of which it is a distinct part, with significant common resource usage of buildings, equipment, personnel, and services.

(ii)The administrator of the SNF or NF reports to and is directly accountable to the management of the institution of which the SNF or NF is a distinct part.

(iii) The SNF or NF must have a designated medical director who is responsible for implementing care policies and coordinating medical care, and who is directly accountable to the management of the institution of which it is a distinct part.
(iv) The SNF or NF is financially integrated with the institution of which it is a distinct part, as evidenced by the sharing of income and expenses with that institution, and the reporting of its costs on that institution's cost report.
(v) A single institution can have a maximum of only one distinct part SNF and one distinct part NF.
(vi) (A) An institution cannot designate a distinct part SNF or NF, but instead must submit a written request with documentation that demonstrates it meets the criteria set forth above to CMS to determine if it may be considered a distinct part.
(B) The effective date of approval of a distinct part is the date that CMS determines all requirements (including enrollment with the fiscal intermediary (FI)) are met for approval, and cannot be made retroactive.
(C) The institution must request approval from CMS for all proposed changes in the number of beds in the approved distinct part.

Exploitation. Exploitation means taking advantage of a resident for personal gain through the use of manipulation, intimidation, threats, or coercion.

Facility defined. For purposes of this subpart, facility means a skilled nursing facility (SNF) that meets the requirements of section s1819(a), (b), (c), and (d) of the Act, or a nursing facility (NF) that meets the requirements of sections 1919(a), (b), (c), and (d) of the Act. "Facility" may include a distinct part of an institution (as defined in paragraph (b) of this section and specified in §440.40 and §440.155 of this chapter), but does not include an institution for individuals with intellectual disabilities or persons with related conditions described in §440.150 of this chapter. For Medicare and Medicaid purposes (including eligibility, coverage, certification, and payment), the "facility" is always the entity that participates in the program, whether that entity is comprised of all of, or a distinct part of, a larger institution. For Medicare, an SNF (see section 1819(a)(1) of the Act), and for Medicaid, and NF (see section 1919(a)(1) of the Act) may not be an institution for mental diseases as defined in §435.1010 of this chapter.

Fully sprinklered. A fully sprinklered long term care facility is one that has all areas sprinklered in accordance with National Fire Protection Association 13 "Standard for the Installation of Sprinkler Systems" without the use of waivers or the Fire Safety Evaluation System.

Licensed health professional. A licensed health professional is a physician; physician assistant; nurse practitioner; physical, speech, or occupational therapist; physical or occupational therapy assistant; registered professional nurse; licensed practical nurse; or licensed or certified social worker; or registered respiratory therapist or certified respiratory therapy technician.

Major modification means the modification of more than 50 percent, or more than 4,500 square feet, of the smoke compartment.

Effective November 28, 2017

Misappropriation of resident property means the deliberate misplacement, exploitation, or wrongful, temporary, or permanent use of a resident's belongings or money without the resident's consent.

Mistreatment means inappropriate treatment or exploitation of a resident.

Neglect is the failure of the facility, its employees or service providers to provide goods and services to a resident that are necessary to avoid physical harm, pain, mental anguish, or emotional distress.

Nurse aide. A nurse aide is any individual providing nursing or nursing-related services to residents in a facility. This term may also include an individual who provides these services through an agency or under a contract with the facility, but is not a licensed health professional, a registered dietitian, or someone who volunteers to provide such services without pay. Nurse aides do not include those individuals who furnish services to residents only as paid feeding assistants as defined in §488.301 of this chapter.

Person-centered care. For purposes of this subpart, person-centered care means to focus on the resident as the locus of control and support the resident in making their own choices and having control over their daily lives.

Resident representative. For purposes of this subpart, the term resident representative means any of the following:

- ***(1) An individual chosen by the resident to act on behalf of the resident in order to support the resident in decision-making; access medical, social or other personal information of the resident; manage financial matters; or receive notifications;***
- ***(2) A person authorized by State or Federal law (including but not limited to agents under power of attorney, representative payees, and other fiduciaries) to act on behalf of the resident in order to support the resident in decision-making; access medical, social or other personal information of the resident; manage financial matters; or receive notifications; or***
- ***(3) Legal representative, as used in section 712 of the Older Americans Act; or***
- ***(4) The court-appointed guardian or conservator of a resident.***
- ***(5) Nothing in this rule is intended to expand the scope of authority of any resident representative beyond that authority specifically authorized by the resident, State or Federal law, or a court of competent jurisdiction.***

Sexual abuse is non-consensual sexual contact of any type with a resident.

Transfer and discharge includes movement of a resident to a bed outside of the certified facility whether that bed is in the same physical plant or not. Transfer and discharge does not refer to movement of a resident to a bed within the same certified facility.

F550
***§483.10*(a) Resident Rights.**

Effective November 28, 2017

The resident has a right to a dignified existence, self-determination, and communication with and access to persons and services inside and outside the facility, *including those specified in this section.*

§483.10(a)(1) **A facility must *treat each resident with respect and dignity and care for each resident* in a manner and in an environment that promotes maintenance or enhancement *of his or her* quality of life, *recognizing each resident's individuality. The facility must protect and promote the rights of the resident.***

§483.10(a)(2) The facility must provide equal access to quality care regardless of diagnosis, severity of condition, or payment source. A facility must establish and maintain identical policies and practices regarding transfer, discharge, and the provision of services under the State plan for all residents regardless of payment source.

§483.10(b) **Exercise of Rights.**
The resident has the right to exercise his or her rights as a resident of the facility and as a citizen or resident of the United States.

§483.10(b)(1) The facility must ensure that the resident can exercise his or her rights without interference, coercion, discrimination, or reprisal from the facility.

§483.10(b)**(2) The resident has the right to be free of interference, coercion, discrimination, and reprisal from the facility in exercising his or her rights *and to be supported by the facility in the exercise of his or her rights as required under this subpart.***

INTENT §§483.10(a)-(b)(1)&(2)
All residents have rights guaranteed to them under Federal and State laws and regulations. This regulation is intended to lay the foundation for the resident rights requirements in long-term care facilities. Each resident has the right to be treated with dignity and respect. All activities and interactions with residents by any staff, temporary agency staff or volunteers must focus on assis*ting* the resident *in* maintain*ing* and enhanc*ing* his or her self-esteem and self-worth *and incorporating the resident's, goals, preferences, and choices.* When providing care and services, *staff must respect each resident's individuality, as well as honor and value their input.*

GUIDANCE §§483.10(a)-(b)(1)&(2)
Examples *of treating residents with dignity and respect include, but are not limited to:*

- Encouraging and assisting residents to dress in their own clothes*, rather than hospital-type gowns, and appropriate footwear for* the time of day and individual preferences;
- *Placing labels on* each resident's clothing in a way that *is inconspicuous and* respects his or her dignity (*for example,* placing labeling on the inside of shoes and clothing *or using a color coding system*);
- Promoting resident independence and dignity *while* dining, such as avoid*ing*:
  - *Daily* use of *disposable* cutlery and dishware;
  - Bibs *or* clothing protectors instead of napkins (except by resident choice);
  - *Staff s*tanding over residents while assisting them to eat;

  - *Staff i*nteracting/conversing only with each other rather than with residents while assisting *with meals;*
- *Protecting and valuing residents'* private space (*for example,* knocking on doors and requesting permission *before entering*, closing doors as requested by the resident*);*
- *Staff should* address residents with *the* name *or pronoun* of the resident's choice, avoid*ing the* use of labels for residents such as "feeders" *or "walkers." Residents should* not *be* exclud*ed* from conversations *during activities or when care is being provided, nor should staff* discuss residents *in settings where* others can overhear private or protected information *or document in charts/electronic health records where others can see a resident's information*;
- Refraining from practices demeaning to residents such as *leaving* urinary catheter bags uncovered, refusing to comply with a resident's request for *bathroom* assistance during meal times, and restricting residents from use of common areas open to the general public such as lobbies and restrooms, unless they are on transmission-based isolation precautions or are restricted according to their care planned needs.

*C*onsider the resident's life style and personal choices *identified through their assessment processes* to obtain a picture of *his or her* individual needs and preferences.

Staff and volunteers must interact with residents in a *manner* that takes into account the physical limitations of the resident, assures communication, and maintains respect. *F*or example, getting down to eye level with a resident who is sitting, *maintaining eye contact when speaking with* a resident with limited hearing*, or* utilizing a hearing amplification device *when needed by a resident*.

Pay close attention to resident or staff interactions that may represent deliberate actions to limit a resident's autonomy or choice. These actions may indicate abuse. See F600, Free from Abuse, for guidance.

The facility must not *establish policies or practices that* hamper, compel, treat differently, or retaliate against a resident for exercising his or her rights.

Justice Involved Residents
"Justice involved residents" *includes the following three categories:*

1. ***Residents under the care of law enforcement:*** *Residents who have been taken into custody by law enforcement. Law enforcement includes local and state police, sheriffs, federal law enforcement agents, and other deputies charged with enforcing the law.*
2. ***Residents under community supervision:*** *Residents who are on parole, on probation, or required to conditions of ongoing supervision and treatment as an alternative to criminal prosecution by a court of law.*
3. ***Inmates of a public institution:*** *Residents currently in custody and held involuntarily through operation of law enforcement authorities in an institution, which is the responsibility of a governmental unit or over which a governmental unit exercises administrative control, such as state or federal prisons, local jails, detention facilities, or other penal settings (such as boot camps, wilderness camps).*

Effective November 28, 2017

Justice involved individuals are entitled to the same rights described in 42 CFR Part 483, Subpart B as all other residents residing in the facility. The facility shall not establish policies or impose conditions on the justice involved resident that result in restrictions which violate the resident's rights. Some Department of Corrections or law enforcement terms of release or placement may conflict with CMS requirements. If the facility accepts responsibility for enforcing restrictive law enforcement terms applied to a resident that are contrary to the Requirements for LTC Facilities, the facility would not be in compliance with federal long term care requirements. In addition, law enforcement jurisdictions may not be integrated with the operations of the facility.

While all portions of 42 CFR Part 483, Subpart B, apply to justice involved individuals, other areas where there may be concerns specific to this population are found at §483.12, F600, Abuse, Neglect, and Exploitation and §483.15(c), F622, Transfer and discharge. In such a case, surveyors should cite under the specific tag associated with the concern identified. For example, if there is a concern about a facility restricting visitors of a justice involved individual, cite such deficiency under §483.10(f)(4)(vi), F564, Resident Right to Visitors.

See Survey & Certification Memorandum 16-21-ALL dated May 3, 2016 (Revised 12/23/16) for additional guidance on justice involved individuals.

PROCEDURES §483.10(a)-(b)(1)&(2)

Deficient practices cited under Resident rights tags may also have negative psychosocial outcomes for the resident. The survey team must consider the potential for both physical and psychosocial harm when determining the scope and severity of deficiencies related to dignity. *Refer to the Psychosocial Outcome Severity Guide in Appendix P.*

Surveyors shall make frequent observations on different shifts, units, floors or neighborhoods to watch interactions between and among residents and staff. If there are concerns that staff or others are not treating a resident with dignity or respect or are attempting to limit a resident's autonomy or freedom of choice, follow-up as appropriate by interviewing the resident, family, or resident representative.

- Observe if staff show respect for each resident and treat them as *an* individual.
- Do staff respond in a timely manner to the resident's requests for assistance?
- Do *staff* explain to the resident what care *is being provided* or where they are taking the resident? *Is the resident's appearance consistent with his or her preferences and in a manner that maintains his or her dignity*?
- *Do staff know the resident's specific needs and preferences?*
- *Do staff make efforts to understand the preferences of those residents, who are not able to verbalize them, due to cognitive or physical limitations?*

Determine if staff members respond to residents with cognitive impairments *in a manner that facilitates communication and allows the resident the time to respond appropriately.* For example, a resident with dementia may be attempting to exit the building *with the intent* to meet her*/his* children at the school bus. *W*alking with the resident without challenging or disputing the

resident's intent and conversing with the resident about the desire (tell me about your children) may reassure *the resident in a manner consistent with the requirements of 483.10(a) and (b)*.

Examples of noncompliance may include, but are not limited to:

- *A resident has not been treated equally as compared to others based on his or her diagnosis, severity of condition, or payment source.*
- *Prohibiting* a resident *from* participat*ing* in group activities *as a form of reprisal or discrimination. This includes prohibiting a resident from group activities without clinical justification or evaluation of the impact the resident's participation has on the group.*
- *A resident's rights, not addressed elsewhere (for example, religious expression, voting, or freedom of movement outside the facility in the absence of a legitimate clinical need) are impeded in some way by facility staff.*
- Requiring residents to seek approval to *post, communicate or* distribute information about the facility *(for example, social media, letters to the editor of a newspaper).*
- *Acting on behalf of the pertinent law enforcement or criminal justice supervisory authority by enforcing supervisory conditions or reporting violations of those conditions to officials for justice involved residents.*

POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION

For deficiencies regarding lack of visual privacy for a resident while that resident is receiving *treatment or* ADL care from staff in the bedroom, bathroom, or bathing room, *r*efer to §483.10(e), *F583*, Privacy and Confidentiality.

For deficiencies regarding a resident's lack of self-determination to make decisions about things that are important in his or her life, refer to §§483.10(f)(1)-(3), (8), F561, Self-determination.

For deficiencies related to failure to keep residents' faces, hands, *teeth,* fingernails, hair, and clothing clean, refer to *§483.24(a)(2), F677*, Activities of Daily Living (ADLs).

If there are indications that a resident is in a secured/locked area without a clinical justification and/or placement is against the will of the resident, their family, and/or resident representative, review regulatory requirements at §483.12 and §483.12(a), F603, Involuntary Seclusion.

F551

§483.10(b)(3)* In the case of a resident who has not been adjudged incompetent *by the state court, the resident has the right to designate a representative*, in accordance with State law and any legal surrogate *so* designated may exercise the resident's rights to the extent provided by *s*tate law. *The same-sex spouse of a resident must be afforded treatment equal to that afforded to an opposite-sex spouse if the marriage was valid in the jurisdiction in which it was celebrated.

(i) The resident representative has the right to exercise the resident's rights to the extent those rights are delegated to the representative.

(ii) The resident retains the right to exercise those rights not delegated to a resident representative, including the right to revoke a delegation of rights, except as limited by State law.

Effective November 28, 2017

§483.10(b)(4) The facility must treat the decisions of a resident representative as the decisions of the resident to the extent required by the court or delegated by the resident, in accordance with applicable law.

§483.10(b)(5) The facility shall not extend the resident representative the right to make decisions on behalf of the resident beyond the extent required by the court or delegated by the resident, in accordance with applicable law.

§483.10(b)(6) If the facility has reason to believe that a resident representative is making decisions or taking actions that are not in the best interests of a resident, the facility shall report such concerns when and in the manner required under State law.

§483.10(b)(7) **In the case of a resident adjudged incompetent under the laws of a State by a court of competent jurisdiction, the rights of the resident *devolve to and* are exercised by *the resident representative* appointed under State law to act on the resident's behalf. *The court-appointed resident representative exercises the resident's rights to the extent judged necessary by a court of competent jurisdiction, in accordance with State law.***

- ***(i) In the case of a resident representative whose decision-making authority is limited by State law or court appointment, the resident retains the right to make those decisions outside the representative's authority.***
- ***(ii) The resident's wishes and preferences must be considered in the exercise of rights by the representative.***
- ***(iii) To the extent practicable, the resident must be provided with opportunities to participate in the care planning process.***

DEFINITIONS §§483.10(b)(3)-(7)

"Court of competent jurisdiction" *means any court with the authority to hear and determine a case or suit with the matter in question.*

"Resident representative" *For purposes of this subpart, the term resident representative may mean any of the following:*

1. *An individual chosen by the resident to act on behalf of the resident in order to support the resident in decision-making; access medical, social or other personal information of the resident; manage financial matters; or receive notifications;*
2. *A person authorized by State or Federal law (including but not limited to agents under power of attorney, representative payees, and other fiduciaries) to act on behalf of the resident in order to support the resident in decision-making; access medical, social or other personal information of the resident; manage financial matters; or receive notifications; or*
3. *Legal representative, as used in section 712 of the Older Americans Act; or*
4. *The court-appointed guardian or conservator of a resident.*
5. *Nothing in this rule is intended to expand the scope of authority of any resident representative beyond that authority specifically authorized by the resident, State or Federal law, or a court of competent jurisdiction.*

Effective November 28, 2017

GUIDANCE §§483.10(b)(3)-(7)

When reference is made to "resident" in the *Guidance*, it also refers to any person who may, under State law, act on the resident's behalf when the resident is unable to act for themselves. That person is referred to as the resident representative. If the resident has been formally declared incompetent by a court, the representative is who*m*ever the court appoints *(for example,* a guardian or conservator*)*.

A *competent* resident may wish to delegate decision-making to specific persons, or the resident and family may have agreed among themselves on a decision-making process. To the degree permitted by State law, the facility *staff* must respect the *delegated resident representative's decisions regarding the* resident's wishes and *preferences so long as the resident representative is acting within the scope of authority contemplated by the agreement authorizing the person to act as the resident's representative*.

In the case of a resident who has been formally declared incompetent by a court, *a court appointed resident representative may be assigned. Facility staff must confer with the appointed resident representative.*

State laws and court orders authorizing guardians, conservators, etc., vary considerably. Many statutes and court orders limit the scope of the authority of the representative to act on behalf of the resident.

Facility staff must obtain documentation that the resident's representative *has been delegated* the necessary authority *to exercise the resident's rights and must* verify that a court-appointed representative has the necessary authority for the decision-making at issue *as determined by the court*. For example, a court-appointed *representative* might have the power to make financial decisions, but not health care decisions. *Additionally, the facility must make reasonable efforts to ensure that it has access to documentation of any change related to the delegation of rights, including a resident's revocation of delegated rights, to ensure that the resident's preferences, are being upheld.*

Whether a resident has or has not been judged incompetent by a court of law, if it is determined that the resident understands the risks, benefits, and alternatives to proposed health care and expresses a preference, then the resident's wishes should be considered to the degree practicable, including resident input into the care planning process.

The involvement of a representative does not relieve facility *staff* of *their* duty to protect and promote the resident's interests. For example, a representative does not have the right to insist that a treatment be performed that is not medically appropriate *or* reject *a* treatment *that* may be subject to State law. *Surveyors must confirm delegation of resident rights to a resident representative. Surveyors must also determine, through interview and record reviews, whether or not the resident's delegation of rights has been followed by facility staff.*

If a resident's representative is a same-sex spouse, he or she must be treated the same as an opposite-sex spouse with regard to exercising the resident's rights. In Obergefell v. Hodges, 576 U.S.___ (2015), the Supreme Court of the United States also ruled that all States must recognize

a marriage between two people of the same sex when their marriage was lawfully licensed and performed out-of-state.

PROCEDURES §483.10(b)(3)-(7)
Surveyors must check whether there has been a delegation of resident rights or designation of a resident representative. Surveyors must also determine, through interview and record reviews, whether or not the resident's delegation of rights has been followed by facility staff.

Determine through interview and record review if the resident has been found to be legally incompetent by a court in accordance with state law.

If yes:

- *Verify the appropriate legal documentation for a court-appointed resident representative is present in the resident's medical record.*
- *Review court orders or other legal documentation to determine the extent of the court-appointed resident representative's authority to make decision on behalf of the resident and any limitations on that authority that may have been ordered by the court.*
- *Determine if the court-appointed representative is making decisions for the resident beyond the scope of the resident representative's decision-making authority and the facility is relying on that authority as the basis of a practice (e.g., health care treatment, managing resident funds, discharge decision). If so, a deficiency may be cited under this regulation.*
- *Determine if the resident was involved in care planning activities and able to make choices, to the extent possible.*
- *Observe resident care and daily activities (e.g., participation in activities) for adherence to resident's or court-appointed resident representative's goals, choices, and preferences. Even when there is a court-appointed resident representative, the facility should seek to understand the resident's goals, choices, and preferences and have honored them to the extent legally possible.*

If no:

- *Determine how decisions are being made for the resident. Does the resident maintain all of his/her rights, even if he/she has designated a representative to assist with decision-making unless a court has limited those rights under state law, and only to the extent that has been specified by a court under state law? Has the resident designated a resident representative and is facility staff respecting the authority of this designate surrogate decision-maker to act on behalf of the resident?*
- *Are all residents informed of their plan of care or treatment in the most understandable manner possible, and given an opportunity to voice their views? Autonomy is also expressed through gestures and actions and this also should be recognized. Residents even without capacity or declared incompetent may be able to express their needs and desires.*
- *Determine whether same-sex spouses are treated in the same manner as an opposite-sex spouse in all states and territories.*
- *If the resident has delegated a resident representative, verify the appropriate documentation is present in the resident's medical record.*

Effective November 28, 2017

KEY ELEMENTS OF NONCOMPLIANCE §§483.10(b)(3)-(7)
To cite deficient practice at F551, the surveyor's investigation will generally show that the facility failed to do any one or more of the following:

- *Ensure a competent resident's choice for a representative is honored* ***or***
- *Ensure that treatment of a same-sex spouse was the same as treatment of an opposite-sex spouse;* ***or***
- *Ensure the resident representative did not make decisions beyond the extent allowed by the court or delegated by the resident;* ***or***
- *Ensure the resident's wishes and preferences were considered when decisions were made by the resident representative;* ***or***
- *Ensure the decisions of the resident representative are given the same consideration as if the resident made the decision themselves;* ***or***
- *Honor the resident's authority to exercise his or her rights, even when he or she has delegated those rights, including the right to revoke a delegation of rights;* ***or***
- *Ensure the resident representative was reported as State law required when not acting in the best interest of the resident;* ***or***
- *Ensure a resident who was found incompetent by the court is provided with opportunities to participate in the care planning process.*

F552
§483.10(c) **Planning and Implementing Care.**
The resident has the right to be informed of, and participate in, his or her treatment*, including:*

§483.10(c)(1) **The right to be fully informed in language that he or she can understand of his or her total health status, including but not limited to, his or her medical condition.**

§483.10(c)(4) **The right to be informed, in advance, *of the* care *to be furnished and the type of care giver or professional that will furnish care.***

§483.10(c)(5) The right to be informed in advance, by the physician or other practitioner or professional, of the risks and benefits of proposed care, of treatment and treatment alternatives or treatment options and to choose the alternative or option he or she prefers.

DEFINITIONS §483.10(c)(1), (4)-(5)
"Total health status" *includes functional status, nutritional status, rehabilitation and restorative potential, ability to participate in activities, cognitive status, oral health status, psychosocial status, and sensory and physical impairments.*

"Treatment" *refers to medical care, nursing care, and interventions provided to maintain or restore health and well-being, improve functional level, or relieve symptoms.*

GUIDANCE §§483.10(c)(1), (4)-(5)
*Health i*nformation *and services* must be *provided* in *ways* that *are easy for* the resident and/or the resident's representative *to* understand. This includes, *but is not limited to, communicating in*

plain language, explaining technical and medical terminology in a way that makes sense to the resident, offering language assistance services to residents who have limited English proficiency, and providing qualified sign language interpreters or auxiliary aids if hearing is impaired. This does not mean that a facility is required to supply and pay for hearing aids.

The physician or other practitioner or professional must inform the resident *or their representative in advance of treatment risks and benefits, options, and alternatives. The* information *should be* communicated at times it would be most useful to them, such as when they are expressing concerns, raising questions, *or when a change in treatment is being proposed*. *The resident or resident representative has the right to choose the option he or she prefers.*

Discussion and documentation of the resident's choices regarding future health care may take place during the development of the initial comprehensive assessment and care plan and periodically thereafter.

> ***NOTE:*** *While surveyors must only cite F552 when deficient practice is found related to applicable program requirements as reflected in the CFR, the following information may inform surveyors about important considerations in making compliance decisions.* The Federal Patient Self - Determination Act contained in Public Law 101-508 is the authority on an individual's rights and facility responsibilities related to *a*dvance *d*irectives. This includes, the right of an individual to direct his or her own medical treatment, including withholding or withdrawing life-sustaining treatment. *If there are concerns with advance directives, refer to §483.10(g)(12), F578.*

See §483.21(a), F655 (Baseline Care Plans), Comprehensive Person-Centered Care Planning, for additional guidance.

F553

§483.10(c)(2) **The right to participate in** ***the development and implementation of his or her person-centered plan of care, including but not limited to:***

- ***(i) The right to participate in the planning process, including the right to identify individuals or roles to be included in the planning process, the right to request meetings and the right to request revisions to the person-centered plan of care.***
- ***(ii) The right to participate in establishing the expected goals and outcomes of care, the type, amount, frequency, and duration of care, and any other factors related to the effectiveness of the plan of care.***
- ***(iii)*** **The right to be informed, in advance, of changes** ***to the plan of care.***
- ***(iv) The right to receive the services and/or items included in the plan of care.***
- ***(v) The right to see the care plan, including the right to sign after significant changes to the plan of care.***

§483.10***(c)(3) The facility shall inform the resident of the right to participate in his or her treatment and shall support the resident in this right. The planning process must—***

- ***(i) Facilitate the inclusion of the resident and/or resident representative.***
- ***(ii) Include an assessment of the resident's strengths and needs.***

(iii) Incorporate the resident's personal and cultural preferences in developing goals of care.

INTENT §483.10(c)(2)-(3)
To ensure facility staff facilitates the inclusion of the resident or resident representative in all aspects of person-centered care planning and that this planning includes the provision of services to enable the resident to live with dignity and supports the resident's goals, choices, and preferences including, but not limited to, goals related to the their daily routines and goals to potentially return to a community setting.

GUIDANCE §483.10(c)(2)-(3)
*R*esidents *and their representative(s) must be* afforded the opportunity *to participate in their care planning process and to be included in* decisions and changes in care*,* treatment*,* and/*or interventions*. This applies both to initial decisions about care and treatment, as well as the refusal of care or treatment. *Facility staff must support and encourag*e *participation* in the care planning process. *This may include ensuring that* residents, families, or representatives understand the *comprehensive* care planning process*,* holding care planning meetings at the time of day when a resident is functioning best*, providing sufficient notice in advance of the meeting, scheduling these meetings to accommodate a resident's representative (such as conducting the meeting in-person, via a conference call, or video conferencing), and* planning enough time for information exchange and decision making.

A resident has the right to *select or* refuse specific treatments options before the care plan is instituted, *based on the information provided as required under §§483.10(c)(1), (4)-(5), F552*. While Federal regulations affirm a resident's right to participate in care planning and to refuse treatment, the regulations do not *require the facility to provide* specific medical intervention*s* or treatment*s requested by the resident, family, and/or resident representative* that the *resident's physician* deems inappropriate *for the resident's medical condition.*

A resident whose ability to make decisions about care and treatment is impaired, or a resident who has been declared incompetent by a court, must, to the extent practicable, be kept informed and be consulted on personal preferences.

The resident has the right to see the care plan and sign after significant changes are made.

PROCEDURES §§483.10(c)(2)-(3)
During observations, interviews, and record reviews, surveyors must:

- *Interview the resident, and/or his or her representative to determine the level of participation in care planning.*
- *Identify ways staff involve residents and/or their representative(s) in care planning.*
- *Determine if care plan meetings are scheduled to accommodate residents and/or their representative.*
- *Determine how facility staff addressed questions or concerns raised by a resident or his or her representative, including if they are addressed at times when it would be beneficial to the resident, such as when they are expressing concerns or raising questions.*

- *Determine if the resident and representative were unable to participate, did facility staff consult them in advance about care and treatment changes.*
- *Interview staff to determine how they inform residents or their representative of their rights and incorporate their personal preferences, choices, and goals into their care plan.*
- *When the resident request is something that facility staff feels would place the individual at risk (i.e., the resident chooses not to use the walker, recommended by therapy), is there a process in place to examine the risk/benefit and guide decision-making?*
- *Review the resident's medical record to determine if facility staff included an assessment of the resident's strengths and needs and whether these, as well as the resident's personal and cultural preferences, were incorporated when developing his or her care plan.*
- *Determine how facility staff observes and responds to the non-verbal communication of a resident who is unable to verbalize preferences (i.e., if the resident spits out food, is this considered to be a choice and alternative meal options offered).*

POTENTIAL TAGS FOR ADDITIONAL CONSIDERATION
If facility staff do not provide access to the care plan within 24 hours (excluding weekends and holidays) or provide, if requested, a copy of the care plan in written or electronic form within two working days of the request, see §§483.10(g)(2)-(3), F573, Right to Access/Purchase Copies of Records.

If facility staff do not provide a summary of the baseline care plan to the resident and their representative, see §483.21(a), F655, Baseline Care Plans.

Also refer to §483.21(b), F656, Comprehensive Care Plans for more information on Care Plans.

F554
§483.10*(c)(7) The right to* self-administer *medications* if the interdisciplinary team, as defined by §483.*21(b)(2)(ii),* has determined that this practice is *clinically appropriate.*

GUIDANCE §483.10(c)(7)
If a resident requests *to* self-administer *medication(s)*, it is the responsibility of the interdisciplinary team *(IDT) (as defined in §483.21(b), F657, Comprehensive Care Plans)* to determine that it is safe before the resident exercise*s* that right. A resident may only self-administer medications after the *IDT* has determined *which medications may be self-administered.*

When determining if self-administration is clinically appropriate for a resident, the IDT should at a minimum consider the following:
- *The medications appropriate and safe for self-administration;*
- *The resident's physical capacity to swallow without difficulty and to open medication bottles;*
- *The resident's cognitive status, including their ability to correctly name their medications and know what conditions they are taken for;*

- *The resident's capability to follow directions and tell time to know when medications need to be taken;*
- *The resident's comprehension of instructions for the medications they are taking, including the dose, timing, and signs of side effects, and when to report to facility staff.*
- *The resident's ability to understand what refusal of medication is, and appropriate steps taken by staff to educate when this occurs.*
- *The resident's ability to ensure that medication is stored safely and securely.*

Appropriate notation of these determinations *must* be *documented* in the resident's *medical record and* care plan. *If a resident is self-administering medication, review the resident's record to verify that this decision was made by the IDT, including the resident.* The decision that a resident has the ability to self-administer medication is subject to periodic *assessment* by the *IDT*, based on change*s* in the resident's *medical and decision-making* status. *If self-administration is determined not to be safe, the IDT should consider, based on the assessment of the resident's abilities, options that allow the resident to actively participate in the administration of their medications to the extent that is safe (i.e., the resident may be assessed as not able to self-administer their medications because they are not able to manage a locked box in their room, but they may be able to get the medications from the nurse at a designated location and then safely self-administer them).*

Medication errors occurring with residents who self-administer should not be counted in the facility's medication error rate and should not be cited at ***§****483.45(f)(1) F759 and* ***§****483.45(f)(2) F760, Medication Errors. However, this may* call into question the judgment *of facility staff* in allowing self-administration *of medication* for *that* resident.

PROCEDURES AND PROBES §483.10(c)(7)
Determine that facility staff have a process to demonstrate that the resident has taken the self-administered medication.

- *Ask residents if they requested to self-administer medications and if they received a response.*
- *How do staff determine if a resident is able to safely self-administer medications?*
- *If the interdisciplinary team has determined that the resident can safely self-administer medications, was this request honored?*

If the interdisciplinary team was not involved in determining whether the self-administration of medications was clinically appropriate, cite here at F554. If other concerns related to care planning are identified, see guidance at §483.21, Comprehensive Person-Centered Care Planning.

F555
§483.10(d) **Choice of Attending Physician.**
The resident has the right to choose *his or her* attending physician.

§483.10(d)(1) The physician must be licensed to practice, and

Effective November 28, 2017

§483.10(d)(2) If the physician chosen by the resident refuses to or does not meet requirements specified in this part, the facility may seek alternate physician participation as specified in paragraphs (d)(4) and (5) of this section to assure provision of appropriate and adequate care and treatment.

§483.10(d)(3) **The facility must** ***ensure that*** **each resident** ***remains informed*** **of the name, specialty, and way of contacting the physician** ***and other primary care professionals*** **responsible for his or her care.**

§483.10(d)(4) The facility must inform the resident if the facility determines that the physician chosen by the resident is unable or unwilling to meet requirements specified in this part and the facility seeks alternate physician participation to assure provision of appropriate and adequate care and treatment. The facility must discuss the alternative physician participation with the resident and honor the resident's preferences, if any, among options.

§483.10(d)(5) If the resident subsequently selects another attending physician who meets the requirements specified in this part, the facility must honor that choice.

DEFINITIONS ***§§483.10(d)(1)-(5)***
"Attending physician" *refers* to the primary physician *who* is responsible for managing the resident's medical care. This does not include other physicians whom the resident may see periodically, such as specialists.

GUIDANCE §§483.10(d)(1)-(5)
The right to choose a personal physician does not mean that a resident is required to do so. It also does not mean that the physician the resident chose is obligated to provide service to the resident. *If a resident or his or her representative declines to designate a personal physician or* if a physician of the resident's choosing fails to fulfill *their responsibilities*, as *specified in §483.30, F710, Physician Services, or elsewhere as required in these regulations,* facility *staff may choose another physician after informing the resident or the resident's representative*. Before consulting an alternate physician, the medical director *must have a discussion with* the attending physician. Only after a failed attempt to work with the attending physician or mediate differences *may* facility *staff* request an alternate physician.

*F*acility *staff* may not interfere in the process by which a resident chooses his or her physician. If a resident does not have a physician, or if the resident's physician becomes unable or unwilling to continue providing care to the resident, facility *staff* must assist the resident or the resident's representative in finding a replacement.

If it is a condition for admission to a *nursing home contained within a C*ontinuing *C*are *R*etirement *Community (CCRC),* the requirement for free choice is met if a resident chooses a personal physician from among those who have practice privileges at the *CCRC*.

A resident in a distinct part of a general acute care hospital may choose his or her own physician. If the hospital requires that physicians *who supervise* residents in the distinct part have privileges, then the resident cannot choose a physician who lacks them.

Effective November 28, 2017

PROBES §483.10(d)(1)-(5)

- *Through interviews with facility staff and residents and/or their representatives, determine how residents or their representative are informed of and are supported in:*
  - *His or her right to choose a physician;*
  - *How to contact their physician and other primary care professionals responsible for their care;*
  - *His or her options to choose an alternate physician or other primary care professional.*
- *If his or her physician is unable or not willing to provide necessary care and services, determine if facility staff worked with the resident to choose another physician.*

F556
This tag number is in reserve for future use and there will be no citations under this tag.

F557
§483.10(e) **Respect and Dignity.**
The resident has a right to be treated with respect and dignity, including:

§483.10(e)(2) The right to retain and **use personal possessions,** ***including furnishings, and clothing, as space permits, unless to do so would infringe upon the rights or health and safety of other residents.***

INTENT ***§483.10(e)(2)***
All residents' possessions, regardless of their apparent value to others, must be treated with respect.

GUIDANCE §483.10(e)(2)
The right to retain and use personal possessions *promotes a homelike environment and supports each resident in maintaining their independence.*

If residents' rooms have few personal possessions, ask residents, *their* families*, or representative(s), as well as* the local ombudsman if:

- Residents are encouraged to have and to use them; *and*
- *Residents may choose to retain personal possessions.*

PROCEDURES §483.10(e)(2)
If facility staff refused to allow a resident to retain his or her personal possession(s), determine if such a restriction was appropriate due to insufficient space, protection of health and safety, and maintaining other resident rights, and whether the reason for the restriction was communicated to the resident.

Examples of noncompliance may include, but are not limited to:

- *Residents, their representatives, or family members have been discouraged from bringing personal items to the facility.*

- *A decision to refuse to allow a resident to retain any personal belongings was not based on space limitations or on a determination that the rights, health or safety of other residents would be infringed.*

F558
§483.10(e)(3) The right to **reside and receive services in the facility with reasonable accommodation of** ***resident*** **needs and preferences except when** ***to do so would endanger*** **the health or safety of the** ***resident*** **or other residents.**

INTENT §483.10(e)(3)
The accommodation of resident needs and preferences is essential to creating an individualized, home-like environment.

DEFINITIONS §483.10(e)(3)
"Reasonable accommodation of resident needs and preferences" *means the facility's efforts to individualize the resident's physical environment.*

GUIDANCE §483.10(e)(3)
Reasonable accommodation(s) of resident needs and preferences includes*, but is not limited to,* individualizing the physical environment of the resident's bedroom and bathroom, as well as individualizing *common living areas* as much as feasible. *These reasonable accommodations may* be directed toward assisting the resident in maintaining and/or achieving independent functioning, dignity, and well-being to the extent possible in accordance with the resident's own needs and preferences.

The environment must reflect the unique needs and preferences *of each resident* to the extent reasonable and does not endanger the health or safety of individuals or other residents.

Common areas frequented by residents should accommodate residents' physical limitations. Furnishings in common areas *may* enhance residents' abilities to maintain their independence. *Resident* seating *should have* appropriate seat height, depth, firmness, and with arms that assist residents to independently rise to a standing position. *Functional furniture must be arranged to accommodate residents' needs and preferences*.

PROCEDURES §483.10(e)(3)
Observe resident*s in their* room*s* and common areas and interview resident*s,* if possible*,* to determine if their environment accommodate*s their* needs and preferences. Observe staff/resident interactions to determine if staff *interact in a manner* that a resident with limited sight or hearing can see and hear them. Determine if staff keep needed items within the resident's reach and provide necessary assistance to help maintain the resident's independen*ce*. Determine if the resident has the call system within reach and is able to use it if desired.

Examples of noncompliance may include, but are not limited to:

- *Storing a wheelchair or other adaptive equipment out of reach of a resident who is otherwise able to use them independently, such as a wheelchair stored across the room*

for a resident who is able to self-transfer or storing eyeglasses out of reach for a resident.

- *Having areas of worship inaccessible to residents with mobility limitations.*
- *Not providing a riser on a toilet to maintain independence.*

F559

§483.10(e)(4) **The right to share a room with his or her spouse when married residents live in the same facility and both spouses consent to the arrangement.**

§483.10(e)(5) The right to share a room with his or her roommate of choice when practicable, when both residents live in the same facility and both residents consent to the arrangement.

§483.10(e)**(6) The right to receive *written* notice, *including the reason for the change,* before the resident's room or roommate in the facility is changed.**

GUIDANCE §483.10(e)(4)-(6)

Residents have the right to share a room with whomever they wish, as long as both residents are in agreement. These arrangements could include opposite-sex and same-sex married couples or domestic partners, siblings, or friends.

There are some limitations to these rights. Residents do not have the right to demand that a current roommate is displaced in order to accommodate the couple that wishes to room together. In addition, residents are not able to share a room if one of the *residents* has a different payment source for which the facility is not certified (if the room is in a distinct part *of the facility*, unless one of the *residents* elects to pay *privately* for his or her care) *or one of the individuals is not eligible to reside in a nursing home*.

Moving to a new room or changing roommates is challenging for residents. A resident's preferences should be taken into account when considering such changes. When a resident is being moved at the request *of facility staff, the resident, family, and/or resident representative must receive an* explana*tion in writing of why the* move *is required. The resident should be provided* the opportunity to see the new location*,* meet the new roommate, and ask questions about the move.

A resident receiving a new roommate should *be* give*n* as much *advance* notice *as possible. The resident* should *be* support*ed when a* roommate passe*s* away by providing time to adjust before moving another person into the room. The length of time needed to adjust may differ depending upon the resident. *F*acility *staff* should provide necessary social services for a resident who is grieving over the death of a roommate.

If the survey team identifies potential compliance issues related to social services, refer to §483.*40(d), F745,* Social Services.

F560

§483.10(e)(7) **The right to refuse to transfer to another room in the facility, if the purpose of the transfer is:**

(i) ***to relocate*** **a resident of a SNF from the distinct part of the institution that is a SNF to a part of the institution that is not a SNF, or**
(ii) ***to relocate*** **a resident of a NF from the distinct part of the institution that is a NF to a distinct part of the institution that is a SNF.**
(iii) solely for the convenience of staff.

§483.10(e)(8) **A resident's exercise of the right to refuse transfer does not affect the resident's eligibility or entitlement to Medicare or Medicaid benefits.**

DEFINITIONS §483.10(e)(7)-(8)
"Campus": *Under §413.65(a)(2), "Campus means the physical area immediately adjacent to the provider's main buildings, other areas and structures that are not strictly contiguous to the main buildings but are located within 250 yards of the main buildings, and any other areas determined on an individual case basis, by the CMS regional office, to be part of the provider's campus."*

"Composite distinct part": *Under §483.5, a composite distinct part is a type of distinct part SNF or NF consisting of two or more noncontiguous components that are not located within the same campus, as that term is defined in §413.65(a)(2).*

"Distinct Part": *A distinct part SNF or NF is part of a larger institution or institutional complex. The distinct part SNF or NF is physically distinguishable from the larger institution or complex and may be comprised of one or more buildings or parts of buildings (such as wings, wards, or floors). Distinct part SNFs or NFs must be immediately adjacent or in close proximity to the institution's main buildings. CMS may determine, on an individual basis that other areas are part of the institution's campus and considered to be a distinct part SNF or NF. A distinct part SNF or NF must include all of the beds within the designated area, and cannot consist of a random collection of individual rooms or beds that are scattered throughout the physical plant. The term "distinct part" also includes composite distinct part SNFs or NFs. Additional requirements specific to distinct part SNFs or NFs are found at §483.5.*

GUIDANCE §483.10(e)(7)-(8)
A resident can decline relocation from a room in one *institution's* distinct part *SNF or NF* to a room in another *institution's* distinct part *SNF or NF* for purposes of obtaining Medicare or Medicaid eligibility. *Facility staff are responsible for notifying the resident or resident representative of changes in eligibility for Medicare or Medicaid covered services and of what the resident's financial responsibility may be.* If the resident is unable to pay for those services, then after giving the resident a *discharge* notice, *the resident may be* transferr*ed* or discharge*d* under the provisions of §483.*15(b), F621, Equal Access to Quality Care.*

When a resident occupies a bed in a distinct part NF that *is certified to* participate in Medicaid *only* and not in Medicare, he or she may not be moved involuntarily *(or required to be moved by the State) from that distinct part NF* to another part of the *larger* institution *(e.g., hospital or intermediate care facility for individuals with intellectual disabilities) that houses the distinct part* solely for the purpose of assuring *eligibility for* Medicare payments. Such moves are only appropriate *only* when they occur at the request of a resident.

A resident also has the right to refuse transfer if that transfer is solely for the convenience of staff. For example, a resident may experience a change in condition that requires additional care. Facility staff may wish to move the resident to another room with other residents who require a similar level of services, because it is easier for staff to care for residents with similar needs. The resident would have the right to stay in his or her room and refuse this transfer.

PROBES §483.10(e)(7)-(8)

For residents moved between Medicare or Medicaid approved distinct parts:

- Was the resident moved to a different room because of a change in payment source *or staff convenience*?
- Did facility *staff* give the resident the opportunity to refuse the transfer?

POTENTIAL TAGS FOR ADDITIONAL CONSIDERATION

- *42 CFR §483.10(e)(6), F559, Notification of Roommate Change.*
  - *Determine if the resident received prior notification of a room change.*
- *42 CFR §483.10(g)(17), F582, Medicare/Medicaid Coverage.*
  - *Determine if the resident was notified of changes in eligibility for Medicare or Medicaid covered services, what the resident's financial responsibility may be, and their appeal rights.*
- *For additional guidance regarding admission to, discharges, or transfers from a SNF or NF, including bed-hold policies and therapeutic leave, see §483.15, F620 Admission, Transfer, and Discharge Rights.*

F561

§483.10(f) Self-determination.

The resident has the right to and the facility must promote and facilitate resident self-determination through support of resident choice, including but not limited to the rights specified in paragraphs (f)(1) through (11) of this section.

§483.10(f)(1) The resident has a right to **choose activities, schedules** ***(including sleeping and waking times),*** **health care and** ***providers of health care services*** **consistent with his or her interests, assessments, and plan of care and** ***other applicable provisions of this part.***

§483.10(f)(2) The resident has a right to **make choices about aspects of his or her life in the facility that are significant to the resident.**

§483.10(f)(3) The resident has a right to **interact with members of the community** ***and participate in community activities*** **both inside and outside the facility.**

§483.10(f)(8) The resident has a right to participate in other activities, including **social, religious, and community activities that do not interfere with the rights of other residents in the facility.**

Effective November 28, 2017

INTENT ***§483.10(f)(1)-(3), (8)***
The intent of this requirement is to *ensure* that *each resident has* the *opportunity* to exercise his or her autonomy regarding *those things that are* important *in* his or her life. This includes the residents' interests and preferences.

GUIDANCE §483.10(f)(1)-(3), (8)
It is important *for* residents to have *a* choice *about which activities they* participate in, whether they are part of the formal activities program or self-directed. *Additionally, a resident's needs and choices for how he or she spends time, both inside and outside the facility, should also be supported and accommodated, to the extent possible, including making transportation arrangements.*

Residents have the right to *choose* their schedules, consistent with their interests, assessments, and *care* plans. *This* includes, but is not limited to, choices *about* the schedules that are important to the resident, such as waking, eating, bathing, and going to bed at night. *Choices about schedules and ensuring that residents are able to get enough sleep is an important contributor to overall health and well-being.* Residents *also* have the right to choose health care schedules consistent with their interests and preferences, and *information* should *be* gather*ed to proactively assist residents with the fulfillment of their choices*. *Facilities must not develop a schedule for care, such as waking or bathing schedules, for staff convenience and without the input of the residents.*

Examples that demonstrate the support and accommodation of resident goals, preferences, and choices include, but are not limited to:

- *If a resident shares that attendance at family gatherings or external community events is of interest to them, the resident's goals of attending these events should be accommodated, to the extent possible.*
- *If a resident mentions that his or her therapy is scheduled at the time of a favorite television program, the resident's preference should be accommodated, to the extent possible.*
- *If a resident refuses a bath because he or she prefers a shower or a different bathing method, such as in-bed bathing, prefers to bathe at a different time of day or on a different day, does not feel well that day, is uneasy about the aide assigned to help or is worried about falling, the resident's preferences must be accommodated.*

PROCEDURES §§483.10(f)(1)-(3), (8)
During interviews with residents or their family and/or representative(s), determine if they are given the opportunity to choose and whether facility staff accommodate his or her preferences for:

- *Activities that interest them;*
- *Their sleep cycles;*
- *Their bathing times and methods;*
- *Their eating schedule;*
- *Their health care options; and*
- *Any other area significant to the resident.*

Effective November 28, 2017

Interview facility staff about what the resident's goals, preferences, and choices are and the location of that information. Interview facility staff to determine how they sought information from the resident's family and/or representative(s) regarding a resident's preferences and choices for residents who are unable to express their choices. Additionally, the resident's preferences should be accommodated by facility staff and reflected through adjustments in the care plan.

Ask the social worker or other appropriate staff how they help residents pursue activities outside the facility.

Examples of noncompliance may include, but are not limited to:

- *Residents are not given the opportunity to choose activities that interest them.*
- *Facility staff have a set schedule for waking residents or putting residents in bed, without consideration of resident preference.*
- *Facility staff have a practice of showering all residents when a bath is available and preferred by a resident.*
- *Residents are not afforded the opportunity to choose among offered healthcare options.*
- *Restriction of any one of these rights are placed on any resident, including a justice involved resident solely based on their status as a justice involved individual, without consideration of how exercising their rights affected the rights of other residents.*

POTENTIAL TAGS FOR ADDITIONAL CONSIDERATION

- *If other concerns are identified regarding justice involved residents, see §483.10(a), F550, Resident Rights for further guidance.*
- For issues regarding *a resident's accommodation of needs*, see §483.*10(e)(3),* F*558.*
- *For issues related to resident visitation, see §§483.10(f)(4)(ii)-(v), F563.*
- *If it is determined a resident's preferences is not honored due to possible concerns with insufficient numbers of staff or staff competencies, see §483.35(a), F725, Sufficient Nursing Staff.*

F562

§483.10(f)(4)(i) **The facility must provide immediate access to any resident by:**

(A) Any representative of the Secretary,

(B) Any representative of the State,

(C) Any representative of the Office of the **State long term care ombudsman, (established under section** ***712*** **of the Older Americans Act of 1965,** ***as amended 2016 (42 U.S.C. 3001 et seq.),***

(D) The resident's individual physician,

(E) Any representative of the **protection and advocacy systems,** ***as designated by the state, and as*** **established under the Developmental Disabilities Assistance and Bill of Rights Act** ***of 2000 (42 U.S.C. 15001 et seq),***

(F) Any representative of the **agency responsible for the protection and advocacy system** ***for*** **individuals with** ***mental disorder*** **(established under the Protection and Advocacy for Mentally Ill Individuals Act** ***of 2000 (42 U.S.C. 10801 et seq.), and***

(G) The resident representative.

Effective November 28, 2017

GUIDANCE §483.10(f)(4)(i)
The facility must provide immediate access to the resident by the resident's physician, representative, and various state and federal officials and organizations as outlined in the regulation, which would include state and federal surveyors.

Surveyors are considered representatives of the Secretary and/or the State. Facility staff cannot prohibit surveyors from talking to residents, family members, and resident representatives.

***NOTE**: If facility staff attempt to interfere with the survey process and restrict a surveyor's ability to gather necessary information to determine compliance with requirements, surveyors should consult with the CMS Regional Office.*

F563
§483.10(f)(4) The resident has a right to receive visitors of his or her choosing at the time of his or her choosing, subject to the resident's right to deny visitation when applicable, and in a manner that does not impose on the rights of another resident.

- ***(ii) The facility must provide immediate access to a resident by*** **immediate family and other relatives of the resident,** ***subject to the*** **resident's right to deny or withdraw consent at any time;**
- ***(iii) The facility must provide immediate access to a resident by others who are visiting with the consent of the resident*****, subject to reasonable** ***clinical and safety*** **restrictions and the resident's right to deny or withdraw consent at any time;**
- ***(iv)*** **The facility must provide reasonable access to a resident by any entity or individual that provides health, social, legal, or other services to the resident, subject to the resident's right to deny or withdraw consent at any time;** ***and***
- ***(v) The facility must have written policies and procedures regarding the visitation rights of residents, including those setting forth any clinically necessary or reasonable restriction or limitation or safety restriction or limitation, when such limitations may apply consistent with the requirements of this subpart, that the facility may need to place on such rights and the reasons for the clinical or safety restriction or limitation.***

DEFINITIONS ***§483.10(f)(4)(ii)-(v)***
"Reasonable ***clinical and safety*** **restrictions"** *include a facility's policies, procedures* or *practices* that protect the *health and* security of all residents *and staff. These may include, but are not be limited to:*

- *Restrictions placed to prevent community-associated infection or communicable disease transmission to the resident. A resident's risk factors for infection (e.g., immunocompromised condition) or current health state (e.g., end-of-life care) should be considered when restricting visitors. In general, visitors with signs and symptoms of a transmissible infection (e.g., a visitor is febrile and exhibiting signs and symptoms of an influenza-like illness) should defer visitation until he or she is no longer potentially infectious (e.g., 24 hours after resolution of fever without antipyretic medication). If deferral cannot occur such as the case of end-of-life, the visitor should follow respiratory hygiene/cough etiquette as well as other infection prevention and control practices such as appropriate hand hygiene.*

- Keeping the facility locked *or secured* at night *with a system in place for allowing visitors approved by the resident*;
- Denying access or providing limited and supervised access to an individual if that individual *is suspected of abusing, exploiting, or coercing a resident until an investigation into the allegation has been completed or* has been *found* to be abusing, exploiting, or coercing a resident;
- Denying access to individuals who have been found to have been committing criminal acts such as theft; or
- Denying access to individuals who are inebriated *or* disruptive.

GUIDANCE §483.10(f)(4)(ii)-(v)

For purposes of this regulation, immediate family is not restricted to individuals united by blood, adoptive, or marital ties, or a State's common law equivalent. It is important to understand that there are many types of families, each of which being equally viable as a supportive, caring unit. For example, it might also include a foster family where one or more adult serves as a temporary guardian for one or more children to whom they may or may not be biologically related. Residents have the right to define their family. During the admissions process, facility staff should discuss this issue with the resident. If the resident is unable to express or communicate whom they identify as family, facility staff should discuss this with the resident's representative.

Resident's family members are not subject to visiting hour limitations or other restrictions ***not imposed by the resident.*** With the consent of the resident, facilities must provide 24-hour access to other non-relative visitors, *subject to reasonable clinical and safety restrictions.*

If these visitation rights infringe upon the rights of other residents, facility staff must find a location other than a resident's room for visits. For example, if a resident's family visits in the late evening when the resident's roommate is asleep, then the visit should take place somewhere other than their shared room so that the roommate is not disturbed.

Individuals who provide health, social, legal, or other services to the resident have the right of reasonable access to the resident. *F*acility *staff must provide space and privacy for such visits.*

PROCEDURES §483.10(f)(4)(ii)-(v)

- *Through interviews with residents, their representative, family members, visitors and others as permitted under this requirement, determine if they* know that they are able to visit 24-hours a day, subject to *a resident's choice* and reasonable restrictions as defined above.
- *Review the facility's written visitation policy and procedures to determine whether they support the resident's right to visitors and whether they explain those situations where visitors may be restricted due to clinical or safety concerns.*
- If *a concern is identified*, *interview facility staff* to determine how they ensure 24-hour *or immediate access as permitted under these requirements.*

Examples of noncompliance may include, but are not limited to:

- *Facility staff restrict visitors according to the facility's convenience.*

- *Facility staff restrict the rights of a resident to receive visitors, even though this would not affect the rights of other residents.*
- *Facility staff restrict visitors based on expressed wishes of an individual who is a health care power of attorney who does not have the authority to restrict visitation.*
- *A posting or inclusion in the resident handbook or other information provided by the facility, of visiting hours not in compliance with this regulation.*

F564

§483.10(f)(4)(vi) A facility must meet the following requirements:

(A) Inform each resident (or resident representative, where appropriate) of his or her visitation rights and related facility policy and procedures, including any clinical or safety restriction or limitation on such rights, consistent with the requirements of this subpart, the reasons for the restriction or limitation, and to whom the restrictions apply, when he or she is informed of his or her other rights under this section.

(B) Inform each resident of the right, subject to his or her consent, to receive the visitors whom he or she designates, including, but not limited to, a spouse (including a same-sex spouse), a domestic partner (including a same-sex domestic partner), another family member, or a friend, and his or her right to withdraw or deny such consent at any time.

(C) Not restrict, limit, or otherwise deny visitation privileges on the basis of race, color, national origin, religion, sex, gender identity, sexual orientation, or disability.

(D) Ensure that all visitors enjoy full and equal visitation privileges consistent with resident preferences.

GUIDANCE §483.10(f)(4)(vi)

All residents have the right to visitors in accordance to their preferences. The facility policy for restricting or limiting visitors must be communicated to the resident. If limitations are placed on a resident's visitation rights, the clinical or safety reasons for the limitations and the specific individuals the restriction applies to must be communicated to the resident or resident representative in a manner he or she understands.

Facility staff may not place limitations on a resident based solely on their status as a justice involved resident or as a part of restrictive law enforcement requirements, such as conditions of probation or parole. See §483.10(a), F550, Resident Rights for guidance on justice involved residents.

PROCEDURES §483.10(f)(4)(vi)

Through interviews with residents and/or their representatives, determine how they were informed of their visitation rights and related policies and procedures, including their right to consent to receive or deny visitors he or she designates, any clinical or safety restriction, or limitation on such rights imposed by the facility.

Determine if the facility has ensured visitation rights consistent with resident preference.

Effective November 28, 2017

Examples of noncompliance may include, but are not limited to:

- *Prohibiting a resident from having visits from his or her spouse or domestic partner, including a same-sex spouse or partner.*
- *Facility staff did not inform a resident, the family, and/or resident representative of their visitation rights, including any restrictions or limitations of these rights that may be imposed by the facility or the resident, the family, and/or resident representative;*
- *Facility staff denied, limited or restricted a resident's visitation privileges contrary to their choices, even though there were no clinical or safety reasons for doing so.*

F565

§483.10(f)(5) **The resident has a right to organize and participate in resident groups in the facility.**

(i) **The facility must provide a resident or family group, if one exists, with private space;** ***and take reasonable steps, with the approval of the group, to make residents and family members aware of upcoming meetings in a timely manner.***

(ii) **Staff, visitors,** ***or other guests*** **may attend** ***resident group or family group*** **meetings** ***only*** **at the** ***respective*** **group's invitation.**

(iii) **The facility must provide a designated staff person** ***who is approved by the resident or family group and the facility and who is*** **responsible for providing assistance and responding to written requests that result from group meetings.**

(iv) The facility **must** ***consider*** **the views** ***of a resident or family group*** **and act** ***promptly*** **upon the grievances and recommendations** ***of such groups*** **concerning** ***issues of*** **resident care and life in the facility.**

(A) The facility must be able to demonstrate their response and rationale for such response.

(B) This should not be construed to mean that the facility must implement as recommended every request of the resident or family group.

§483.10(f)(6) The resident has a right to participate in family groups.

§483.10(f)(7) The resident has a right to have **family** ***member(s) or other resident representative(s)*** **meet in the facility with the families** ***or resident representative(s)*** **of other residents in the facility.**

DEFINITIONS ***§483.10(f)(5)-(7)***

"A resident or family group" is defined as a group of residents or residents' family members that meets regularly to:

- Discuss and offer suggestions about facility policies and procedures affecting residents' care, treatment, and quality of life;
- Support each other;
- Plan resident and family activities;
- Participate in educational activities; or
- For any other purpose.

Effective November 28, 2017

GUIDANCE §483.10(f)(5)-(7)

This requirement does not require that residents organize a resident or family group. However, whenever residents or their families wish to organize, *they* must *be able* to do so without interference. *Additionally, they* must *be* provide*d* space, privacy for meetings, and staff support. *T*he designated staff person responsible for assistance and liaison between the group and the facility's administration and any other staff members *may* attend the meeting only if *invited by the resident or family group. The resident or family group may meet without staff present*. *The groups should determine how frequently they meet.*

*F*acility *staff are* required to *consider* resident and family group *views* and *act upon* grievances and recommendations. *F*acility *staff* must consider *these* recommendations and attempt to accommodate *them*, to the extent practicable. *This may include* developing *or* changing policies affecting resident care and life. *F*acility *staff should discuss* its decisions *with* the resident and/or family group *and document in writing its response and rationale as required under 42 CFR §483.10(j), F585, Grievances.*

PROCEDURES §483.10(f)(5)-(7)

During the entrance interview, determine:

- *If there is a resident or family group;*
- *Who the resident or family representative is for each of these groups; and,*
- *Who the designated staff person is for assisting and working with each of these groups.*

If residents or their families attempted to organize a group and were unsuccessful, why?

Through interviews with the representatives for the resident and family groups and staff designated for assisting and working with these groups, determine:

- *Are groups able to meet without staff present unless desired?*
- *If a resident wants a family member present during a resident group meeting, how is this handled? Facility staff should not require said family member to leave the group meeting, without the permission of the group.*
- *How views, grievances or recommendations from these groups are considered, addressed and acted upon; and,*
- *How facility staff provide responses, actions, and rationale to the groups.*

Examples of noncompliance may include, but are not limited to:

- *Facility staff impede or prevent residents or family members ability to meet or organize a resident or family group;*
- *Resident and/or families were not always informed in advance of upcoming meetings.*
- *Facility staff impede with meetings and/or operations of family or resident council by mandating that they have a staff person in the room during meetings or assigning a staff person to liaise with the council that is not agreeable to the council;*
- *Private meeting space for these groups is not provided;*
- *The views, grievances or recommendations from these groups have not been considered or acted upon by facility staff;*
- *Facility staff does not provide these groups with responses, actions, and rationale taken regarding their concerns;*

- *Facility staff are not able to demonstrate their response and rationale to grievances;*
- *Facility staff prevent family members or representatives from meeting with those of another resident.*

POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION
For concerns regarding the handling of individual grievances, refer to §483.10(j), F585, Grievances.

F566
§483.10(f)(9) **The resident has a right to choose or refuse to perform services for the facility *and the facility must not require a resident to perform services for the facility. The resident may* perform services for the facility, if he or she chooses, when—**

(i) The facility has documented the resident's need or desire for work in the plan of care;
(ii) The plan specifies the nature of the services performed and whether the services are voluntary or paid;
(iii) Compensation for paid services is at or above prevailing rates; and
(iv) The resident agrees to the work arrangement described in the plan of care.

DEFINITIONS *§483.10(f)(9)*
"Prevailing rate" is the wage paid to *the majority of* workers in the community surrounding the facility for the same type, quality, and quantity of work requiring comparable skills.

GUIDANCE §483.10(f)(9)
All work or services provided by a resident, whether voluntary or paid, must be part of his/her care *plan*. *Any* work assignment must be agreed to *and negotiated* by the resident *or the resident's representative*. The resident also has the right to refuse to *participate in these services or assignments* at any time.

A resident's request *to work or perform services should be discussed by the interdisciplinary team* and be clinically *and psychologically appropriate for the resident*.

PROCEDURES §483.10(f)(9)
- *Through interviews with residents, resident representatives, and staff, determine if residents were given a choice as to whether or not they were willing to perform services.*
- *During observations, note whether* residents *are* engaged in performing these *services (such as* housekeeping, laundry, *meal set up,* etc.).
- *Review the resident's care plan to ensure it includes;*
  - *The nature of the services to be provided, including the resident's desire to do so, and the objectives for this arrangement; and,*
  - *Whether they are provided voluntarily or paid.*

Examples of noncompliance may include, but are not limited to:
- *The resident or his or her representative did not agree to the work arrangements;*

- *The resident's care plan does not specify the nature of the services provided by the resident or whether or not they are voluntary or paid; or*
- *Compensation for paid services is not at or above prevailing rates.*

F567
§483.10(f)(10) **The resident has *a* right to manage his or her financial affairs. *This includes the right to know, in advance, what charges a facility may impose against a resident's personal funds.***

(i) **The facility *must* not require residents to deposit their personal funds with the facility. *If a resident chooses to deposit personal funds with the facility,* upon written authorization of a resident, *the facility must act as a fiduciary of the resident's funds and* hold, safeguard, manage, and account for the personal funds of the resident deposited with the facility, as specified in *this section*.**

(ii) **Deposit of Funds.**

(A) In general: Except as set out in paragraph (f)(l0)(ii)(B) of this section, **the facility must deposit any residents' personal funds in excess of *$100* in an interest bearing account (or accounts) that is separate from any of the facility's operating accounts, and that credits all interest earned on resident's funds to that account. (In pooled accounts, there must be a separate accounting for each resident's share.) The facility must maintain a resident's personal funds that do not exceed *$100* in a non-interest bearing account, interest-bearing account, or petty cash fund.**

(B) Residents whose care is funded by Medicaid: The facility must deposit the residents' personal funds in excess of $50 in an interest bearing account (or accounts) that is separate from any of the facility's operating accounts, and that credits all interest earned on resident's funds to that account. (In pooled accounts, there must be a separate accounting for each resident's share.) The facility must maintain personal funds that do not exceed $50 in a noninterest bearing account, interest-bearing account, or petty cash fund.

INTENT §483.10(f)(10)(i)-(ii)
To assure residents who have authorized the facility in writing to manage any personal funds have ready and reasonable access to those funds.

DEFINITIONS *§483.10(f)(10)(i)-(ii)*
"Hold, safeguard, manage, and account for" means that the facility must act as fiduciary of the resident's funds and report at least quarterly on the status of these funds in a clear and understandable manner. Managing the resident's financial affairs includes money that an individual gives to the facility for the sake of providing a resident with a non-covered service. In these instances, the facility will provide a receipt to the gift giver and retain a copy.

"Interest bearing" means a rate of return equal to or above the rate at local banking institutions in the area. If pooled accounts are used, interest must be prorated per individual on the basis of actual earnings or end-of quarter balance.

Effective November 28, 2017

GUIDANCE §483.10(f)(10)(i)-(ii)

If a resident or resident representative chooses to have the facility manage the resident's funds, facility *staff* may not refuse to handle these funds. *Facility staff are* not expected to be familiar with resident assets not on deposit with *the facility*.

Placement of residents' personal funds of less than *$100.00 ($50.00 for Medicaid residents)* in an interest bearing account is permitted. Thus, a facility may place the total amount of a resident's funds, including funds of *$100.00 ($50.00 for Medicaid residents)* or less, into an interest-bearing account. The law and regulations are intended to assure that residents have access to *$100.00 ($50.00 for Medicaid residents)* in cash within a reasonable period of time, when requested. Requests for less than *$100.00 ($50.00 for Medicaid residents)* should be honored within the same day. Requests for *$100.00 ($50.00 for Medicaid residents)* or more should be honored within three banking days. Although the facility need not maintain *$100.00 ($50.00 for Medicaid residents)* per resident on its premises, it is expected to maintain amounts of petty cash on hand that may be required by residents.

If pooled accounts are used, interest must be prorated per individual on the basis of actual earnings or end-of quarter balance.

Residents should have access to petty cash on an ongoing basis and be able to arrange for access to larger funds. Although the facility need not maintain *$100.00 ($50.00 for Medicaid residents)* per resident on its premises, it is expected to maintain petty cash on hand *to honor resident requests*.

Resident requests for access to their funds should be honored by facility *staff as soon as possible but no later than:*

- The same day for amounts less than *$100.00 ($50.00 for Medicaid residents)*;
- Three banking days for amounts *of $100.00 ($50.00 for Medicaid residents)* or more.

Residents may make requests that the facility temporarily place their funds in a safe place, without authorizing the facility to manage those funds. *The facility must have a system to document the date, time, amount, and who the funds were received from or dispersed to.*

The facility *must have systems in place to safeguard against any* misappropriation of a *resident's* funds.

NOTE: Banks may charge the resident a fee for handling their funds *and pass this fee on to the resident(s)*. Facilities may not charge residents for managing residents' funds because the services are covered by Medicare or Medicaid or by the facility's per diem rate. Monies due residents should be credited to their respective bank accounts within a few business days.

PROCEDURES §§483.10(f)(10)(i)-(ii)

Interview:

- *Residents and/or their representatives to determine if they have experienced problems with the facility's management of their personal funds.*

- *Residents and/or their representatives to determine if they have ready access to their personal funds.*
- *Facility staff to determine how they manage, account for, and safeguard a resident's funds.*

To assure facility staff are not using oral requests by residents as a way to avoid obtaining written authorization to hold, manage, safeguard and account for resident's funds, ensure:

- *Facility staff provide the resident a receipt for these funds and retains a copy for its records.*

Review the facility records for residents selected for a comprehensive review who have authorized the facility to handle their personal funds.

- *Are residents' funds over $100.00 ($50.00 for Medicaid residents) or, at the facility's option, all resident funds, in an interest bearing account(s)?*
- *What procedure was followed when residents requested their funds?*
- *How long does it take for residents to receive: (a) petty cash allotments; (b) funds needing to be withdrawn from bank accounts?*
- *Were limits placed on amounts that could be withdrawn? If yes, was the reason based on resident care needs or facility convenience?*
- *Are funds records treated with privacy as required at F583?*

Examples of noncompliance may include, but are not limited to:

- *Requiring residents to deposit their personal funds with the facility;*
- *Not crediting all interest earned on a resident's funds to the resident's account;*
- *Disbursing the resident's funds to anyone without the resident's or the resident representative's permission;*
- *Not providing a resident access to their funds as soon as possible.*

F568

***§483.10(f)(10)(iii)* Accounting and *R*ecords.**

***(A)* The facility must establish and maintain a system that assures a full and complete and separate accounting, according to generally accepted accounting principles, of each resident's personal funds entrusted to the facility on the resident's behalf.**

***(B)* The system must preclude any commingling of resident funds with facility funds or with the funds of any person other than another resident.**

***(C)* The individual financial record must be available *to the resident* through quarterly statements and upon request.**

GUIDANCE §483.10(f)(10)(iii)

Generally accepted accounting *principles* means that facility *staff* employ proper bookkeeping techniques, by which it can determine, upon request, the amount of individual resident funds and, in the case of an interest bearing account, how much interest these funds have earned for each resident, as last reported by the banking institution to the facility.

Proper bookkeeping techniques include an individual *record* established for each resident on which only those transactions involving his or her personal funds are recorded and maintained.

The record should have information on when transactions occurred, what they were, *and* maintain the ongoing balance for every resident. *For each* transaction, the resident should be given a receipt and the facility retain*s* a copy.

Quarterly statements *must* be provided in writing to the resident or the resident's representative within 30 days after the end of the quarter, and upon request.

PROCEDURES §483.10(f)(10)(iii)
Through interviews with the resident or his or her representative, determine how they receive statements regarding the status of their funds and accounts. If concerns arise based on these interviews, review the facility's records to determine if generally accepted accounting principles are followed. Records must show separate accounting for each resident, including the ongoing balance of each account, as well as the date and amount of any transaction. Additionally, the facility's records must include a copy of all account transactions.

Examples of noncompliance may include, but are not limited to evidence that the facility:

- *Does not* maintain a system that assures a complete and separate accounting of each resident's personal funds.
- *Comingles resident funds with facility funds (for example, comingling an activity fund, volunteer fund, and resident personal funds into one account).*
- *Comingles resident funds with those of someone other than a resident, such as a facility staff member managing a resident's personal funds through the facility staff member's personal bank account.*
- *Does not provide a financial record or quarterly statement to the resident or his or her representative.*

F569
§483.10(f)(10)(iv) Notice of certain balances.
The facility must notify each resident that receives Medicaid benefits—

(A) **When the amount in the resident's account reaches $200 less than the SSI resource limit for one person, specified in section 1611(a)(3)(B) of the Act; and**
(B) **That, if the amount in the account, in addition to the value of the resident's other nonexempt resources, reaches the SSI resource limit for one person, the resident may lose eligibility for Medicaid or SSI.**

§483.10(f)(10)(v) Conveyance upon discharge, eviction, or death.
Upon the *discharge, eviction, or* death of a resident with a personal fund deposited with the facility, the facility must convey within 30 days the resident's funds, and a final accounting of those funds, *to the resident, or in the case of death,* the individual or probate jurisdiction administering the resident's estate, *in accordance with State law.*

PROCEDURES §483.10(f)(10)(iv)-(v)

- As part of closed record review, determine if within 30 days of *discharge, eviction,* or death, facility *staff* conveyed the resident's personal funds and a final accounting to the individual or probate jurisdiction administering the individual's estate as provided by State law.

- *Through interviews with the resident or his or her representative, determine if they lost their SSI or Medicaid eligibility and whether this loss was a result of the facility's staff failure to notify them as required in this regulation.*

F570
§483.10(f)(10)(vi) Assurance of financial security.
The facility must purchase a surety bond, or otherwise provide assurance satisfactory to the Secretary, to assure the security of all personal funds of residents deposited with the facility.

DEFINITION ***§483.10(f)(10)(vi)***
"Surety bond" is an agreement between the principal (the facility), the surety (the insurance company), and the obligee (depending on State law, either the resident or the State acting on behalf of the resident), wherein the facility and the insurance company agree to compensate the resident (or the State on behalf of the resident) for any loss of residents' funds that the facility holds, safeguards, manages, and accounts for.

GUIDANCE §483.10(f)(10)(vi)
The purpose of the surety bond is to guarantee that the facility will pay the resident (or the State on behalf of the resident) for losses occurring from any failure by the facility to hold, safeguard, manage, *or* account for the resident's funds *(for example,* losses occurring as a result of acts or errors of negligence, incompetence, or dishonesty*)*. The surety bond protects the resident or the State, not the facility, from loss. *It* differs from a fidelity bond, which covers no acts or errors of negligence, incompetence, or dishonesty. The surety bond is the commitment of the facility in an objective manner that the facility will hold, safeguard, manage and account for the *personal* funds residents have *deposited with* the facility. The facility assumes the responsibility to compensate the *resident or the State* for the amount of the loss up to the entire amount of the surety bond.

The surety bond is not limited to personal needs allowance funds. Any resident funds that are entrusted to the facility for a resident must be covered by the surety bond, including refundable deposit fees.

The facility cannot be named as a beneficiary.

Self-insurance is not an acceptable alternative to a surety bond. Likewise, funds deposited in bank accounts protected by the Federal Deposit Insurance Corporation, or similar entity, also are not acceptable alternatives.

PROCEDURES §483.10(f)(10)(vi)
Through interviews with residents or their representative, determine if they were compensated for losses occurring from any failure by facility staff to hold, safeguard, manage, or account for the residents' funds (for example, losses occurring as a result of acts or errors of negligence, incompetence, or dishonesty). If concerns arise based on these interviews, review the facility's records to determine whether these concerns are substantiated.

If the State survey agency determines that individual circumstances associated with a facility's surety bond or its alternative are such that the survey agency cannot determine whether or not the facility is in compliance with the*se* requirements, then it would be appropriate to make the referral to the State's fiscal department.

If a corporation has a surety bond that covers all of its facilities, there should be a separate review of the corporation's surety bond by the appropriate State agency, such as the State's fiscal department, to ensure that all the residents in the corporation's facilities within *that* State are covered against any losses due to acts or errors by the corporation or any of its facilities. The focus of the review should be to ensure that if the corporation were to go bankrupt or otherwise cease to operate, the funds of the residents in the corporation's facilities would be protected.

F571

§483.10(f)(11) **The facility *must* not impose a charge against the personal funds of a resident for any item or service for which payment is made under Medicaid or Medicare (except for applicable deductible and coinsurance amounts).**

The facility may charge the resident for requested services that are more expensive than or in excess of covered services in accordance with §489.32 of this chapter. (This does not affect the prohibition on facility charges for items and services for which Medicaid has paid. See §447.15 of this chapter, which limits participation in the Medicaid program to providers who accept, as payment in full, Medicaid payment plus any deductible, coinsurance, or copayment required by the plan to be paid by the individual.)

(i) Services included in Medicare or Medicaid payment. During the course of a covered Medicare or Medicaid stay, facilities *must* not charge a resident for the following categories of items and services:

(A) Nursing services as required at *§483.35.*

(B) Food and Nutrition services as required at §483.60.

(C) An activities program as required at *§483.24(c).*

(D) Room/bed maintenance services.

(E) Routine personal hygiene items and services as required to meet the needs of residents, including, but not limited to, hair hygiene supplies, comb, brush, bath soap, disinfecting soaps or specialized cleansing agents when indicated to treat special skin problems or to fight infection, razor, shaving cream, toothbrush, toothpaste, denture adhesive, denture cleaner, dental floss, moisturizing lotion, tissues, cotton balls, cotton swabs, deodorant, incontinence care and supplies, sanitary napkins and related supplies, towels, washcloths, hospital gowns, over the counter drugs, hair and nail hygiene services, bathing *assistance,* and basic personal laundry.

(F) Medically-related social services as required at *§483.40(d).*

(G) Hospice services elected by the resident and paid for under the Medicare Hospice Benefit or paid for by Medicaid under a state plan.

(ii) Items and services that may be charged to residents' funds. *Paragraphs (f)(11)(ii)(A) through (L) of this section* are general categories and examples of items and services that the facility may charge to residents' funds if they are requested by a resident, *if they are not required to achieve the goals stated in the resident's care plan,* if the

facility informs the resident that there will be a charge, and if payment is not made by Medicare or Medicaid:

(A) Telephone, *including a cellular phone.*

(B) Television/radio, *personal computer or other electronic device* for personal use.

(C) Personal comfort items, including smoking materials, notions and novelties, and confections.

(D) Cosmetic and grooming items and services in excess of those for which payment is made under Medicaid or Medicare.

(E) Personal clothing.

(F) Personal reading matter.

(F) Gifts purchased on behalf of a resident.

(H) Flowers and plants.

(I) Cost to participate in* social events and entertainment outside the scope of the activities program, provided under *§483.24(c).

(J) Non-covered special care services such as privately hired nurses or aides.

(K) Private room, except when therapeutically required (for example, isolation for infection control).

(L) Except as provided in (e)(11)(ii)(L)(1) and (2) of this section,* specially prepared or alternative food requested instead of the food *and meals* generally prepared by the facility, as required by *§483.60.

(1) The facility may not charge for special foods and meals, including medically prescribed dietary supplements, ordered by the resident's physician, physician assistant, nurse practitioner, or clinical nurse specialist, as these are included per §483.60.

(2) In accordance with §483.60(c) through (f), when preparing foods and meals, a facility must take into consideration residents' needs and preferences and the overall cultural and religious make-up of the facility's population.

(iii) Requests for items and services.

(A) The facility *can only* charge a resident for any *non-covered* item or service *if such item or service is specifically requested by the resident.*

(B) The facility must not require a resident to request any item or service as a condition of admission or continued stay.

(C) The facility must inform*, orally and in writing*, the resident requesting an item or service for which a charge will be made that there will be a charge for the item or service and what the charge will be.

GUIDANCE §483.10(f)(11)

Residents must not be charged for universal items such as *computers, telephones, television services or other electronic devices, books, magazines* or newspaper subscriptions intended for use by *all residents*.

PROCEDURES §483.10(f)(11)

During interviews with residents or their representatives determine:

- *How and when they were notified by facility staff regarding the items and services that may not be covered during their stay at the facility.*

- *Whether or not they may have been charged for items or services they believed were covered by the facility or their insurer. If concerns are raised review a resident's billing statements to determine if they were charged for covered items or services. If charges found on these statements indicate that residents may have paid for covered items or services, determine if these items or services are over and above what is paid by Medicare or Medicaid.*
- *How and when they were informed of any items or services that would be charged to them before these items or services are provided.*

KEY ELEMENTS OF NONCOMPLIANCE §483.10(f)(11)
To cite deficient practice at F571, the surveyor's investigation will generally show that the facility failed to do one or more of the following:

- *Made a charge against the resident's personal funds for:*
  - *Any item or service covered under Medicare or Medicaid (except for applicable deductible or coinsurance amounts);* ***or***
  - *Charged a resident for an item or services not required to achieve the goal stated in the resident's care plan, without notifying the resident of the charge;* ***or***
  - *Charged a resident for any item or service* ***not*** *covered under Medicare or Medicaid, but did not inform the resident orally and in writing of the charge;* ***or***
  - *Charged a resident for specially prepared or alternative food when:*
    - *Ordered by a physician or non-physician practitioner,* ***or***
    - *Prepared in consideration of the resident need,* ***or***
    - *Prepared in consideration of the overall cultural and religious make-up of the resident population;* ***or***
  - *Charged a resident for any noncovered item or service when not requested by the resident;* ***or***
- *Made the resident request any item or services as a condition of admission or continued stay.*

F572
§483.10(g) Information and Communication.
§483.10(g)(1) The resident has the right to be informed **of his or her rights and of all rules and regulations governing resident conduct and responsibilities during** ***his or her*** **stay in the facility.**

§483.10(g)(16) The facility must provide a notice of rights and services to the resident **prior to or upon admission and during the resident's stay.**

(i) **The facility must inform the resident both orally and in writing in a language that the resident understands of his or her rights and all rules and regulations governing resident conduct and responsibilities during the stay in the facility.**

(ii) **The facility must also provide the resident with the State-developed notice of** ***Medicaid rights and obligations, if any.***

(iii) **Receipt of such information, and any amendments to it, must be acknowledged in writing;**

Effective November 28, 2017

INTENT ***§483.10(g)(1),(16)***
This requirement is intended to assure that each resident knows his or her rights and responsibilities and that facility staff communicates this information prior to or upon admission, as appropriate during the resident's stay, and when the facility's rules change.

DEFINITIONS §483.10(g)(1),(16)
"All rules and regulations" relates to *State and Federal requirements and* facility policies.

"Both orally and in writing" means if a resident can read and understand written materials without assistance, an oral summary, along with the written document, is acceptable.

"In a language that the resident understands" *means verbally, in writing, and in a language* that is clear and understandable *to the resident and/or his or her representative.*

GUIDANCE §483.10(g)(1),(16)
Any time State or Federal laws *or regulations* relating to resident rights or facility *policies* change during the resident's stay in the facility, he/she must promptly be informed of these changes *in a manner that is clear to the resident*.

A resident cannot be expected to abide by rules he/she has never been told about. Whatever rules *or policies* the facility has formalized, and by which it expects residents to abide, should be included in the *residents'* statement of rights and responsibilities.

If *a* resident *or his/her representative's understanding* of English or the predominant language of the facility is inadequate for *their* comprehension, a means to communicate information in a language *or format* familiar to the resident *or his/her representative* must *be used. T*he facility *must* have written translations, *including Braille,* and make the services of an interpreter available *as needed.* For those residents *who* communicate in American Sign Language (ASL), facility *staff are* expected to provide an interpreter. Large print texts of the facility's statement of resident rights and responsibilities *may* also be made available.

PROCEDURES §483.10(g)(1)(16)
During interviews, determine:

- *When and how residents or their representatives are informed of their rights, services, facility policies and procedures, and resident responsibilities;*
- *If this information was provided in a language and format they understood; and,*
- *If facility staff provide ongoing communication to residents about their rights (e.g., through resident and family groups, presentations from representatives of the Office of the State Long-Term Care Ombudsman, posting of information, etc.)?*

F573
§483.10(g)**(2) The resident has the right to access personal and medical records pertaining to him or herself.**

(i) ***The facility must provide the resident*** **with access to personal and medical records pertaining to him or herself, upon an oral or written request,** ***in the form and format requested by the individual, if it is readily producible in such form and format***

(including in an electronic form or format when such records are maintained electronically), or, if not, in a readable hard copy form or such other form and format as agreed to by the facility and the individual, **within 24 hours (excluding weekends and holidays); and**

(ii) ***The facility must allow the resident to obtain a copy of the records or any portions thereof (including in an electronic form or format when such records are maintained electronically)*** **upon request and 2 working days advance notice to the facility. T*he facility may impose a reasonable, cost-based fee on the provision of copies, provided that the fee includes only the cost of:***

(A) Labor for copying the records requested by the individual, whether in paper or electronic form;

(B) Supplies for creating the paper copy or electronic media if the individual requests that the electronic copy be provided on portable media; and

(C)Postage, when the individual has requested the copy be mailed.

§483.10*(g)(3) With the exception of information described in paragraphs (g)(2) and (g)(11) of this section, the facility must ensure that information is provided to each resident in a form and manner the resident can access and understand, including in an alternative format or in a language that the resident can understand. Summaries that translate information described in paragraph (g)(2) of this section may be made available to the patient at their request and expense in accordance with applicable law.*

DEFINITIONS §483.10(g)(2)-(3)

"Records," *includes all records, in addition to clinical records, pertaining to the resident, such as trust fund ledgers pertinent to the resident and contracts between the resident and the facility.*

GUIDANCE §483.10(g)(2)-(3)

An oral request is sufficient to produce *the resident's personal and medical* record for review.

The facility may charge a reasonable, cost-based fee for providing a copy of the requested records, whether in paper or electronic form. This may only include the cost of labor for copying the records, supplies for creating the paper copy or electronic media, and postage, if applicable. Additional fees for locating the records or typing forms/envelopes may not be assessed.

KEY ELEMENTS OF NONCOMPLIANCE §483.10(g)(2)-(3)

To cite deficient practice at F573, the surveyor's investigation will generally show that the facility failed to do one or more of the following:

- *Support the resident's right to access his or her own personal and medical records;* ***or***
- *Provide the resident access to his or her personal and medical records within 24 hours (excluding weekends and holidays) of a written request;* ***or***
- *Allow the resident to purchase a copy of his or her personal and medical records upon request and with 2 working days advanced notice;* ***or***
- *Charge a reasonable, cost-based fee, including only the cost of labor, supplies, and postage involved in providing or sending the personal and medical records requested;* ***or***

- *Ensure the information is provided:*
  - *In a form the resident can access and understand ;**or***
  - *In a form and format agreed upon by the facility and the resident.*

F574

§483.10(g)(4) The resident has the right to receive notices orally (meaning spoken) and in writing (including Braille) in a format and a language he or she understands, including:

(i) Required notices as specified in this section. **The facility must furnish to each resident a written description of legal rights which includes –**

(A) **A description of the manner of protecting personal funds, under paragraph** ***(f)(10)*** **of this section;**

(B) **A description of the requirements and procedures for establishing eligibility for Medicaid, including the right to request an assessment** ***of resources*** **under section 1924(c)** ***of the Social Security Act.***

(C) A list of **names, addresses** ***(mailing and email),*** **and telephone numbers of all pertinent State** ***regulatory and informational agencies*****,** ***resident*** **advocacy groups such as the** ***State Survey Agency*****, the State licensure office, the State** ***Long-Term Care O*****mbudsman program, the protection and advocacy agency,** ***adult protective services where state law provides for jurisdiction in long-term care facilities, the local contact agency for information about returning to the community*** **and the Medicaid Fraud Control Unit; and**

(D) **A statement that the resident may file a complaint with the State** ***Survey Agency*** **concerning** ***any suspected violation of state or federal nursing facility regulations, including but not limited to*** **resident abuse, neglect,** ***exploitation*****, misappropriation of resident property in the facility, non-compliance with the advance directives requirements** ***and requests for information regarding returning to the community.***

(ii) Information and contact information for State and local advocacy organizations including but not limited to the State Survey Agency, the State Long-Term Care Ombudsman program (established under section 712 of the Older Americans Act of 1965, as amended 2016 (42 U.S.C. 3001 et seq) and the protection and advocacy system (as designated by the state, and as established under the Developmental Disabilities Assistance and Bill of Rights Act of 2000 (42 U.S.C. 15001 et seq.)

(iii) Information regarding Medicare and Medicaid eligibility and coverage;

(iv) Contact information for the Aging and Disability Resource Center (established under Section 202(a)(20)(B)(iii) of the Older Americans Act); or other No Wrong Door Program;

(v) Contact information for the Medicaid Fraud Control Unit; and

(vi) Information and contact information for filing grievances or complaints concerning any suspected violation of state or federal nursing facility regulations, including but not limited to resident abuse, neglect, exploitation, misappropriation of resident property in the facility, non-compliance with the advance directives requirements and requests for information regarding returning to the community.

Effective November 28, 2017

DEFINITIONS §483.10(g)(4)

"Orally and in writing" means if a resident can read and understand written materials without assistance, an oral summary, along with the written document, is acceptable.

"In a language he or she understands" *means verbally, in writing (including Braille), and in a language* that is clear and understandable *to the resident or his or her representative.*

GUIDANCE §483.10(g)(4)

If *a* resident *or his or her representative's understanding* of English or the predominant language of the facility is inadequate for *their* comprehension, a means to communicate information in a language *or format* familiar to the resident *or his or her representative* must *be used. T*he facility *must* have written translations, *including Braille* and make the services of an interpreter available *as needed.* For those residents *who* communicate in American Sign Language (ASL), the facility is expected to provide an interpreter. Large print texts of the facility's statement of resident rights and responsibilities should also be available.

As part of determining Medicaid eligibility, at the time of admission, a married couple has the right to request and have the appropriate State agency assess the couple's resources.

During interviews with residents, their representatives and facility staff determine:

- *When and how information regarding rights and services are communicated; and*
- *If this information was provided in a language and format the resident or representative understood.*

KEY ELEMENTS OF NONCOMPLIANCE §483.10(g)(4)

To cite deficient practice at F574, the surveyor's investigation will generally show that the facility failed to do one or more of the following:

- *Support the resident's right to receive notices orally and in writing in a format he or she understands;* ***or***
- *Provide a written description of the resident's legal rights, including:*
  - *How a resident's personal funds are protected;* ***or***
  - *The requirements and procedures for establishing Medicaid eligibility, including the right to request an assessment of resources;* ***or***
  - *A list of names, mailing and email addresses, and telephone numbers of all pertinent State regulatory and informational agencies and advocacy groups;* ***or***
  - *Informing the resident of their right to file a complaint with the State survey and certification agency;* ***or***
- *Provide information and contact information for:*
  - *State and local advocacy organizations;* ***or***
  - *The Aging and Disability Resource Center or other No Wrong Door Program;* ***or***
- *Inform the resident of Medicare and Medicaid eligibility and coverage;* ***or***
- *Provide contact information for the Medicaid Fraud Control Unit;* ***or***
- *Provide information and contact information for filing grievances or complaints concerning any suspected violation of State or Federal nursing facility regulations.*

Effective November 28, 2017

F575

§483.10(g)(5) The facility must post, in a form and manner accessible and understandable to residents, resident representatives:

(i) A list of **names, addresses** *(mailing and email),* **and telephone numbers of all pertinent State** *agencies and* **advocacy groups, such as the State** *Survey Agency*, **the State licensure office,** *adult protective services where state law provides for jurisdiction in long-term care facilities, the Office of the State Long-Term Care* **Ombudsman program, the protection and advocacy network***, home and community based service programs, and* **the Medicaid Fraud Control Unit; and**

(ii) A statement that the resident may file a complaint with the State *Survey Age***ncy concerning** *any suspected violation of state or federal nursing facility regulation, including but not limited to* **resident abuse, neglect,** *exploitation,* **misappropriation of resident property in the facility, and non-compliance with the advanced directives requirements** *(42 CFR part 489 subpart I) and requests for information regarding returning to the community.*

F576

§483.10(g)(6) **The resident has the right to have reasonable access to the use of a telephone,** *including TTY and TDD services, and a place in the facility* **where calls can be made without being overheard.** *This includes the right to retain and use a cellular phone at the resident's own expense.*

§483.10(g)(7) The facility must protect and facilitate that resident's right to communicate with individuals and entities within and external to the facility, including **reasonable access to:**

(i) A telephone, *including TTY and TDD services;*

(ii) *The internet, to the extent available to the facility; and*

(iii) Stationery, postage, writing implements *and the ability to send mail.*

§483.10(g)(8) **The resident has the right to send and receive mail,** *and to receive letters, packages and other materials delivered to the facility for the resident through a means other than a postal service, including the right to:*

(i) Privacy of such communications consistent with this section; and

(ii) *A***ccess to stationery, postage, and writing implements at the resident's own expense.**

§483.10(g)(9) The resident has the right to have reasonable access to and privacy in their use of electronic communications such as email and video communications and for internet research.

(i) If the access is available to the facility

(ii) At the resident's expense, if any additional expense is incurred by the facility to provide such access to the resident.

(iii) Such use must comply with State and Federal law.

DEFINITIONS §483.10(g)(6)-(9)

"Reasonable access" means that telephones, *computers and other communication devices are easily* accessible to residents and are adapted to accommodate resident's needs and *abilities*, such as hearing or vision loss.

"TTY (TeleTYpe) and TDD (Telecommunications Device for the Deaf)" are *acronyms used interchangeably to refer to any type of text-based telecommunications equipment used by a person who does not have enough functional hearing to understand speech, even with amplification.*

GUIDANCE §483.10(g)(6)-(9)
*Resident access to t*elephones in staff offices or at nurses' stations *alone* does not meet the provisions of this requirement. Examples of facility accommodations to provide reasonable access to the use of a telephone without being overheard include providing cordless telephones or having telephone jacks in residents' rooms.

The facility is responsible for providing reasonable access to the internet to the extent it is available onsite. Computers in public areas for general use must be located in a manner to protect resident privacy in email, communications, and internet use.

POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION
If concerns are identified regarding charges to the resident for access to internet, telephone, etc., refer to §483.10(f)(11), F571.

If concerns are identified to indicate a resident is being denied the right to private communication, refer to §483.10(h), F583, Privacy and confidentiality.

F577
***§483.10*(g)*(10)* The resident has the right to-**
- ***(i)*** **Examine the results of the most recent survey of the facility conducted by Federal or State surveyors and any plan of correction in effect with respect to the facility; and**
- ***(ii)*** **Receive information from agencies acting as client advocates, and be afforded the opportunity to contact these agencies.**

§483.10*(g)*(11) The facility must--
- ***(i) Post* in a place readily accessible to residents, *and family members and legal representatives of residents, the results of the most recent survey of the facility.***
- **(ii) Have reports *with respect to any* surveys, *certifications, and complaint investigations* made respecting the facility *during the 3 preceding years*, and any plan of correction in effect with respect to the facility, *available for any individual to review upon request; and***
- **(iii) Post notice of the *availability of such reports in areas of the facility that are prominent and accessible to the public.***
- ***(iv) The facility shall not make available identifying information about complainants or residents.***

DEFINITIONS §483.10(g)(10)-(11)
"**Place readily accessible**" is a place (such as a lobby or other area frequented by most residents, *visitors or other individuals*) where individuals wishing to examine survey results do not have to ask to see them.

Effective November 28, 2017

"Results of the most recent survey" means the Statement of Deficiencies (Form CMS-2567) and the Statement of Isolated Deficiencies generated by the most recent standard survey and any subsequent extended surveys, and any deficiencies resulting from any subsequent complaint investigation(s).

GUIDANCE §483.10(g)(10)-(11)
The survey results may not be altered by the facility unless authorized by the State agency.

F578
§483.10(c)(6) **The right to *request,* refuse, *and/or discontinue* treatment, *to participate in or* refuse to participate in experimental research, and to formulate an advance directive.**

§483.10(c)**(8) Nothing in this paragraph should be construed as the right of the resident to receive the provision of medical treatment or medical services deemed medically unnecessary or inappropriate**

§483.10(g)(12) **The facility must comply with the requirements specified in *42 CFR part 489,* subpart I *(Advance Directives).***

- ***(i)*** **These requirements include provisions to inform and provide written information to all adult residents concerning the right to accept or refuse medical or surgical treatment and, at the *resident's* option, formulate an advance directive.**
- ***(ii)*** **This includes a written description of the facility's policies to implement advance directives and applicable State law.**
- ***(iii) Facilities are permitted to contract with other entities to furnish this information but are still legally responsible for ensuring that the requirements of this section are met.***
- ***(iv) If an adult individual is incapacitated at the time of admission and is unable to receive information or articulate whether or not he or she has executed an advance directive, the facility may give advance directive information to the individual's resident representative in accordance with State Law.***
- ***(v) The facility is not relieved of its obligation to provide this information to the individual once he or she is able to receive such information. Follow-up procedures must be in place to provide the information to the individual directly at the appropriate time.***

DEFINITIONS *§483.10(c)(6), (c)(8), (g)(12)*
"Advance care planning" *is a process of communication between individuals and their healthcare agents to understand, reflect on, discuss, and plan for future healthcare decisions for a time when individuals are not able to make their own healthcare decisions.*

"Advance directive" *is "a written instruction, such as a living will or durable power of attorney for health care, recognized under State law (whether statutory or as recognized by the courts of the State), relating to the provision of health care when the individual is incapacitated." See §489.100.*

"Physician Orders for Life-Sustaining Treatment (or POLST) paradigm form" *is a form designed to improve patient care by creating a portable medical order form that records*

patients' treatment wishes so that emergency personnel know what treatments the patient wants in the event of a medical emergency, taking the patient's current medical condition into consideration. A POLST paradigm form is not an advance directive.

"Experimental research" *refers to the development, testing and use of a clinical treatment, such as an investigational drug or therapy that has not yet been approved by the FDA or medical community as effective and conforming to accepted medical practice.*

"Health care decision-making" refers to consent, refusal to consent, or withdrawal of consent to health care, treatment, service, or a procedure to maintain, diagnose, or treat a *resident*'s physical or mental condition.

"Health care decision-making capacity" refers to possessing the ability (as defined by State law) to make decisions regarding health care and related treatment choice.

GUIDANCE §483.10(c)(6), (c)(8), (g)(12)
The resident has the right to request treatment; however, facility staff are not required to provide medical treatment or services if the requested treatment or services are medically unnecessary or inappropriate. While the resident also has the right to refuse any treatment or services, the resident's refusal does not absolve facility *staff* from providing other care that allows him/her to attain or maintain his or her highest practicable physical, mental, and psychosocial well-being. For example, facility *staff* would still be expected to provide appropriate measures for pressure *injury* prevention, even if a resident has refused food and fluids and is nearing death.

If a resident (directly or through an advance directive) declines treatment (such as refuses artificial nutrition or IV hydration, despite having lost considerable weight), the resident may not be treated against his or her wishes. If a resident is unable to make a health care decision, a decision by the resident's legal representative to forego treatment may, subject to State requirements, be equally binding on the facility. A resident *may not be transferred or discharged* for refusing treatment unless the criteria for transfer or discharge are otherwise met. *Facility staff should attempt to determine the reason for the refusal of care, including whether a resident who is unable verbalize their needs is refusing care for another reason (such as pain, fear of a staff member, etc.), and address the concern, if possible. Any services that would otherwise be required, but are refused, must be described in the comprehensive care plan. See F656, Comprehensive Care Plans, for further guidance.*

The resident has the right to refuse to participate in experimental research. A resident being considered for participation in experimental research must be fully informed of the nature of the experimental research (*for example*, medication or other treatment) and the possible consequences of participating. The resident must provide informed consent prior to participation and initiation of experimental research. If the resident is incapable of understanding the situation and of realizing the risks and benefits of the proposed research, but a *resident* representative gives consent, facility *staff* ha*ve* a responsibility to ensure that the consent is properly obtained and that essential measures are taken to protect the resident from harm or mistreatment. The resident (or his or her representative if the resident lacks health care decision-making capacity)

must have the opportunity to refuse to participate both before and during the experimental research activity.

The ability of a dying person to control decisions about medical care and daily routines has been identified as one of the key elements of quality care at the end of life. The process of advance care planning is ongoing and affords the resident, family, and others on the resident's interdisciplinary health care team an opportunity to reassess the resident's goals and wishes as the resident's medical condition changes. Advance care planning is an integral aspect of the facility's comprehensive care planning process and assures re-evaluation of the resident's desires on a routine basis and when there is a significant change in the resident's condition. The process can help the resident, family and interdisciplinary team prepare for the time when a resident becomes unable to make decisions or is actively dying.

The facility is required to establish, maintain, and implement written policies and procedures regarding the residents' right to formulate an advance directive, refuse medical or surgical treatment. In addition, the facility *management* is responsible for ensuring that staff follow *those* policies and procedures.

The facility's policies and procedures delineate the various steps necessary to promote and implement these rights, including, *but not limited to*:

- Determining on admission whether the resident has an advance directive and, if not, determining whether the resident wishes to formulate an advance directive;
- *Providing information in a manner easily understood by the resident or resident representative about the right to refuse medical or surgical treatment and formulate an advanced directive. This includes a written description of the facility's policies to implement advance directives and applicable State law regarding advance directives.*
- Determining if facility *staff* periodically assesses the resident for decision-making capacity and invokes health care agent or representative if the resident is determined not to have decision-making capacity*;*
- Identifying the primary decision-maker (assessing the resident's decision-making capacity and identifying or arranging for an appropriate representative for the resident assessed as unable to make relevant health care decisions);
- Defining and clarifying medical issues and presenting the information regarding relevant health care issues to the resident or his or her representative, as appropriate;
- Identifying, clarifying, and periodically reviewing, as part of the comprehensive care planning process, the existing care instructions and whether the resident wishes to change or continue these instructions;
- Identifying situations where health care decision-making is needed, such as a significant decline or improvement in the resident's condition;
- Establishing mechanisms for documenting and communicating the resident's choices to the interdisciplinary team *and to staff responsible for the resident's care*; and
- Identifying the process (as provided by State law) for handling situations in which the facility *staff* and/or physician do not believe that they can provide care in accordance with the resident's advance directives or other wishes on the basis of conscience.

If the resident or the resident's representative has executed one or more advance directive(s), or executes one upon admission, copies of these documents *must* be obtained *and* maintained in the same section of the resident's medical record readily retrievable by any facility staff. *F*acility *staff* must communicate the resident's wishes to the resident's direct care staff and physician.

If the resident *does not have* an advance directive, facility *staff must inform* the resident *or resident representative* of *their* right to establish *one* as set forth in the laws of the State *and provide* assistance if the resident wishes to execute one or more directive(s). *Facility staff must* document in the resident's medical record these discussions and any advance directive(s) that the resident executes.

The resident has the option to execute advance directives, but cannot be required to do so. As required by 42 C.F.R. §489.102(a)(3), the facility may not condition the provision of medical care or discriminate against a resident based on whether he or she has executed an advance directive. *F*acility *staff are* not required to provide care that conflicts with an advance directive. In addition, facility *staff are* not required to implement an advance directive if, as a matter of conscience, the provider cannot implement an advance directive and State law allows the provider to conscientiously object.

NOTE: *Other directives a resident may choose to exercise may include, but are not limited to, a directive to the attending physician, a medical power of attorney, a pre-existing medical order for "do not resuscitate" (DNR), or another document that directs the resident's health care such as Do Not Hospitalize (DNH). Several States have adopted the use of a portable and enduring order form that documents the resident's choices related to life-sustaining treatments while some States recognize documented oral instruction.*

Facility staff should periodically review with the resident and resident representative the decisions made regarding treatments, experimental research and any advance directive and its provisions, as preferences may change over time.

PROCEDURES §483.10(c)(6), (c)(8), (g)(12)

- *Observe for efforts on the part of facility staff to inform residents or their representative of their rights and that information is communicated at times it would be most useful to them, such as when they are expressing concerns, or raising questions.*
- *Interview the resident, resident's representative and facility staff to determine if:*
  - *Residents are informed in a manner they understand of their right to request or refuse treatment;*
  - *A resident has an advance directive and if staff are aware of what this directive states;*
  - *A resident does not have an advance directive and, if so, how the resident was informed of his or her right to develop one and was the resident provided assistance in doing so; and*
  - *Staff periodically assess a resident's decision making capacity, how often and how and by whom is this done.*
- *Review the resident's medical record to determine if:*

- *The resident has an advance directive and a copy is located in the medical record; and*
- *The facility has policies and procedures to implement advance directives.*

KEY ELEMENTS OF NONCOMPLIANCE §483.10(c)(6), (c)(8), (g)(12):
To cite deficient practice at F574, the surveyor's investigation will generally show that the facility failed to do one or more of the following:

- *Provide information to the resident regarding their right to refuse medical or surgical treatment or to formulate an advance directive once the resident was able to receive the information; or*
- *Honor a resident's, their family, and/or their representative's decision to request, refuse, or discontinue experimental research; or*
- *Ensure that a current copy of a resident's advance directive was in the resident's medical record; or*
- *Have policies and procedures for implementing advance directives; or*
- *Follow policies to implement advance directives and applicable State laws regarding advance directives.*

POTENTIAL TAGS FOR ADDITIONAL CONSIDERATION
Examples of some of the related requirements that may be considered when non-compliance has been identified include, but are not limited to, the following:

- *42 CFR §§483.10(a)(3)-(7), F551*
  - *For concerns regarding designation of resident representative.*
- *42 CFR §§483.10(c)(2)-(3), F553, Right to Participate in Planning Care*
  - *For concerns regarding the resident's right to participate in and be informed of his or her treatment.*

F579
§483.10(g)(13) **The facility must display in the facility written information, and provide to residents and applicants for admission, oral and written information about how to apply for and use Medicare and Medicaid benefits, and how to receive refunds for previous payments covered by such benefits.**

DEFINITIONS §483.10(g)(13)
"**Refunds for previous payments**" refers to refunds due as a result of Medicaid and Medicare payments when eligibility has been determined retroactively.

GUIDANCE §483.10(g)(13)
To fulfill this requirement, facility *staff* may use written materials issued by the State Medicaid agency and the Federal government relating to these benefits. Facilities may fulfill their obligation to orally inform residents or *prospective residents* about how to apply for Medicaid or Medicare by assisting them *in working with* the local Social Security Office or the local unit of the State Medicaid agency. *Simply providing a phone number is not sufficient in assisting resident or the resident representative.* Facilities are not responsible for orally providing detailed information about Medicare and Medicaid eligibility rules.

Effective November 28, 2017

F580
§483.10(g)(14) **Notification of Changes.**

(i) A facility must immediately inform the resident; consult with the resident's physician; and notify, *consistent with his or her authority,* the resident representative*(s)* when there is—

(A) An accident involving the resident which results in injury and has the potential for requiring physician intervention;

(B) A significant change in the resident's physical, mental, or psychosocial status (*that is*, a deterioration in health, mental, or psychosocial status in either life-threatening conditions or clinical complications);

(C) A need to alter treatment significantly (*that is*, a need to discontinue an existing form of treatment due to adverse consequences, or to commence a new form of treatment); or

(D) A decision to transfer or discharge the resident from the facility as specified in *§483.15(c)(1)(ii).*

(ii) When making notification under paragraph (g)(14)(i) of this section, the facility must ensure that all pertinent information specified in §483.15(c)(2) is available and provided upon request to the physician.

(iii) **The facility must also promptly notify the resident and the resident representative, *if any,* when there is—**

(A) A change in room or roommate assignment as specified in *§483.10(e)(6);* or

(B) A change in resident rights under Federal or State law or regulations as specified in paragraph *(e)(10)* of this section.

(iv) **The facility must record and periodically update the address *(mailing and email)* and phone number of the resident representative*(s)*.**

DEFINITIONS §483.10(g)(14)

"**A need to alter treatment significantly**" means a need to stop a form of treatment because of adverse consequences (such as an adverse drug reaction), or commence a new form of treatment to deal with a problem (for example, the use of any medical procedure, or therapy that has not been used on that resident before).

GUIDANCE §483.10(g)(14)

While the regulatory obligation is not limited to these symptoms, physician notification should occur when a resident experiences symptoms such as chest pain, loss of consciousness, or other signs or symptoms of heart attack or stroke that may signify a significant change.

Even when a resident is mentally competent, *his or her* designated *resident representative or family, as appropriate,* should be notified of significant changes in the resident's health status because the resident may not be able to notify them personally, especially in the case of sudden illness or accident.

If the resident is not capable of making decisions, facility staff must contact the designated resident representative, consistent with his or her authority, to make any required decisions, but the resident *must* still be told what is happening to him or her.

In the case of the death of a resident, the resident's physician is to be notified immediately *by facility staff* in accordance with State law.

§483.10(g)(15)
***A*dmission to a composite distinct part. A facility that is a composite distinct part (as defined in *§483.5*) must disclose in its admission agreement its physical configuration, including the various locations that comprise the composite distinct part, and must specify the policies that apply to room changes between its different locations under *§483.15(c)(9)*.**

If there is a deficiency specific to the requirement at §483.10(g)(15), do not cite here, but cite under §§483.15(a)(1)-(7), F620, regarding admission policies.

F581
This tag number is in reserve for future use and there will be no citations under this tag.

F582
***§483.10(g)(17)* The facility must--**
- **(i) Inform each *Medicaid-eligible* resident, in writing, at the time of admission to the nursing facility *and* when the resident becomes eligible for Medicaid of—**
  - **(A) The items and services that are included in nursing facility services under the State plan and for which the resident may not be charged;**
  - **(B) Those other items and services that the facility offers and for which the resident may be charged, and the amount of charges for those services; and**
- **(ii) Inform each *Medicaid-eligible* resident when changes are made to the items and services specified in §*483.10(g)(17)*(i)(A) and (B) of this section.**

***§483.10(g)(18)* The facility must inform each resident before, or at the time of admission, and periodically during the resident's stay, of services available in the facility and of charges for those services, including any charges for services not covered under Medicare/ Medicaid or by the facility's per diem rate.**
- ***(i) Where changes in coverage are made to items and services covered by Medicare and/or by the Medicaid State plan, the facility must provide notice to residents of the change as soon as is reasonably possible.***
- ***(ii) Where changes are made to charges for other items and services that the facility offers, the facility must inform the resident in writing at least 60 days prior to implementation of the change.***
- ***(iii) If a resident dies or is hospitalized or is transferred and does not return to the facility, the facility must refund to the resident, resident representative, or estate, as applicable, any deposit or charges already paid, less the facility's per diem rate, for the days the resident actually resided or reserved or retained a bed in the facility, regardless of any minimum stay or discharge notice requirements.***
- ***(iv) The facility must refund to the resident or resident representative any and all refunds due the resident within 30 days from the resident's date of discharge from the facility.***
- ***(v) The terms of an admission contract by or on behalf of an individual seeking admission to the facility must not conflict with the requirements of these regulations.***

Effective November 28, 2017

DEFINITIONS §483.10(g)(17)-(18)
"**Periodically**" means whenever changes are being introduced that will affect the resident's liability and whenever there are changes in services.

GUIDANCE §483.10(g)(17)-(18)
Residents *must* be told in advance when changes will occur in their bills. Providers must fully inform the resident of services and related changes.

A Medicare beneficiary who requires services upon admission that are not covered under Medicare may be required to submit a deposit provided the notice provisions of *§483.10(g)(17)* if applicable, are met. *Facility staff must notify residents of services or items that they may be charged for, if they are not required by the resident's care plan, such as hair salon services beyond basic services or incontinence briefs the resident requests per personal preference in lieu of the briefs provided by the facility.* See *§483.10(f)(11)* for those items and services that must be included in payment under skilled nursing and nursing facility benefits.

The facility's responsibility regarding refunds applies to all residents for "any deposit or charges already paid" by a resident during their nursing home stay. For residents residing in a Continuing Care Retirement Community (CCRC) an exception can be considered for those residents who were admitted to the CCRC's nursing home, had deposits and charges related to the CCRC separate from those incurred during the nursing home stay, and who were discharged/transferred from the nursing home back to the same CCRC's independent or assisted living residences.

For Medicare Covered Part A Beneficiaries:
If a SNF believes upon admission or during a resident's stay that Medicare will not pay for skilled nursing or specialized rehabilitative services and the SNF believes that an otherwise covered item or service may be denied as not being reasonable and necessary, facility staff must inform the resident or his or her legal representative in writing why these specific services may not be covered and of the beneficiary's potential liability for payment for the non-covered services.

If the SNF provides the beneficiary with either a Skilled Nursing Facility Advanced Beneficiary Notice (SNFABN), form CMS-10055, or one of the uniform Denial Letters at the initiation, reduction, or termination of Medicare Part A benefits, the facility has met its obligation to inform the beneficiary of his or her potential liability for payment and related standard claim appeal rights. Issuing the Notice to Medicare Provider Non-coverage (NOMNC), form CMS-10123, to a beneficiary only conveys notice to the beneficiary of his or her right to an expedited review of a service termination and does not fulfill the facility's obligation to advise the beneficiary of potential liability for payment. A facility must still issue the SNFABN or a Denial Letter to address liability for payment.

The NOMNC informs the beneficiary of his or her right to an expedited review of a services termination. The SNF must issue this notice when there is a termination of all Medicare Part A services for coverage reasons. The SNF may not issue this notice if the beneficiary exhausts the Medicare covered days as the number of SNF benefit days is set in law and the Quality

Improvement Organization (QIO) cannot extend the benefit period. Thus, a service termination due to the exhaustion of benefits is not considered a termination for "coverage" reasons.

The NOMNC is issued when all covered services end for coverage reasons. If after issuing the NOMNC, the SNF expects the beneficiary to remain in the facility in a non-covered stay, either the SNFABN or a Denial Letter must be issued to inform the beneficiary of potential liability for the non-covered stay.

In most cases when all covered services end for coverage reasons, a SNF provider will issue:

- *NOMNC and a Denial Letter; or*
- *NOMNC and the SNFABN; or only*
- *The NOMNC.*

In cases where all Medicare covered services are ending, the beneficiary is being discharged and is not requesting an expedited review, only the NOMNC is required. Additionally, there are rare instances where a SNF would issue only a Denial Letter or SNFABN. An example of this is when there is a reduction or termination in one Medicare Part A service while other Medicare Part A covered services are continuing.

The SNF:

- *Must file a claim when requested by the beneficiary; and*
- *May not charge the resident for Medicare covered Part A services while an expedited review and final decision is pending.*

***NOTE**: A facility's requirement to notify and explain the SNFABN notices that the individual is no longer receiving Medicare Part A services is separate and unrelated from the admission and discharge requirements under 42 CFR **§**483.15 which outline the notification and requirements under which an individual may be discharged from the facility.*

KEY ELEMENTS OF NONCOMPLIANCE §483.10(g)(17)-(18)

To cite deficient practice at F582, the surveyor's investigation will generally show the facility failed to do one or more of the following:

- *Notify each Medicaid- eligible resident in writing of the items and services which are/are not covered under Medicaid or by the facility's per diem rate, including the cost of those items and services:*
  - *At the time of admission, **or***
  - *When the resident became eligible for Medicaid, **or***
- *Inform each Medicaid-eligible resident when changes were made to the items and services covered by Medicaid; **or***
- *Inform each resident of services available in the facility and the charges for those services not covered under Medicare/Medicaid or by the facility's per diem rate:*
  - *Before admission or at the time of admission, and periodically during the resident's stay; **or***
  - *As soon as reasonably possible when a change in coverage occurs; **or***
  - *At least 60 days prior to implementation of changes made to charges for other items and services that the facility offers; **or***

- *Refund the applicable funds to the resident, resident representative, or estate when a resident died, or was hospitalized, or was transferred and did not return to the facility;* ***or***
- *Refund any and all funds due the resident:*
  - *Within 30 days from the date of discharge;* ***or***
  - *To the resident or resident representative;* ***or***
- *Included terms in the admission contract that conflicted with the requirements of these regulations.*

F583
§483.10(h) **Privacy and Confidentiality.**
The resident has a right to personal privacy and confidentiality of his or her personal and ***medical*** **records.**

§483.10(h)**(l) Personal privacy includes accommodations, medical treatment, written and telephone communications, personal care, visits, and meetings of family and resident groups, but this does not require the facility to provide a private room for each resident.**

§483.10(h)(2) The facility must respect the residents right to personal **privacy*****, including the right to privacy in his or her oral (that is, spoken),*** **written,** ***and electronic*** **communications,** ***including the right*** **to send and promptly receive unopened mail** ***and other letters, packages and other materials delivered to the facility for the resident, including those delivered through a means other than a postal service.***

§483.10(h)(3) The resident has a right to secure and confidential personal and medical records.

(i) **The resident** ***has the right to*** **refuse the release of personal and** ***medical*** **records** ***except as provided at §483.70(i)(2) or other applicable federal or state laws.***

(ii) The facility must allow representatives of the ***Office of the*** **State** ***Long-Term Care*** **Ombudsman to examine a resident's** ***medical, social, and administrative*** **records** ***in accordance*** **with State law.**

DEFINITIONS §483.10(h)
"*Confidentiality*" is defined as safeguarding the content of information including video, audio, or other computer stored information from unauthorized disclosure without the consent of the resident and/or the individual's surrogate or representative. If there is information considered too confidential to place in the record used by all staff, such as the family's financial assets or sensitive medical data, it may be retained in a secure place in the facility, such as a locked cabinet in the administrator's office. The record *must* show the location of this confidential information.

"Promptly" means delivery of mail or other materials to the resident within 24 hours of delivery by the postal service (including a post office box) and delivery of outgoing mail to the postal service within 24 hours, except when there is no regularly scheduled postal delivery and pick-up service.

Effective November 28, 2017

"Right to *personal* privacy" *includes* the resident's right to *meet or communicate with whomever they want without being watched or overheard.* Private space may be created flexibly and need not be dedicated solely for visitation purposes.

GUIDANCE §483.10(h)
Each resident has the right to privacy and confidentiality for all aspects of care and services. A nursing home resident has the right to personal privacy of not only his or her own physical body, but of his or her personal space, including accommodations and personal care.

Residents in nursing homes have varying degrees of physical/psychosocial needs, intellectual disabilities, and/or cognitive impairments. A resident may be dependent on nursing home staff for some or all aspects of care, such as assistance with eating, ambulating, bathing, daily personal hygiene, dressing, and bathroom needs. Only authorized staff directly involved in providing care and services for the resident may be present when care is provided, unless the resident consents to other individuals being present during the delivery of care. During the delivery of personal care and services, staff must remove residents from public view, pull privacy curtains *or* close doors, *and provide clothing or draping to prevent exposure of body parts.*

Photographs or recordings of a resident and/or his or her private space without the resident's, or designated representative's written consent, is a violation of the resident's right to privacy and confidentiality. Examples include, but are not limited to, staff taking unauthorized photographs of a resident's room or furnishings (which may or may not include the resident), or a resident eating in the dining room, or a resident participating in an activity in the common area. Taking unauthorized photographs or recordings of residents in any state of dress or undress using any type of equipment (for example, cameras, smart phones, and other electronic devices) and/or keeping or distributing them through multimedia messages or on social media networks is a violation of a resident's right to privacy and confidentiality.

Personal and *medical* records include all types of records the facility might keep on a resident, whether they are medical, social, fund accounts, automated, *electronic,* or other. *Care must be taken to protect the privacy of personal information on all residents, including gender identity and sexual orientation.*

Posting signs in residents' rooms or in areas *visible to others* that include clinical or personal information *could be considered a violation of a resident's privacy*. It is allowable to post signs with this type of information in more private locations not *visible to the* public. An exception can be made in an individual case if a resident *or his or her representative requests* the posting of information at the bedside (*such as instructions to* not take blood pressure in right arm). This does not prohibit the display of resident names on their doors nor does it prohibit display of resident memorabilia and/or biographical information in or outside their rooms with their consent or the consent of his or her representative. (This does not include isolation precaution *information* for public health protection, as long as the sign does not reveal the type of infection).

Personal resident information *must be communicated* in a way that protects the confidentiality of the information and the dignity of residents. This includes both verbal and written communications such as *the presence of* lists of residents with certain conditions such as

incontinence and pressure ulcers at nursing stations in view or in hearing of residents and visitors. This does not include clinical information written in a resident's record.

Privacy for visitation or meetings might be arranged by using a dining area between meals, a vacant chapel, office or room; or an activities area when activities are not in progress. Arrangements for private space could be accomplished through cooperation between the facility's administration and resident or family groups so that private space is provided for those requesting it without infringement on the rights of other residents.

All residents have the right to privacy in their communications, including justice involved residents. Additional *guidance* on mail, *telephone, electronic communications and* visitation rights are addressed in §483.10(*g*)*(6)-(9), F576* and *§483.10(f)(4)(i)(A)-(G), F562.* See §483.*9*0(*e*)(1)(iv)*, F914,* for full visual privacy around beds.

With the exception of the explicit requirement for privacy curtains in all initially certified facilities (see §483.*9*0(*e*)(1)(v)*, F914*), the facility is free to innovate to provide privacy for its residents. This may, but need not, be through the provision of a private room.

PROCEDURES §483.10(h)

- *Observe for situations where facility staff may not be honoring the resident's privacy, including during visits, treatment, or leaving medical records out for public view.*
- *During interviews with residents, their representatives, visitors or families determine if their privacy has been honored by facility staff.*
- *Interview the representative of the Office of the State Long-Term Care Ombudsman who serves residents of the facility, to determine if the facility allows him/her to examine the resident's records with the permission of the resident or resident representative or as otherwise authorized by State law.*
- Are there signs regarding care information posted in view in residents' rooms? If these are observed, determine if such signs are there by resident or *resident representative* direction. If so, these signs are allowable.
- *Is personal resident* information *communicated* in a way that protects the confidentiality of the information and the dignity of residents?
- *If concerns are found, interview staff regarding facility policy or procedures regarding protecting resident privacy and confidentiality.*

F584
***§483.10(i) Safe* Environment.**
The resident has a right to a safe, clean, comfortable and homelike environment, including but not limited to receiving treatment and supports for daily living safely.

The facility must provide—
***§483.10(i)(1)* A safe, clean, comfortable, and homelike environment, allowing the resident to use his or her personal belongings to the extent possible.**

(i) This includes ensuring that the resident can receive care and services safely and that the physical layout of the facility maximizes resident independence and does not pose a safety risk.

Effective November 28, 2017

(ii) The facility shall exercise reasonable care for the protection of the resident's property from loss or theft.

§483.10(i)**(2) Housekeeping and maintenance services necessary to maintain a sanitary, orderly, and comfortable interior;**

§483.10(i)**(3) Clean bed and bath linens that are in good condition;**

§483.10(i)(4) Private closet space in each resident room, as specified in §483.90 (e)(2)(iv);

§483.10(i)**(5) Adequate and comfortable lighting levels in all areas;**

§483.10(i)**(6) Comfortable and safe temperature levels. Facilities initially certified after October 1, 1990 must maintain a temperature range of 71 to 81°F; and**

§483.10(i)**(7) For the maintenance of comfortable sound levels.**

DEFINITIONS §483.10(i)

"**Adequate lighting**" means levels of illumination suitable to tasks the resident chooses to perform or the facility staff must perform.

"**Comfortable lighting**" means lighting that minimizes glare and provides maximum resident control, where feasible, over the intensity, location, and direction *of lighting to meet their needs* or enhance independent functioning.

"Comfortable and safe temperature levels" means that the ambient temperature *should* be in a relatively narrow range that minimizes residents' susceptibility to loss of body heat and risk of hypothermia*, or hyperthermia,* or and is *comfortable for the residents*.

"Comfortable sound levels" do not interfere with resident's hearing and enhance privacy when privacy is desired, and encourage interaction when social participation is desired. Of particular concern to comfortable sound levels is the resident's control over unwanted noise.

"**Environmen**t" refers to any environment in the facility that is frequented by residents, including (but not limited to) the residents' rooms, bathrooms, hallways, dining areas, lobby, outdoor patios, therapy areas and activity areas.

A "**homelike environment**" is one that de-emphasizes the institutional character of the setting, to the extent possible, and allows the resident to use those personal belongings that support a homelike environment. A determination of "homelike" *should* include the resident's opinion of the living environment.

"**Orderly**" is defined as an uncluttered physical environment that is neat and well-kept.

Effective November 28, 2017

"**Sanitary**" includes, but is not limited to, preventing the spread of disease-causing organisms by keeping resident care equipment clean and properly stored. Resident care equipment includes, *but is not limited to, equipment used in the completion of the activities of daily living.*

GUIDANCE §483.10(i)

A personalized, homelike environment recognizes the individuality and autonomy of the resident, provides an opportunity for self-expression, and encourages links with the past and family members. The intent of the word "homelike" in this regulation is that the nursing home should provide an environment as close to that of the environment of a private home as possible.

This concept of creating a home setting includes the elimination of institutional odors, and practices to the extent possible. *Some practices that can be eliminated to decrease the institutional character of the environment include, but are not limited to, the following:*

- Overhead paging *(including frequent announcements)* and piped-in music throughout the building.
- Meal service using trays (some residents may wish to eat certain meals on trays).
- Institutional signs labeling work rooms/closets in areas visible to residents and the public.
- Medication *or treatment* carts (some innovative facilities store medications in locked areas in resident rooms *or in secured carts that appear like furniture*).
- The widespread and long-term use of audible chair and bed alarms, instead of their limited use for selected residents for diagnostic purposes or according to their care planned needs. These devices can startle the resident and constrain the resident from normal repositioning movements, which can be problematic.
- Furniture *that does not reflect a home-like environment or is uncomfortable*; *the absence of window treatments or drapes; the lack of textures or the absence of bedspreads or personal items in rooms or on walls.*
- Large, centrally located nursing/care team stations, *including those with barriers (such as Plexiglas) that prevent the staff from interacting with residents.*

Many facilities cannot immediately make these types of changes, but it *should* be a goal for all facilities that have not yet made these types of changes to work toward them. A nursing facility is not considered non-compliant if it still has some of these institutional features, but the facility is expected to do all it can within fiscal constraints to provide an environment that enhances quality of life for residents, in accordance with resident preferences.

A "homelike" environment is not achieved simply through enhancements to the physical environment. It concerns striving for person-centered care that emphasizes individualization, relationships and a psychosocial environment that welcomes each resident and makes her/him comfortable. *It is the responsibility of all facility staff to create a "homelike" environment and promptly address any cleaning needs.*

In a facility in which most residents come for a short-term stay, *residents* would not typically move his or her bedroom furniture into the room, but may desire to bring a television, chair or other personal belongings to have while staying in the facility.

Effective November 28, 2017

There needs to be sufficient individual closet space so that resident clothing is kept separate from a roommate's. Closets must be structured so the resident can get to and reach their hanging clothing whenever they choose. Out-of-season items may be stored in alternate locations outside the resident's room.

Adequate lighting design has these features:

- Lighting with minimum glare in areas frequented by residents. Elimination of high levels of glare produced by shiny flooring and from unshielded window openings;
- Even light levels in common areas and hallways, avoiding patches of low light caused by too much space between light fixtures, within limits of building design constraints;
- Use of daylight as much as possible;
- Extra lighting, such as table and floor lamps to provide sufficient light to assist residents with tasks such as reading;
- Lighting for residents who need to find their way from bed to bathroom at night (*for example*, red colored night lights preserve night vision); and
- Dimming switches in resident rooms (where possible and when desired by the resident) so that staff can tend to a resident at night with limited disturbances to them or a roommate. If dimming is not feasible, another option may be for staff to use flashlights/pen lights when they provide night care.

While facilities certified after October 1, 1990, *are required to maintain an air temperature range of 71-81°F, there may be brief periods of time where* that temperature *falls outside of that range* only during rare, brief *periods of unseasonable weather*. This interpretation would apply in cases where it does not adversely affect resident health and safety, *and facility staff took appropriate steps to ensure resident comfort. This* would enable facilities in areas of the country with relatively cold *or hot* climates to avoid the expense of installing equipment that would only be needed infrequently.

PROCEDURES §483.10(i)

Verify the air temperature above floor level in resident rooms, dining areas, and common areas. If the temperature is out of the 71-81° F range, then ask staff what actions they take when residents complain of heat or cold, *such as*, provid*ing* extra fluids during heat waves and extra blankets and sweaters in cold.

During interviews, ask residents and families whether they think the facility is as homelike as possible, and whether they have been encouraged to bring in personal property items (within space constraints).

Observe bedrooms of sampled residents for personalization. Does the room tell the survey team anything about the resident's everyday life and interests? Observe for personal items such as family photographs, books and magazines, etc. that belong to the residents. For residents who have no relatives or friends, or few assets, has facility *staff* assisted these residents to make their rooms homelike, if they so desire? If potential issues are discovered, ask staff about their efforts to provide a homelike environment. Determine if the resident's preferences are honored or is the facility's goal of having a sanitary, safe, and uncluttered environment preventing the resident from having an individualized area?

Observe and question sampled residents throughout the survey and note if they are having difficulty reading or doing tasks due to insufficient lighting, or if they are wearing sunglasses or visors indoors due to glare, if they have difficulty seeing food on their plate, experiencing squinting or shading their eyes from glare or other signs that lighting does not meet their needs.

PROBES *§483.10(i)*

- Does the resident have any concerns with lighting, noise, temperature, or anything else that may affect their comfort?
- Are resident care areas and equipment kept clean and in good repair?
- Does the resident's room appear cluttered and disorderly, with a lack of storage for clothing, belongings or personal care equipment?
- *Are areas of the facility used by residents* designed or organized to ensure the resident can receive care and services safely, without risk of falling or injury, while maximizing resident independence?
- Do window treatments, bed linens, towels, privacy curtains, etc., appear clean and in good condition?
- *How does facility staff ensure resident personal property is kept safe from loss or theft?*

POTENTIAL TAGS FOR ADDITIONAL CONSIDERATION

Examples of some of the related requirements that may be considered when non-compliance has been identified include, but are not limited to, the following:

- *For concerns regarding the resident's right to have personal possessions, including furnishings, see §483.10(e)(2), F557;*
- *For concerns related to misappropriation of resident property, see §483.12, F602, Misappropriation of Resident Property;*
- For issues of safety of the environment, presence of hazards and hazardous practices, *see* §483.25*(d), F689,* Accidents;
- For kitchen sanitation, see §483.*60(i)*, *F812, Food Safety Requirements;*
- For facility-wide sanitary practices affecting the quality of care, see *§483.80, F880,* Infection Control.
- For issues of fire danger, *see* §483.*90(a), F905, Fire Safety*; or
- For issues of cleanliness of areas of the facility used by staff only (*such as the* break room, medication room, laundry, kitchen, etc.) or the public only (*such as the* parking lot), *see* §483.*90*(h), *F921,* Other Environmental Conditions.

F585

***§483.10(j)* Grievances.**

§483.10(j)*(1) The resident has the right to *v*oice grievances *to the facility or other agency or entity that hears grievances* without discrimination or reprisal *and without fear of discrimination or reprisal.* Such grievances include those with respect to care and treatment which has been furnished as well as that which has not been furnished, *the behavior of staff and of other residents, and other concerns regarding their LTC facility stay.

§483.10(j)*(2) The resident has the right to *and the facility must mak*e prompt efforts by the facility to resolve grievances *the resident may have, in accordance with this paragraph.

Effective November 28, 2017

§483.10(j)(3) The facility must make information on how to file a grievance or complaint available to the resident.

§483.10(j)(4) The facility must establish a grievance policy to ensure the prompt resolution of all grievances regarding the residents' rights contained in this paragraph. Upon request, the provider must give a copy of the grievance policy to the resident. The grievance policy must include:

- ***(i) Notifying resident individually or through postings in prominent locations throughout the facility of the right to file grievances orally (meaning spoken) or in writing; the right to file grievances anonymously; the contact information of the grievance official with whom a grievance can be filed, that is, his or her name, business address (mailing and email) and business phone number; a reasonable expected time frame for completing the review of the grievance; the right to obtain a written decision regarding his or her grievance; and the contact information of independent entities with whom grievances may be filed, that is, the pertinent State agency, Quality Improvement Organization, State Survey Agency and State Long-Term Care Ombudsman program or protection and advocacy system;***
- ***(ii) Identifying a Grievance Official who is responsible for overseeing the grievance process, receiving and tracking grievances through to their conclusions; leading any necessary investigations by the facility; maintaining the confidentiality of all information associated with grievances, for example, the identity of the resident for those grievances submitted anonymously, issuing written grievance decisions to the resident; and coordinating with state and federal agencies as necessary in light of specific allegations;***
- ***(iii) As necessary, taking immediate action to prevent further potential violations of any resident right while the alleged violation is being investigated;***
- ***(iv) Consistent with §483.12(c)(1), immediately reporting all alleged violations involving neglect, abuse, including injuries of unknown source, and/or misappropriation of resident property, by anyone furnishing services on behalf of the provider, to the administrator of the provider; and as required by State law;***
- ***(v) Ensuring that all written grievance decisions include the date the grievance was received, a summary statement of the resident's grievance, the steps taken to investigate the grievance, a summary of the pertinent findings or conclusions regarding the resident's concerns(s), a statement as to whether the grievance was confirmed or not confirmed, any corrective action taken or to be taken by the facility as a result of the grievance, and the date the written decision was issued;***
- ***(vi) Taking appropriate corrective action in accordance with State law if the alleged violation of the residents' rights is confirmed by the facility or if an outside entity having jurisdiction, such as the State Survey Agency, Quality Improvement Organization, or local law enforcement agency confirms a violation for any of these residents' rights within its area of responsibility; and***
- ***(vii) Maintaining evidence demonstrating the result of all grievances for a period of no less than 3 years from the issuance of the grievance decision.***

Effective November 28, 2017

INTENT ***§483.10(j)***
To support each resident's right to voice grievances (*such as* those about treatment, care, management of funds, lost clothing, or violation of rights) *and to ensure that a policy is in place to process grievances. F*acility *staff are responsible for making prompt efforts to resolve a grievance and to* keep the resident appropriately apprised of progress toward resolution.

DEFINITIONS §483.10(j)
"**Prompt efforts to resolve**" include facility acknowledgment of a complaint/grievance and actively working toward resolution of that complaint/grievance.

PROCEDURES §483.10(j)
If *a resident's response* indicate*s* problems in voicing grievances and getting grievances resolved, determine how facility *staff* deal with and make prompt efforts to resolve resident complaints and grievances.

- With permission *from the resident council president or officer*, review resident council minutes.
- Interview staff about how grievances are handled.
- *How does facility staff protect residents from discrimination or reprisal when a grievance is voiced?*
- *How does facility staff ensure the right of the residents to file a grievance anonymously is supported?*
- Interview staff about communication with resident regarding progress toward resolution of complaint/grievance.
- *Review facility grievance policy to see if compliant with necessary requirements as listed above.*
- *Determine how information on how to file a grievance is made available to the resident.*
- *Review grievance decisions to determine if required information was provided to residents and facility documentation was maintained for at least 3 years.*

POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION
If the facility failed to allow a resident to exercise his or her right to file a grievance, including the right to file an anonymous grievance, without interference, coercion, discrimination, or reprisal from the facility, see guidance at §483.10(b)(1), F550, Resident Rights and Dignity.

If facility staff failed to report all alleged violations involving neglect, abuse, including injuries of unknown source, and/or misappropriation of resident property, see guidance at §483.12(c)(1), (4), F609, Reporting of Alleged Violations.

KEY ELEMENTS OF NONCOMPLIANCE §483.10(j)
To cite deficient practice at F585, the surveyor's investigation will generally show that the facility failed to do one or more of the following:

- *Support the resident's right to voice any grievance without discrimination, reprisal, or the fear of discrimination or reprisal;* ***or***
- *Make prompt efforts to resolve the resident's grievance;* ***or***
- *Make information on how to file a grievance or complaint available to the resident;* ***or***

Effective November 28, 2017

- *Establish a grievance policy that includes:*
  - *Notifying the resident individually or with prominent postings throughout the facility about:*
    - *The right to file a grievance in writing or orally;*
    - *The right to file a grievance anonymously;*
    - *The reasonable timeframe the resident can expect a completed review of the grievance;*
    - *The right to obtain the review in writing;*
    - *The required contact information of the grievance official;*
    - *The contact information of independent entities with whom grievances may also be filed;* ***or***
  - *Identify the grievance official;* ***or***
  - *Prevent any further potential violation of any resident right during the grievance review, if necessary;* ***or***
  - *Immediately report certain violations as required by State law to the Administrator;* ***or***
  - *Ensure written grievance decisions meets documentation requirements;* ***or***
  - *Take appropriate corrective action in accordance with State law if the grievance is confirmed by the facility or an outside entity having jurisdiction;* ***or***
  - *Maintain evidence of the result of all grievances for no less than 3 years from the date the grievance decision was issued.*

F586

§483.10(k) Contact with External Entities.

A facility must not prohibit or in any way discourage a resident from communicating with federal, state, or local officials, including, but not limited to, federal and state surveyors, other federal or state health department employees, including representatives of the Office of the State Long-Term Care Ombudsman and any representative of the agency responsible for the protection and advocacy system for individuals with mental disorder (established under the Protection and Advocacy for Mentally Ill Individuals Act of 2000 (42 U.S.C. 10801 et seq.), regarding any matter, whether or not subject to arbitration or any other type of judicial or regulatory action.

INTENT §483.10(k)

Facility staff must ensure that residents are able to communicate freely with representatives of these entities for whatever matter.

If concerns are identified regarding being provided contact information for representatives of these entities, see guidance at 42 CFR §483.10(j)(4)(i), F585, Grievances.

F600

§483.12 Freedom from Abuse, Neglect, and Exploitation

The resident has the right to be free from abuse, ***neglect, misappropriation of resident property, and exploitation as defined in this subpart. This includes but is not limited to freedom*** **from corporal punishment, involuntary seclusion** ***and any physical or chemical restraint not required to treat the resident's medical symptoms.***

Effective November 28, 2017

§483.12(a) **The facility must—**

§483.12(a)(1) **Not use verbal, mental, sexual, or physical abuse, corporal punishment, or involuntary seclusion;**

INTENT
Each resident has the right to be free from **abuse, neglect and corporal punishment of any type by anyone.**

NOTE*: Refer to tag F602 for misappropriation of resident property and exploitation, and F603 for cases of involuntary seclusion.*

DEFINITIONS
"**Abuse**," *is defined at §483.5 as* "the willful infliction of injury, unreasonable confinement, intimidation, or punishment with resulting physical harm, pain or mental anguish. *Abuse* also includes the deprivation by an individual, including a caretaker, of goods or services that are necessary to attain or maintain physical, mental, and psychosocial well-being. *Instances of abuse of all residents, irrespective of any mental or physical condition, cause physical harm, pain or mental anguish. It includes verbal abuse, sexual abuse, physical abuse, and mental abuse including abuse facilitated or enabled through the use of technology."*

"**Neglect**," *as defined at §483.5,* means "*the* failure *of the facility, its employees or service providers* to provide goods and services *to a resident that are* necessary to avoid physical harm, *pain,* mental *anguish or emotional distress."*

"**Sexual abuse**," *is defined at §483.5 as "non-consensual sexual contact of any type with a resident."*

*"**Willful**," as defined at §483.5 and as used in the definition of "abuse," "means the individual must have acted deliberately, not that the individual must have intended to inflict injury or harm."*

GUIDANCE
NOTE: *For purposes of this guidance, "staff" includes employees, the medical director, consultants, contractors, and volunteers. Staff would also include caregivers who provide care and services to residents on behalf of the facility, students in the facility's nurse aide training program, and students from affiliated academic institutions, including therapy, social, and activity programs.*

ABUSE
Sections §§1819 and 1919 of the Social Security Act provide that each resident has the right to be free from, among other things, physical or mental abuse and corporal punishment. The facility must provide a safe resident environment and protect residents from abuse.

Effective November 28, 2017

Staff to Resident Abuse of Any Type

Nursing homes have diverse populations including, among others, residents with dementia, mental disorders, intellectual disabilities, ethnic/cultural differences, speech/language challenges, and generational differences. When a nursing home accepts a resident for admission, the facility assumes the responsibility of ensuring the safety and well-being of the resident. It is the facility's responsibility to ensure that all staff are trained and are knowledgeable in how to react and respond appropriately to resident behavior. All staff are expected to be in control of their own behavior, are to behave professionally, and should appropriately understand how to work with the nursing home population. A facility cannot disown the acts of staff, since the facility relies on them to meet the Medicare and Medicaid requirements for participation by providing care in a safe environment. CMS does not consider striking a combative resident an appropriate response in any situation. *It is also not acceptable for an employee to claim his/her action was "reflexive" or a "knee-jerk reaction" and was not intended to cause harm.* Retaliation by staff is abuse, *regardless of whether harm was intended, and must be cited.*

***NOTE**: It should not be assumed that every accident or disagreement that occurs between an employee and a resident should be considered to be abuse. Accidents that may not be considered to be abuse include instances such as a staff member tripping and falling onto a resident; or a staff member quickly turning around or backing into a resident that they did not know was there.*

Resident to Resident Abuse of Any Type

A resident to resident altercation should be reviewed as a potential situation of abuse. When investigating an allegation of abuse between residents, the surveyor should not automatically assume that abuse did not occur, especially in cases where either or both residents have a cognitive impairment or mental disorder. Having a mental disorder or cognitive impairment does not automatically preclude a resident from engaging in deliberate or non-accidental actions. In determining whether F600-Free from Abuse and Neglect should be cited in these situations, it is important to remember that abuse includes the term "willful". The word "willful" means that the individual's action was deliberate (not inadvertent or accidental), regardless of whether the individual intended to inflict injury or harm. An example of a deliberate ("willful") action would be a cognitively impaired resident who strikes out at a resident within his/her reach, as opposed to a resident with a neurological disease who has involuntary movements (e.g., muscle spasms, twitching, jerking, writhing movements) and his/her body movements impact a resident who is nearby. If it is determined that the action was not willful (a deliberate action), the surveyor must investigate whether the facility is in compliance with the requirement to maintain an environment as free of accident hazards as possible, and that each resident receives adequate supervision (See F689).

The facility may provide evidence that it completed a resident assessment and provided care planning interventions to address a resident's distressed behaviors such as physical, sexual or verbal aggression. However, based on the presence of resident to resident altercations, if the facility did not evaluate the effectiveness of the interventions and staff did not provide immediate interventions to assure the safety of residents, then the facility did not provide sufficient protection to prevent resident to resident abuse. For example, redirection alone is not a

sufficiently protective response to a resident who will not be deterred from targeting other residents for abuse once he/she has been redirected.

Staff should monitor for any behaviors that may provoke a reaction by residents or others, which include, but are not limited to:

- *Verbally aggressive behavior, such as screaming, cursing, bossing around/demanding, insulting to race or ethnic group, intimidating;*
- *Physically aggressive behavior, such as hitting, kicking, grabbing, scratching, pushing/shoving, biting, spitting, threatening gestures, throwing objects;*
- *Sexually aggressive behavior such as saying sexual things, inappropriate touching/grabbing;*
- *Taking, touching, or rummaging through other's property; and*
- *Wandering into other's rooms/space.*

Also, resident to resident abuse could involve a resident who has had no prior history of aggressive behaviors, since a resident's behavior could quickly escalate into an instance of abuse. For example, a resident pushes away or strikes another resident who is rummaging through his/her possessions.

Visitor to Resident Abuse of Any Type

Allegations of abuse have been reported between spouses, or residents and their parents or children, in addition to visitors who are not members of a resident's immediate family. The surveyor may obtain information from the resident's social history, to the extent possible that identifies concerns or issues regarding relationships between the resident and relatives, friends, and/or visitors. The surveyor should interview the social worker and review the resident's assessment and care plan to determine whether the facility identified and provided interventions on how to address the concerns. (Also see F745-Medically Related Social Services).

In addition, the survey team must review whether the facility has developed and implemented policies and procedures related to visitor access. This would include safety restrictions, such as denying access or providing limited and supervised access to a visitor who has been found to be abusing, exploiting, or coercing a resident or who is suspected of abusing, exploiting, or coercing a resident until an investigation into the allegation has been completed. Any such restriction should be discussed with the resident or resident representative first. Also, the resident maintains the right to deny visitation according to his/her preferences. See guidance at F563- Visitation Rights and F564- Resident Right to Visitors.

TYPES OF ABUSE

Identified facility characteristics [1,2] that could increase the risk for abuse include, but are not limited to:

- *Unsympathetic or negative attitudes toward residents;*
- *Chronic staffing problems;*

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1 Adapted from "Elder Abuse Fact Sheet." WHO, Sept. 2016, www.who.int/mediacentre/factsheets/fs357/en/, Accessed 21 Mar 2017.

2 "Elder Abuse: Risk and Protective Factors." CDC, Jun 2016, www.cdc.gov/violenceprevention/elderabuse/riskprotectivefactors.html, Accessed 21 Mar 2017.

- *Lack of administrative oversight, staff burnout, and stressful working conditions;*
- *Poor or inadequate preparation or training for care giving responsibilities;*
- *Deficiencies of the physical environment; and*
- *Facility policies operate in the interests of the institution rather than the residents.*

In addition, the risk for abuse may increase when a resident exhibits a behavior(s) that may provoke a reaction by staff, residents, or others, such as 3:

- *Verbally aggressive behavior, such as screaming, cursing, bossing around/demanding, insulting to race or ethnic group, intimidating;*
- *Physically aggressive behavior, such as hitting, kicking, grabbing, scratching, pushing/shoving, biting, spitting, threatening gestures, throwing objects;*
- *Sexually aggressive behavior such as saying sexual things, inappropriate touching/grabbing;*
- *Taking, touching, or rummaging through other's property;*
- *Wandering into other's rooms/space; and*
- *Resistive to care and services.*

Some situations of abuse do not result in an observable physical injury or the psychosocial effects of abuse may not be immediately apparent. In addition, the alleged victim may not report abuse due to shame, fear, or retaliation. Other residents may not be able to speak due to a medical condition and/or cognitive impairment (e.g., stroke, coma, Alzheimer's disease), cannot recall what has occurred, or may not express outward signs of physical harm, pain, or mental anguish. Neither physical marks on the body nor the ability to respond and/or verbalize is needed to conclude that abuse has occurred.

Abuse may result in psychological, behavioral, or psychosocial outcomes including, but not limited to, the following:

- *Fear of a person or place, of being left alone, of being in the dark, and/or disturbed sleep and nightmares;*
- *Extreme changes in behavior, including aggressive or disruptive behavior toward a specific person; and*
- *Running away, withdrawal, isolating self, feelings of guilt and shame, depression, crying, talk of suicide or attempts.*

The guidance below identifies some characteristics of specific types of abuse.

Physical Abuse

Physical abuse includes, but is not limited to, hitting, slapping, punching, biting, and kicking.

Corporal punishment, which is physical punishment, is used as a means to correct or control behavior. Corporal punishment includes, but is not limited to, pinching, spanking, slapping of hands, flicking, or hitting with an object.

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3 Adapted from Lachs MS, Rosen T, Teresi JA, Eimicke JP, Ramirez M, Silver S, Pillemer K Verbal and physical aggression directed at nursing home staff by residents. J Gen Intern Med. 2013 May; 28(5):660-7.

Possible indicators of physical abuse include an injury that is suspicious because the source of the injury is not observed, the extent or location of the injury is unusual, or because of the number of injuries either at a single point in time or over time.

Examples of injuries that could indicate abuse include, but are not limited to:

- *Injuries that are non-accidental or unexplained;*
- *Fractures, sprains or dislocations;*
- *Burns, blisters, or scalds on the hands or torso;*
- *Bite marks, scratches, skin tears, and lacerations with or without bleeding, including those that are in locations that would unlikely result from an accident;*
- *Bruises, including those found in unusual locations such as the head, neck, lateral locations on the arms, or posterior torso and trunk, or bruises in shapes (e.g., finger imprints); and*
- *Facial injuries, including but not limited to, broken or missing teeth, facial fractures, black eye(s), bruising, bleeding or swelling of the mouth or cheeks.*

Deprivation of Goods and Services by Staff

Abuse also includes the deprivation by staff of goods or services that are necessary to attain or maintain physical, mental, and psychosocial well-being. In these cases, staff has the knowledge and ability to provide care and services, but choose not to do it, or acknowledge the request for assistance from a resident(s), which result in care deficits to a resident(s).

Mental and Verbal Abuse

Mental abuse is the use of verbal or nonverbal conduct which causes or has the potential to cause the resident to experience humiliation, intimidation, fear, shame, agitation, or degradation.

Verbal abuse may be considered to be a type of mental abuse. Verbal abuse includes the use of oral, written, or gestured communication, or sounds, to residents within hearing distance, regardless of age, ability to comprehend, or disability.

Examples of mental and verbal abuse include, but are not limited to:

- *Harassing a resident;*
- *Mocking, insulting, ridiculing;*
- *Yelling or hovering over a resident, with the intent to intimidate;*
- *Threatening residents, including but limited to, depriving a resident of care or withholding a resident from contact with family and friends; and*
- *Isolating a resident from social interaction or activities.*

***NOTE**: Although a finding of mental abuse indicates that a facility is not promoting an environment that enhances a resident's dignity, surveyors must cite a finding of mental abuse at F600 at the appropriate severity level with consideration of the psychosocial outcome to residents.*

Mental abuse includes abuse that is facilitated or enabled through the use of technology, such as smartphones and other personal electronic devices. This would include keeping and/or distributing demeaning or humiliating photographs and recordings through social media or multimedia messaging. If a photograph or recording of a resident, or the manner that it is used, demeans or humiliates a resident(s), regardless of whether the resident provided consent and regardless of the resident's cognitive status, the surveyor must consider non-compliance related to abuse at this tag. This would include, but is not limited to, photographs and recordings of residents that contain nudity, sexual and intimate relations, bathing, showering, using the bathroom, providing perineal care such as after an incontinence episode, agitating a resident to solicit a response, derogatory statements directed to the resident, showing a body part such as breasts or buttocks without the resident's face, labeling resident's pictures and/or providing comments in a demeaning manner, directing a resident to use inappropriate language, and showing the resident in a compromised position. Depending on what was photographed or recorded, physical and/or sexual abuse may also be identified.

Sexual Abuse

"Sexual abuse" is non-consensual sexual contact of any type with a resident, as defined at 42 CFR 483.5. Sexual abuse includes, but is not is not limited to:

- *Unwanted intimate touching of any kind especially of breasts or perineal area;*
- *All types of sexual assault or battery, such as rape, sodomy, and coerced nudity;*
- *Forced observation of masturbation and/or pornography; and*
- *Taking sexually explicit photographs and/or audio/video recordings of a resident(s) and maintaining and/or distributing them (e.g. posting on social media). This would include, but is not limited to, nudity, fondling, and/or intercourse involving a resident.*

Generally, sexual contact is nonconsensual if the resident either:

- *Appears to want the contact to occur, but lacks the cognitive ability to consent; or*
- *Does not want the contact to occur.*

Other examples of nonconsensual sexual contact may include, but are not limited to, situations where a resident is sedated, is temporarily unconscious, or is in a coma.

Any investigation of an allegation of resident sexual abuse must start with a determination of whether the sexual activity was consensual on the part of the resident. A resident's apparent consent to engage in sexual activity is not valid if it is obtained from a resident lacking the capacity to consent, or consent is obtained through intimidation, coercion or fear, whether it is expressed by the resident or suspected by staff. Any forced, coerced or extorted sexual activity with a resident, regardless of the existence of a pre-existing or current sexual relationship, is considered to be sexual abuse. A facility is required to conduct an investigation and protect a resident from non-consensual sexual relations anytime the facility has reason to suspect that the resident does not wish to engage in sexual activity or may not have the capacity to consent.

Non-Sexual Physical Contact with Residents

Nothing in this guidance is intended to limit a resident's ability to receive non-sexual contact, such as holding a resident's hand. It is not the intent of this guidance for facilities to foster "no contact of any type" policies/procedures/practices between staff and residents or residents and

others, assuming such contact is consistent with the resident's preferences. It should also not be assumed that all physical contact involving a resident would constitute sexual abuse.

Capacity and Consent
Residents have the right to engage in consensual sexual activity. However, anytime the facility has reason to suspect that a resident may not have the capacity to consent to sexual activity, the facility must ensure the resident is evaluated for capacity to consent. Residents without the capacity to consent to sexual activity may not engage in sexual activity.

***NOTE**: For information related to determining consent, refer to "Assessment of Older Adults with Diminished Capacity: A Handbook for Psychologists - © American Bar Association Commission on Law and Aging – American Psychological Association, located at http://www.apa.org/pi/aging/programs/assessment/capacity-psychologist-handbook.pdf This resource includes a discussion on determining issues related to determining consent including:*

> *The legal standards and criteria for sexual consent vary across states (Lyden, 2007; Stavis et al., 1999). The most widely accepted criteria, which are consistent with those applied to consent to treatment, are: (1) knowledge of relevant information, including risks and benefits; (2) understanding or rational reasoning that reveals a decision that is consistent with the individual's values (competence); and (3) voluntariness (a stated choice without coercion) (Grisso, 2003; Kennedy, 1999; Stavis, 1991; Stavis et al., 1999; Sundram et al., 1993).*

When investigating an allegation of sexual abuse, the facility must conduct a thorough investigation to determine the facts specific to the case investigated, including whether the resident had the capacity to consent and whether the resident actually consented to the sexual activity. A resident's voluntary engagement in sexual activity may appear to mean consent to the activity; in these instances, if the facility has reason to suspect that the resident may not have the capacity to consent, the facility must protect the resident from potential sexual abuse while the investigation is in progress.

Determinations of capacity to consent depend on the context of the issue and one determination does not necessarily apply to all decisions made by the resident. For example, the resident may not have the capacity to make decisions regarding medical treatment, but may have the capacity to make decisions on daily activities (e.g., when to wake up in the morning, what activities to engage in). Determinations of capacity in this context are complex and cannot necessarily be based on a resident's diagnosis alone. Capacity on its most basic level means that a resident has the ability to understand potential consequences and choose a course of action for a given situation. Decisions of capacity to consent to sexual activity must balance considerations of safety and resident autonomy, and capacity determinations must be consistent with State law, if applicable. The facility's policies, procedures and protocols, should identify when, how, and by whom determinations of capacity to consent to a sexual contact will be made and where this documentation will be recorded. See also 42 CFR 483.10(f) [F561] for concerns related to the resident's right to self-determination through support of resident choice, and 42 CFR

483.10(b)(3)-(7) [F551] for concerns related to the exercise of the resident's rights by the resident representative.

***NOTE**: CMS is not requiring facilities to adopt a specific approach in determining a resident's capacity to consent. However, the facility administration, nursing and medical director may wish to consider establishing an ethics committee, that includes legal consultation, in order to assist in the development and implementation of policy related to aspects of quality of life and/or care, advance directives, intimacy and relationships.*

Cognitive functioning may change due to health issues such as, but not limited to stroke, dementia, depression/psychiatric illnesses or other impacts such as medication(s), hearing/visual loss, and stress. Therefore, the facility should continue to monitor and re-evaluate a resident's capacity to consent over time, as needed, based on the individual resident's physical, mental and psycho-social needs. See also 42 CFR 483.10(g)(14) [F580-Notification of Changes].

Residents With Designated or Legally Appointed Representatives
A resident may have a representative that has been appointed legally under State law through, for example, a power of attorney, guardian, limited guardian, or conservatorship. These legal appointments vary in the degree that they empower the appointed representative to make decisions on behalf of the resident. While a legal representative may have been empowered to make some decisions for a resident, it does not necessarily mean that the representative is empowered to make all decisions for the resident. The individual arrangements for legal representation will have to be reviewed to determine the scope of authority of the representative on behalf of the resident.

A resident may also have designated an individual to speak on his/her behalf for decisions for care or other issues. However, it is necessary for the resident, his/her representative and the facility to have a clear understanding of the types and scope of decision- making authority the representative has been delegated.

Any decision-making power that is not legally granted to a representative under state law is retained by the resident. It is the responsibility of the facility to ascertain what decisions the representative is legally empowered to make on behalf of the resident.

More specifically, regarding consent for sexual activity, State law and the legal instruments setting up resident representation may be silent on that topic. The facility must be aware of the representative's scope of authority regarding resident decision-making.

When a resident with capacity to consent to sexual activity and his/her representative disagree about the resident engaging in sexual activity, the facility must honor the resident's wishes irrespective of that disagreement if the representative's legal authority does not address that type of decision-making for sexual activity. If the resident representative's legal authority addresses decision-making for sexual activity, then the facility must honor the resident representative's decision consistent with 42 CFR 483.10(b).

Effective November 28, 2017

***NOTE**: See F551 at 42 CFR 483.10(b)(6)- If the facility has reason to believe that a resident representative is making decisions or taking actions that are not in the best interests of a resident, the facility shall report such concerns in the manner required under State law.*

Indicators of Potential Sexual Abuse

In addition to reports from residents and others that sexual abuse occurred, possible physical indicators of sexual abuse that would require investigation by the facility and survey team include, but are not limited to:

- *Bruises around the breasts, genital area, or inner thighs;*
- *Unexplained sexually transmitted disease or genital infections;*
- *Unexplained vaginal or anal bleeding; and/or*
- *Torn, stained, or bloody underclothing.*

Literature indicates that the most prevalent psychosocial outcomes of abuse are depression, anxiety, and posttraumatic disorder [4]. Other possible outcomes of sexual abuse [5],6 may include SUDDEN OR UNEXPLAINED CHANGES in the following behaviors and/or activities such as fear or avoidance of a person or place, of being left alone, of the dark, nightmares, and/or disturbed sleep.

Allegations of Sexual Abuse

There are additional considerations when investigating allegations of sexual abuse involving:

- *Sexual abuse by a staff member;*
- *Resident to resident sexual abuse; and*
- *Sexual abuse by a spouse or visitor.*

For any alleged violation of sexual abuse, the facility must:

- *Immediately implement safeguards to prevent further potential abuse;*
- *Immediately report the allegation to appropriate authorities;*
- *Conduct a thorough investigation of the allegation; and*
- *Thoroughly document and report the result of the investigation of the allegation.*

See Tags F608, F609, and F610.

Allegations of Staff to Resident Sexual Abuse

Nursing home staff are entrusted with the responsibility to protect and care for the residents of that facility. Nursing home staff are expected to recognize that engaging in a sexual relationship with a resident, even an apparently willingly engaged and consensual relationship, is not consistent with the staff member's role as a caregiver and will be considered an abuse of power.

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[4] Dong X, Chen R, Chang ES, Simon M. Elder abuse and psychological well-being: a systematic review and implications for research and policy--a mini review. Gerontology. 2013;59(2):132-42.

5 Adapted from Burgess AW, Dowdell EB, Prentky RA. Sexual abuse of nursing home residents. J Psychosoc Nurs Ment Health Serv. 2000 Jun; 38(6):10-8.

6 Adapted from Burgess AW, Clements PT. Information processing of sexual abuse in elders. J Forensic Nurs. 2006 Fall; 2(3):113-20.

Also, for some health care professionals, it is prohibited by licensure or certification requirements for professionals to have a relationship with a resident (or patient).

***NOTE**: Refer to applicable State professional licensure/certification requirements and/or scope of practice.*

Any sexual relationship between a staff member and a resident with or without diminished capacity may constitute sexual abuse in the absence of a sexual relationship that existed before the resident was admitted to the facility, such as a spouse or partner, and must be thoroughly investigated. However, in a rare situation, it may not be considered to be sexual abuse when a nursing home employee has a pre-existing sexual relationship with an individual, (i.e., spouse or partner) who is then admitted to the nursing home, unless there are concerns about the relationship not being consensual.

Allegations of Resident To Resident Sexual Abuse

Studies show that a considerable amount of unwanted sexual contact in nursing homes may be initiated by a resident who is sexually aggressive as a result of disease processes such as brain injuries or dementia. In addition, a resident may have a pre-occupation for sexual activity, or have had a prior history of sexual abuse. The resident who is sexually aggressive may target a resident who is unable to protect him/herself, and may involve various types of sexual aggression such as fondling both over and under clothing, masturbation in the presence of another resident and is unwanted by that other resident, forcing oral sex, or sexual intercourse.

If there is an allegation that a resident did not wish to engage in sexual activity with another resident or may not have the capacity to consent, the facility must respond to it as an alleged violation of sexual abuse.

Allegations of Visitor to Resident Sexual Abuse

In certain situations, sexual activity between a resident and a visitor (e.g., spouse, partner) may not be considered to be abuse, if there was a pre-existing sexual relationship, the resident has the capacity and ability to consent, and the resident wishes to continue with the sexual relationship. Regardless, the nursing home must ensure that a visitor(s) is not subjecting any resident(s) to sexual abuse. In addition, the nursing home staff must immediately act on any allegation or suspicion that a visitor is engaging in improper sexual activity with a resident (See F608, F609, F610).

Response to Alleged Violations of Sexual Abuse

If an allegation of sexual abuse has been reported, the facility must immediately protect the alleged victim(s) involved, report the alleged violations to the Administrator and appropriate State and local authorities, and begin an investigation of the allegation. See also 42 CFR 483.12 (c)(1)-(4), F609-Reporting of Alleged Violations and F610-Response to Alleged Violations. As the facility conducts its investigation, the facility must not tamper with evidence. Tampering with evidence would impede completion of a thorough investigation by the facility and other investigating authorities. Examples of tampering include, but are not limited to: washing linens or clothing, destroying documentation, bathing or cleaning the resident until *the resident has been examined (including a rape kit, if appropriate), or otherwise impeding a law*

enforcement investigation. If the surveyor identifies that the facility has tampered with evidence, the surveyor should investigate whether the facility is in compliance with F607 and F610.

Determination of Findings and Potential to Foresee Abuse

It has been reported that some facilities have identified that they are in compliance with F600-Free from Abuse and Neglect because that they could not foresee that abuse would occur and they have "done everything to prevent abuse," such as conducted screening of potential employees, assessed residents for behavioral symptoms, monitored visitors, provided training on abuse prevention, suspended or terminated employment of the perpetrator, developed and implemented policies and procedures to prohibit abuse, and met reporting requirements. However, this interpretation would not be consistent with the regulation, which states that "the resident has the right to be free from verbal, sexual, physical, and mental abuse…" Therefore, if the survey team has investigated and collected evidence that abuse has occurred, it is appropriate for the survey team to cite the current or past noncompliance at F600-Free from Abuse and Neglect.

Determination of Past Non-Compliance

Past noncompliance occurs when noncompliance has occurred in the past, but the facility corrects the deficiency and is in substantial compliance at the time of the current survey. More specifically, a deficiency citation at past noncompliance meets the following three criteria:

1. *The facility was not in compliance with the specific regulatory requirement(s) at the time the situation occurred;*
2. *The noncompliance occurred after the exit date of the last standard (recertification) survey and before the survey (standard, complaint, or revisit) currently being conducted, and*
3. *There is sufficient evidence that the facility corrected the noncompliance and is in substantial compliance at the time of the current survey for the specific regulatory requirement(s), as referenced by the specific F-tag or K-tag.*

The surveyors must document the facility's corrective actions in the CMS-2567; the facility is not required to submit a plan of correction. Refer to Appendix Pof the State Operations Manual (SOM) for more specific information on determining and documenting past noncompliance. Refer to SOM Section 7510.1 for information on the imposition of a civil monetary penalty related to a finding of past noncompliance.

NEGLECT

***NOTE**: For purposes of this guidance, "staff" includes employees, the medical director, consultants, contractors, volunteers. Staff would also include caregivers who provide care and services to residents on behalf of the facility, students in the facility's nurse aide training program, and students from affiliated academic institutions, including therapy, social, and activity programs.*

The Link between Noncompliance at Resident's Rights/Quality of Care/Quality of Life and Neglect of Goods and Services

Neglect at F601 should not automatically be cited in addition to the Resident's Rights/Quality of Care/Quality of Life tags. While the latter citations identify potential or actual negative

outcomes in the areas of resident's rights, quality of care, and quality of life, neglect identifies the facility's failure to provide the required structures and processes in order to meet the needs of one or more residents. This may include, but is not necessarily limited to, the facility's failure to provide necessary staff, supplies, services, policies, training, or staff supervision and oversight to meet the resident's needs.

Identifying Neglect

If the facility is aware of, or should have been aware of, goods or services that a resident(s) requires but the facility fails to provide them to the resident(s). Neglect may be the result of a pattern of failures or may be the result of one or more failures involving one resident and one staff person.

Neglect of goods or services may occur when staff are aware, or should be aware, of residents' care needs, based on assessment and care planning, but are unable to meet the identified needs due to other circumstances, such as lack of training to perform an intervention (e.g., suctioning, transfers, use of equipment), lack of sufficient staffing to be able to provide the services, lack of supplies, or staff lack of knowledge of the needs of the resident. Examples include, but are not limited to:

- *A nurse aide was assigned to care for several residents, who required, assistance to eat, drink, dress, bathe, toilet, walk, and positioning in bed or chair. Due to the workload and resident care requirements, the nurse aide is unable to respond to call lights or complete the assignments for all of the residents that she is assigned to provide care for. In addition, due to insufficient numbers of staff in the facility, there is no other nurse aide available to assist her. This inability of the nurse aides in this unit to respond to call lights and to complete resident care assignments occurs throughout the shift, resulting in omissions in delivery of services to meet the resident's needs. Physical harm occurred as a result of the lack of sufficient staff to implement the care plan as ordered and inadequate supervision to assure that care was provided as ordered and/or as planned. In addition, staff had reported to administration their concerns about not meeting the residents' needs, but administration failed to respond.*
- *The nursing home utilizes temporary staffing agencies, but does not have processes in place to provide orientation, or medical or care plan information for the temporary staff regarding the individual resident's needs on the unit to which the temporary employee is assigned.*
- *The nursing home failed to respond to residents refusing to bathe/shower, based on complaints of cold water during bathing/showering. Maintenance staff identified equipment failures and reported them to the facility's administrator with recommendations to replace the water heating system. However, the administrator did not address these failures, resulting in the diminished quality of life for residents.*

Identification of Goods and Services Required by Residents

When a resident is admitted to a nursing home, the nursing home has determined that it has the capability and capacity to provide goods and services to meet the needs of the resident by its staff. In addition, other services as needed by the resident must be assessed and addressed by the nursing home. This does not mean that all services must be directly provided by the nursing home, but the nursing home must assist and/or make referrals for the resident to receive

necessary services. Examples of structures and processes the facility must have in place, include but are not limited to:

- *Structures - The nursing home's capability and capacity to provide needed care and services such as:*
  - *A facility's assessment to determine what resources are necessary to care for its residents competently;*
  - *The provision of sufficient numbers of qualified, trained staff based upon the facility's assessment and as needed to meet resident needs;*
  - *An effective orientation, training, and evaluation program, which includes, but is not limited to, nursing home resident care policies specific to resident's identified care needs, resident care requirements based upon assignments and duties including types of services and treatments required for each resident, and other interventions necessary to meet a resident(s) needs;*
  - *Oversight and monitoring of staff performance including conducting performance evaluations for direct care staff (nurse aides), and how weaknesses or training needs are addressed;*
  - *Oversight and monitoring of contracted services or services provided under arrangement;*
  - *Resident care policies and procedures to ensure that the facility provides care and services in accordance with current standards of practice, that address resident's diagnosis, and that provide clinical and technical direction to meet the needs of each resident admitted;*
  - *Sufficient amounts of food to meet dietary needs;*
  - *Availability of medications and supplies necessary to provide care;*
  - *Implementation of an infection control and prevention program that includes staff procedures for care including hand hygiene, standard and transmission based precautions, including use of PPE;*
  - *A safe and sanitary environment;*
  - *Provision of sufficient clean linens;*
  - *Adequate and appropriate equipment and devices and other available technology, including procedures for how to use, clean, maintain and store equipment;*
  - *An effective communication system across all shifts for communicating necessary care and information between staff, practitioners and resident representatives; and*
  - *If admitted, the provision of specialized services for residents who require rehabilitation services, dialysis, respiratory therapy (mechanical ventilation or oxygen therapy), IV therapy, and hospice.*
- *Processes so that the needs of each resident are met, based upon:*
  - *Initial and ongoing assessments of the clinical needs of the resident including any acute changes in condition, such as cardio/respiratory failure, choking, hemorrhaging, poor glycemic control, onset of delirium, behavioral emergencies, or falls resulting in head injuries or fractures;*
  - *The provision and implementation of a resident-specific care plan including the ongoing evaluation and revision of the care plan as necessary;*
  - *Ongoing monitoring and supervision of staff to assure the implementation of the care plan as written; and*

- *Effective communication between staff, health care practitioners, and the resident/resident representative.*

The cumulative effect of different individual failures in the provision of care and services by staff leads to an environment that promotes neglect. Examples of individual failures include, but are not limited, to the following:

- *Failure to provide sufficient, qualified, competent staff, to meet resident's needs;*
- *Failure to provide orientation and/or training to staff;*
- *Failure to provide training on new equipment or new procedures or medications required for the care of a specified resident or required due to changes in acceptable standards of practice;*
- *Failure to oversee the implementation of resident care policies;*
- *Failure to provide supervision and/or monitoring of the delivery and implementation of care;*
- *Failure of staff to implement resident interventions, even when residents are assessed and interventions are identified in the care plan;*
- *Failure to identify, assess, and/or contact a physician and/or prescriber for an acute change in condition, and/or a change in condition that requires the plan of care to be revised to meet the resident's needs in a timely manner;*
- *Failure to ensure staff respond correctly to medical or psychiatric emergencies;*
- *Failure to monitor and/or provide adequate supervision to assure that environmental hazards are not present including but not limited to:*
  - *Access to hot water of sufficient temperature to cause tissue injury;*
  - *Non-functioning call system without a compensatory action;*
  - *Improper handling/disposal of hazardous materials, chemicals and waste;*
  - *Infestation by insects/rodents;*
- *Failure to provide adequate monitoring and supervision, if smoking is allowed;*
- *Failure to meet financial obligations for the delivery of care and the maintenance of the facility (e.g. payment for staff, utilities, contractors);*
- *Failure of the Quality Assurance and Assessment committee to develop and implement appropriation action plans to correct identified quality deficiencies;*
- *Failure of administration to effectively and efficiently use its resources to attain or maintain the highest practicable physical, mental, and psychosocial well-being; and*
- *Failure to provide oversight of medical services that are provided in the facility.*

The failure to provide necessary care and services resulting in neglect may not only result in a negative physical outcome, but may also impact the psychosocial well-being of the resident, with outcomes such as mental anguish, feelings of despair, abandonment, and fear. (Refer to Psychosocial Outcome Severity Guide in Appendix P)

INVESTIGATIVE SUMMARY FOR ABUSE AND NEGLECT
INVESTIGATION OF ALLEGATIONS OF ABUSE

The process to review concerns are outlined in the Abuse Critical Element Pathway (Form CMS-20059).

Effective November 28, 2017

Summary of Procedures

Identify if there is an alleged violation of abuse, physical punishment or allegations of an individual depriving a resident of care or services.

- *Refer to the Neglect Critical Element Pathway to investigate concerns about structures or processes leading to a resident(s) failing to receive required care and services.*
- *Refer also to the Investigative Protocol for F608-Reporting Reasonable Suspicion of a Crime, if a covered individual did not report a reasonable suspicion of a crime or an allegation of retaliation.*

***NOTE**: If you receive an unreported allegation of abuse, report this immediately to the facility administrator or person in charge.*

Use observations, interviews, and record review to gather and corroborate information related to:

- *The alleged abuse, including anything that could have placed the alleged victim at risk for abuse, who was involved, what happened, and when and where did it happen;*
- *Any injuries and/or physical/psychosocial outcomes, including whether interventions/medical treatment was required;*
- *Details of actions taken, including protecting the resident(s), reporting, investigating, and corrective actions;*
- *Whether there is any indication that retaliation may have occurred; and*
- *What types of training and/or orientation staff may have received related to abuse.*

For specific allegations of abuse, the surveyor should review:

- *For allegations of staff to resident abuse, staffing rosters to determine staffing at the time of the alleged abuse, timecards for staff on duty at the time, and conduct staff interviews to determine whether there was adequate monitoring and supervision of staff at the time of the allegation. The surveyor should also review staff training logs to determine whether staff was trained on abuse prevention, and review the alleged perpetrator personnel records, including screening and disciplinary records, if any.*
- *For allegations of resident to resident abuse, whether there is a history of distressed behaviors that could place residents at risk, whether resident assessments identified concerns related to behavior, mood, cognitive status, communication, and mobility and whether care planning addressed the concerns identified with specific interventions, whether interventions were implemented, and whether there was adequate monitoring and supervision of the resident(s).*
- *For allegations of visitor to resident abuse, whether there was any indication of risk to the resident(s) and whether adequate monitoring and supervision were provided as appropriate.*

INVESTIGATION FOR ALLEGATIONS OF NEGLECT

The process to review concerns are outlined in the Neglect Critical Element Pathway (Form CMS-20130).

Effective November 28, 2017

Use

Use the Neglect Critical Element (CE) Pathway, and the above Guidance when investigating concerns related to structures or processes that have led to resident outcome such as unrelieved pain, avoidable pressure injuries, avoidable dehydration, lack of continence care, or malnourishment.

Utilize appropriate Critical Element Pathways for care issues, in order to identify whether noncompliance for a care concern exists first and determine whether further investigation is needed as to whether the facility has the structures and processes to provide necessary to provide goods and services to residents.

Summary of Procedures

Interview staff and review facility policies and procedures to determine:

- *How the facility monitors and provides oversight of the provision of care and services; and*
- *How the facility responds when there are concerns that a resident(s) is not receiving necessary goods and services.*

KEY ELEMENTS OF NONCOMPLIANCE FOR ABUSE AND NEGLECT

To cite deficient practice at F600, the surveyor's investigation will generally show that the facility:

- *Failed to protect a resident's right to be free from any type of abuse, including corporal punishment, and neglect, that results in, or has the likelihood to result in physical harm, pain, or mental anguish; or*
- *Failed to ensure that a resident was free from neglect when it failed to provide the required structures and processes in order to meet the needs of one or more residents.*

POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION

During the investigation, the surveyor may have determined that concerns may also be present with related outcome, process and/or structure requirements. The surveyor is cautioned to investigate these related requirements before determining whether non-compliance may be present. Some examples of related requirements that should be considered include the following:

- *42 CFR 483.10(f)(4)(ii)-(v), F563 - Visitation Rights*
  - *Determine if the facility provided immediate access and visitation by family, designated representatives or other individuals, subject to reasonable restrictions and the resident's right to deny or withdraw consent.*
- *42 CFR 483.10(f)(4)(vi), F564- Resident Right to Visitors*
- *42 CFR 483.10(g)(1), F572 - Notice of Rights and Rules*
- *42 CFR 483.10(h), F583- Personal Privacy/Confidentiality of Records*
- *42 CFR 483.12(a)(3)-(4), F606 - Not Employ/Engage Staff with Adverse Actions*
- *42 CFR 483.12(b)(1)-(4), F607 – Develop/Implement Abuse/Neglect, etc. Policies*
- *42 CFR 483.12(b)(5), F608 - Reporting of Reasonable Suspicion of a Crime*
- *42 CFR 483.12(c)(1), (4), F609 – Reporting of Alleged Violations*
- *42 CFR 483.12(c)(2) - (4), F610 – Alleged Violations-Investigate/Prevent/Correct*
- *42 CFR 483.24, F675 - Quality of Life*

- *42 CFR 483.25(d), F689- Free of Accident Hazards/Supervision/Devices*
  - *Determine if the facility ensured that the resident environment remains as free from accident hazards as is possible and each resident receives adequate supervision to prevent accidents related to resident-to-resident altercations where the resident's action is not willful.*
- *42 CFR 483.35, 483.35(a), and 483.35(c)- F725 and F726 – Sufficient and Competent Staff*
- *42 CFR 483.35(a)(3) and (a)(4), 483.35(c), F726 – Competent Staff*
- *42 CFR 483.40(b)-(b)(1), F742- Treatment/Svc for Mental/Psychosocial Concerns*
- *42 CFR 483.75 (g)(2)(ii)- F867- QAA Activities*
- *42 CFR 483.95(c), F942- Abuse, Neglect, and Exploitation Training*
- *42 CFR 483.95(g), F946-Required In-Service Training for Nurse Aide*

DEFICIENCY CATEGORIZATION

In addition to actual or potential physical harm, always consider whether psychosocial harm has occurred when determining severity level (See Appendix P, Section IV, E, Psychosocial Outcome Severity Guide).

Examples of Severity Level 4 Noncompliance Immediate Jeopardy to Resident Health or Safety include, but are not limited to:

- *The facility failed to protect a resident from sexual abuse resulting in serious psychosocial harm. A resident, with moderate confusion and who was dependent on staff for care, reported to staff that she was "touched down there" and identified the alleged perpetrator. However, staff, who thought the resident was confused, did not report her allegation to facility administration and failed to provide protection for the resident allowing ongoing access to the resident by the alleged perpetrator. The resident expressed recurring fear whenever the perpetrator approached the resident, exhibited crying and agitation, and declined to leave her room.*
- *The facility failed to protect two residents from mental abuse and extreme humiliation perpetuated by two staff who posted videos and photographs on social media, of the residents during bathing, using the bathroom and grooming, which included nude photos and photos of genitalia. In addition, on the videos, the two staff verbally taunted and made cruel remarks to the residents including making fun of the way the resident looked and acted. One resident who was cognitively impaired was shown on the video to be crying in response to the remarks made to her by the staff. One resident, who was cognitively intact, told surveyors that he was extremely humiliated and angry when he found out that these items were posted.*
- *The facility failed to ensure that a resident was free from neglect when it did not have the structures to provide necessary goods and services to residents. During facility tour, the surveyor noted a strong urine odor. Residents were observed to be in bed with soiled clothes and linens. Residents told the surveyor that they did not get out of bed or dressed since there were not enough nurse aides to assist them. During interviews with nurse aides, it was reported that the facility lacked supplies, such as incontinence briefs, laundry/housekeeping supplies, gloves and food. Interview with the Director of Nurses revealed that the medical supply vendor was suspended and no longer providing supplies to the facility due to non-payment. Multiple staff also reported not receiving their last*

paychecks. During interviews with residents, residents reported mice in their rooms. During observation of the kitchen and interview with the dietary manager, there was evidence of rodent infestation, including staff seeing rodents eating and finding torn bags and crumbs on the floor. The administrator reported that the pest control company had visited the facility recently, but there was no record of the visit or proposal for remediation. Also, there was no sanitizer for the dishwasher and no alternative method for sanitizing dishes.

Examples of Severity Level 3 Noncompliance Actual Harm that is not Immediate Jeopardy include, but are not limited to:

- *The facility failed to ensure that a resident was free from physical abuse. A resident, who required supervision due to physical aggression, was observed to have escalating behaviors, resulting in striking out at staff and residents in the vicinity. The staff failed to ensure that residents in the vicinity were safe, and the resident pushed another resident who was walking to his/her room. The resident fell to the floor with a resulting fracture to her arm that required treatment at the hospital, placement of a cast and was in moderate pain due to the fracture. There was no significant decline in mental or physical functioning.*
- *The facility failed to ensure that a resident was free from corporal punishment. A resident who had a cognitive disability carried a doll around with her throughout the day. During an activity, the resident placed the doll in a chair next to her and refused to allow another resident to use the chair. The staff slapped the resident's hand and removed the doll so the other resident could sit down. The staff told the resident she could not attend any more activities with the doll, or he would get rid of it and the resident would never see it again. The resident began to scream, cry for her doll and left the room. The resident will not leave her room to attend any activities for fear that the staff person will take her doll. The resident's behavior has declined and now cries and expresses fear when taken for bathing and meals without her doll.*
- *The facility deprived residents of care related to failure of staff to respond timely to residents' requests and treat residents with dignity and respect which resulted in ongoing embarrassment, humiliation, and the failure to provide incontinence care as needed to meet the needs of several residents. Based on family and resident group interview, other residents and their family members complained that residents often waited a long time (up to an hour) before staff took them to the bathroom, resulting in residents urinating in their beds and lying in urine for long periods of time. Residents indicated that this is a problem, especially on the night shift. Residents were told by nurse aides to just urinate on their beds and staff would change the sheets in the morning. Two night-shift staff members confirmed that they had seen other staff disconnect call lights in residents' rooms so that they were not functioning. After investigation, it was determined that the nursing home failed to provide necessary care. [**NOTE**: In this example, the surveyor had already identified noncompliance at dignity (F550) and urinary incontinence (F690)]*
- *The facility deprived a resident of care by failing to provide access for resident communication and response to resident's requests for necessary care resulting in resident's ongoing fear and anxiety. During a survey, the surveyor observed that a resident's call light was pinned to a privacy curtain out of reach of the resident. The*

resident stated that staff removes the call light at night because the nursing staff said he used it too much and they did not have time to answer the light all the time. The resident began crying, and expressed fear that something would happen and he would have no way of getting assistance as staff would not come if he called out for help.

- *The facility neglected to provide supervision and monitoring to assure that continence care is provided with dignity, respect and meets the needs of a resident. During a complaint survey, the investigation revealed that a cognitively-impaired resident had been left with his lower body uncovered and completely exposed, and unattended for several hours. Also, the investigation also identified that his catheter bag had been left lying flat on the bed so that urine could not flow freely or drain, resulting in expressions of pain and discomfort. Interview with the charge nurse revealed that she was the only nurse in the building during the night shift and stated that the she was unable to monitor the nurse aides' provision of care because she was providing treatments on other units. It was identified that insufficient nurse staffing has been reported to the administration and that this was an ongoing concern.*

Examples of Severity Level 2 ConsiderationsNoncompliance No Actual Harm with Potential for More Than Minimal Harm that is Not Immediate Jeopardy include, but are not limited to:

- *The facility failed to assure that a resident was free from verbal abuse. A resident with cognitive impairment did not want to be bathed and began yelling at a staff person and called her a derogatory name. The staff person yelled back at the resident saying, "You can't call me that!" and called the resident the derogatory name. Another staff member in the bathing area, overheard the exchange and immediately reported the exchange to the charge nurse. The resident was reported to be upset initially, but did not exhibit any further changes in behavior and requested not to be assigned to that staff person.*
- *The facility failed to assure that structures and processes were in place when using student nurse aides to provide necessary care, based on the resident's care plan. On observation, a resident was observed with broken and chipped fingernails, which were caked with feces. In interviews, the student nurse aides stated that they did not know that they had to provide nail care, and that they had not received orientation or sufficient training in this type of care. There was no monitoring by staff or student instructors of the provision of grooming for residents, nor attention to the care plan interventions.*

Severity Level 1: No Actual Harm with Potential for Minimal Harm

The failure of the facility to prevent abuse or neglect is more than minimal harm. Therefore, Severity Level 1 does not apply for this regulatory requirement.

F602

§483.12

The resident has the right to be free from abuse, *neglect, misappropriation of resident property, and exploitation as defined in this subpart. This includes but is not limited to freedom* from corporal punishment, involuntary seclusion *and any physical or chemical restraint not required to treat the resident's medical symptoms.*

INTENT

*Each resident has the right to be free from **misappropriation of property and exploitation**.*

Effective November 28, 2017

***NOTE**: Refer to F608 for requirements related to reporting of a reasonable suspicion of a crime.*

DEFINITIONS

*"**Exploitation**," as defined at §483.5, means "taking advantage of a resident for personal gain, through the use of manipulation, intimidation, threats, or coercion."*

"**Misappropriation of resident property**," *as defined at §483.5,* means "the deliberate misplacement, exploitation, or wrongful, temporary, or permanent use of a resident's belongings or money without the resident's consent."

GUIDANCE

Residents' property includes all residents' possessions, regardless of their apparent value to others since they may hold intrinsic value to the resident. Residents are permitted to keep personal clothing and possessions for their use while in the facility, as long as it does not infringe upon the rights of other residents (See F557). Examples of resident property include jewelry, clothing, furniture, money, and electronic devices, the resident's personal information such as name and identifying information, credit cards, bank accounts, driver's licenses, and social security cards.

Examples of misappropriation of resident property include, but are not limited to:

- *Identity theft;*
- *Theft of money from bank accounts;*
- *Unauthorized or coerced purchases on a resident's credit card;*
- *Unauthorized or coerced purchases from resident's funds;*
- *A resident who provides a gift to staff in order to receive ongoing care, based on staff's persuasion; and*
- *A resident who provides monetary assistance to staff, after staff had made the resident believe that staff was in a financial crisis.*

Facility staff are in a position that may be perceived as one of power over a resident. As such, staff may be able to manipulate or unduly influence decisions by the resident. Staff must not accept or ask a resident to borrow personal items or money, nor should they attempt to gain access to a resident's holdings, money, or personal possessions through persuasion, coercion, request for a loan, or solicitation. For example, exploitation may include, but is not limited to, when a resident, or resident representative, has given his/her money or belongings to staff as a result of coercion, or because the resident, or resident representative, believes that it was necessary (e.g., in order to receive good care). A resident's apparent consent is not valid if it is obtained from a resident lacking the capacity to consent, or consent is obtained through intimidation, coercion or fear, whether it is expressed by the resident or suspected by staff.

Another example of misappropriation of resident property is the diversion of a resident's medication(s), including, but not limited to, controlled substances for staff use or personal gain.

INVESTIGATIVE PROTOCOL FOR MISAPPROPRIATION OF RESIDENT PROPERTY AND EXPLOITATION

Effective November 28, 2017

OBJECTIVES

To determine:

- *Whether a resident(s) was free from misappropriation of resident property and exploitation (F602);*
- *If the facility developed, implemented and educated staff on policies and procedures that prohibit misappropriation of resident property and exploitation (F607);*
- *If the facility developed and implemented pre-employment procedures (F606); and*
- *How the facility protects, reports, investigates, and acts upon alleged violations of misappropriation of resident property and exploitation (F608, F609, F610).*

USE

Use this protocol during any type of survey as necessary in order to investigate an allegation of misappropriation of property or exploitation.

PROCEDURES

OFFSITE SURVEY PREPARATION

Information related to an alleged violation may be obtained from:

- *Reports from the ombudsmen or other State Agencies;*
- *Any related previously-cited deficiencies (CASPER Report 3); and*
- *A complaint and/or facility self-report including:*
  - *Name of alleged victim(s), alleged perpetrator(s) and witnesses, if any;*
  - *Narrative/specifics of the allegation(s) including frequency and pervasiveness of the allegation; and*
  - *Whether the allegation was reported by the facility and to other agencies.*

ONSITE SURVEY ACTIVITIES

If a surveyor receives an allegation of misappropriation of resident property or exploitation during the survey, he/she must immediately report this to the facility administrator, or his/her designated representative if the administrator is not present. The survey team should determine whether the facility then takes appropriate action in accordance with the requirements at F609 and F610.

During the course of the investigation, if it is determined that the resident's property was misplaced and found and not misappropriated, or the property loss was not related to a facility failure to protect the property (e.g., resident/family accidentally disposed of the item or took the item home), the investigation may be stopped.

Obtain and review the facility's policies and procedures related to misappropriation of resident property and exploitation. It is not necessary for these items to be maintained in one document or manual.

OBSERVATION

Depending on the nature of the incident, the surveyor should conduct observations that are related to the allegation. Observations include, but are not limited to,

- *For allegations of theft of medications, how medications are secured and accessed.*

- *For allegations of stolen property, where the property was stored, whether it was in a secure area, and how the property was accessed.*

Interview:
The surveyor follows the guidelines below for interviews, which include, but are not limited to:

- *Conduct interviews in a private location, preferably seated in order to be able to maintain eye contact with the individual being interviewed;*
- *Be impartial, use discretion, and non-judgmental language and to the extent possible, ask open-ended, non-leading questions;*

  NOTE*: It is important to maintain the confidentiality of the names of the person(s), to the extent possible, who reported the allegation.*

- *Conduct follow up interviews, as necessary, to evaluate new information obtained, discrepancies or changes in information; and*
- *Maintain documentation of interviews including dates, times, locations and names of individuals interviewed.*

NOTE: *It is important to attempt to obtain as accurate information as possible, and it may be necessary to obtain assistance from an interpreter if English is not the spoken language of the resident or staff.*

Resident/Family Interview. *Interview the alleged victim privately; however, the alleged victim may request that another person be present. If so, be aware that the alleged victim may not be comfortable speaking openly in the presence of another person, and another interview may be necessary to follow up on any discrepancies identified. A resident with a cognitive impairment and/or mental illness may mistakenly be assumed to be an incompetent witness. In those situations, interview the alleged victim, to the extent possible, and corroborate statements with other observations, interviews and record review. During the interview, observe the resident's emotions and tone, as well as any nonverbal expressions or gesturing to a particular body area, in response to the questions. Interview the resident, or resident's representative, to determine:*

- *For an allegation of misappropriation of resident property:*
  - *What is missing. If the missing item is money, how much;*
  - *For how long the item has been gone;*
  - *Whether the resident has any idea of what might have happened to the item;*
  - *Whether the resident suspects a specific person(s) was involved in the loss of the item(s) and the name, title (if any) and/or relationship to the resident;*
  - *Whether the resident/family reported the missing property to facility staff and, if so, when and to whom and the facility's response;*
  - *Whether local law enforcement or other outside agencies were notified, and if so, any response that they are aware of; and*
  - *How the resident feels about losing the item.*
- *For an allegation of exploitation:*
  - *When and where the alleged exploitation occurred;*
  - *What occurred prior to, during and immediately following the alleged exploitation;*

- *Whether he/she can identify who was involved including the alleged perpetrator and/or any witnesses;*
- *Why the resident gave the item to the alleged perpetrator or allowed the alleged perpetrator to take the item;*
- *How the resident values the item;*
- *Whether he/she reported the alleged exploitation to the facility, when and to whom reported and the facility's response; and*
- *Whether he/she feels safe, is afraid of anyone, or fearful of retaliation.*

Staff Interview
Review staff attendance records from any department to determine who was working at the time of the alleged misappropriation or exploitation and who may have had access to the resident and/or the resident's room to collect information about:

- *Whether he/she had knowledge of the allegation and what actions, if any, he/she took in response to the allegation;*
- *Any changes in the resident's behavior as a result of the allegation;*
- *Whether an individual has been identified as the alleged perpetrator and how the alleged perpetrator and resident related to one another prior to and after the incident;*
- *Whether he/she reported the allegation to management/administrative staff or any State or local agencies, and if so, to whom was the allegation reported and when;*
- *If not reported, what prevented him/her from reporting;*
- *Whether he/she is fearful of retaliation;*
- *If he/she reported the allegation, whether he/she feels that retaliation has occurred as a result of reporting the allegation, and if so, what actions were taken against staff; and*
- *Whether he/she has received training from the facility on misappropriation and exploitation identification, prevention, and reporting requirements.*

Alleged Perpetrator Interview*:*
If the alleged perpetrator is a staff member, the staff member may have been suspended or re-assigned until the investigation is completed and in some situations, the facility may have terminated the employment of the individual. In some cases, the alleged perpetrator may not be in the facility or may refuse to be interviewed. If possible, interview the alleged perpetrator either in person or by phone to determine:

- *What information he/she can provide regarding to the allegation of missing property or exploitation;*
- *Whether he/she was present in the nursing home at the time the alleged misappropriation of property or exploitation occurred;*
- *Whether he/she has any information on the allegation, such as:*
  - *When and where the alleged incident occurred; and*
  - *If he/she has any other information that he/she wishes to share in regard to the investigation.*

Facility Investigator Interview*. If the facility was aware of the allegation, identify the staff member responsible for the initial reporting and investigation of alleged misappropriation of resident property or exploitation. This may be the administrator in some facilities. Obtain a copy of the investigation report. Interview the responsible staff person to determine:*

- *How the facility investigated the allegation of misappropriation or exploitation;*
- *If the facility did not know if the resident had the property prior to the alleged loss, and how the facility protects the resident's property from loss or theft;*
- *Whether local law enforcement or other outside agencies were notified, and if so, any response that they are aware of; and*
- *What findings and resolutions have occurred.*

Record Review

It may be necessary to obtain copies of specific entries in the record for the period of time that is relevant to the allegation.

Review the alleged victim's record to obtain necessary information as applicable such as:

- *The diagnosis and physician orders including medications;*
- *The RAI, to include the resident's cognitive status;*
- *Care plan and interventions/goals;*
- *Physician's, nurse's, social worker's and other staff members progress notes, as applicable; (e.g. for investigation of drug diversion, whether there was indication of unrelieved pain during certain times of the day for residents who were prescribed the allegedly diverted medication);*
- *Any lists of resident valuables or resident items brought in to the facility; and*
- *Social and psychological history.*

If staff is identified as the alleged perpetrator, review the staff member's personnel file for information related to:

- *The allegation being investigated or history of other allegations;*
- *Adverse personnel actions taken relevant to exploitation or misappropriation of property;*
- *Screening that occurred prior to and during employment; and*
- *Training and orientation related to abuse and neglect prevention.*

For an alleged theft of monies if the resident's funds are managed or held by the facility, review the accounting records for the resident's funds, including receipts for expenditures from the resident's funds. Attempt to reconcile whether the items are in the resident's possession. Review interdisciplinary notes that relates to the alleged exploitation or misappropriation of property for documentation of the following:

- *The date/time of the alleged exploitation/misappropriation and/or the date/time when the alleged exploitation/misappropriation was first discovered;*
- *Any change in the alleged victim's mood and demeanor before and after the alleged misappropriation/exploitation, such as:*
  - *Distrust;*
  - *Fear (e.g., fear of being touched or shying away from being touched);*
  - *Angry outbursts, tearfulness, agitation, trembling, cowering;*
  - *Panic attacks; and*
  - *Changes in sleeping patterns.*

Reports from Other Investigatory Agencies
At the time of the survey, if another investigatory agency(ies) has completed its investigation, the surveyor should request a copy of the report. Other investigatory agencies may include State adult protective services, State professional licensing boards, and law enforcement/police reports.

Interview with Person Responsible for Quality Assurance
Interview the person responsible for Quality Assurance activities. Determine how the committee is providing monitoring and oversight of potential and/or actual reported allegations of misappropriation of resident property and exploitation. Evaluate whether the committee has made recommendations such as policy revision and/or training.

Administrator Interview
The administrator is responsible for the overall implementation of the facility policies/procedures to prohibit misappropriation of resident property and exploitation. This includes the obligation to report, investigate, protect the alleged victim, and take corrective actions, as necessary, based upon the outcome of the investigation. Obtain and review the copy of the investigation report, if any. ***NOTE*** *that some of this information may have already been obtained from the facility investigator. Interview the administrator to determine:*

- *When he/she was notified of the alleged exploitation/misappropriation, and when the initial report was made to the required agencies and law enforcement as required;*
- *Who was/is responsible for the investigation, whether it has been completed and the outcome, or whether the investigation is ongoing;*
- *When the results of the investigation were reported to the administrator and to the required agencies;*
- *Whether the alleged perpetrator, if an employee, had previous warnings or incidents at the facility;*
- *How the alleged victim and other residents at risk of exploitation/misappropriation were protected during the investigation;*
- *What actions were taken to prevent misappropriation and exploitation after the investigation was completed;*
- *Whether any changes were necessary to the facility's policies and procedures;*
- *How the facility assures that retaliation does not occur when staff or a resident reports an allegation of misappropriation of resident property or exploitation;*
- *What actions have been taken for education of staff and residents regarding the facility's prevention plan and reporting requirements; and*
- *How does the facility protect the resident's property from loss or theft.*

Provide an opportunity for the facility to provide any other information regarding the alleged misappropriation of the resident's property or exploitation.

Additional Investigatory Activities Related to Allegations of Drug Diversion
For allegations of drug diversion, the surveyor determines:

- *If there is evidence and/or potential outcomes such as unrelieved pain. For example, there may be evidence that on a particular shift, or when a particular staff member is working, a resident's pain symptoms are not relieved to the extent possible, but the pain*

symptoms are relieved on other shifts, based upon validated evidence (see also tag F697 for concerns related to pain management);

- *Whether pharmacy policies at a minimum, address safeguarding and access, monitoring, administration, documentation, reconciliation and destruction of controlled substances (see also tag F755 for concerns related to facility procedures for pharmacy services);*
- *Whether the pharmacist has established a system of records of receipt and disposition of all controlled drugs in sufficient detail to enable accurate reconciliation and that the drug records are in order and that an account of all controlled drugs is maintained and periodically reconciled (see also tag F755 for concerns related to responsibilities of the licensed pharmacist); and*
- *Determine whether the resident's clinical record provides accurate documentation of the administration of a controlled medication and resident outcomes related to the medication administration (see also tag F755 for concerns related to procedures for administration and documentation of controlled substances).*

If the surveyor, during the investigation, has determined that a resident's medications were diverted, the State agency (SA) should make referrals to the following agencies as appropriate, such as:

- *Drug Enforcement Administration (DEA),*
- *Local law enforcement,*
- *State Boards of Nursing, Pharmacy, and Nursing Home Administrators, and/or*
- *Other agencies the SA is required to notify in accordance with State law.*

KEY ELEMENTS OF NONCOMPLIANCE

To cite deficient practice at F602, the surveyor's investigation will generally show that the facility failed to protect a resident's right to be free from misappropriation of resident property and/or exploitation.

POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION

During the investigation, the surveyor may have determined that concerns may also be present with related outcome, process and/or structure requirements. The surveyor is cautioned to investigate these related requirements before determining whether non-compliance may be present. Some examples of related requirements that should be considered include the following:

- *42 CFR 483.10(e)(2), F557- Right to Have Personal Property*
- *42 CFR 483.10(f)(10)(i)-(ii), F567-Protection/Management of Personal Funds*
- *42 CFR 483.10(i), F584 – Safe Environment*
- *42 CFR 483.10(j), F585- Grievances*
- *42 CFR 483.12(a)(3)-(4), F606 - Not Employ/Engage Staff with Adverse Actions*
- *42 CFR 483.12(b)(1)-(4), F607 – Develop/Implement Abuse/Neglect, etc. Policies*
- *42 CFR 483.12(b)(5), F608 - Reporting of Reasonable Suspicion of a Crime*
- *42 CFR 483.12(c)(1), (4), F609 – Reporting of Alleged Violations*
- *42 CFR 483.12(c)(2) - (4), F610 – Alleged Violations-Investigate/Prevent/Correct*
- *42 CFR 483.25(k), F697- Pain Management - Determine if there is evidence and/or potential outcomes such as unrelieved pain. For example, evidence that on a particular*

shift, or when a particular staff member is working, a resident's pain symptoms are not relieved to the extent possible, but the pain symptoms are relieved on other shifts, based upon validated evidence.

- *42 CFR 483.45, 483.45(a)-(b), F755- Pharmacy Svcs/Procedures/Pharmacist/Records and 42 CFR 483.45(g)-(h), F761- Label/Store Drugs & Biologicals - Determine whether pharmacy policies at a minimum, address safeguarding and access, monitoring, administration, documentation, reconciliation and destruction of controlled substances; Determine whether the pharmacist has established a system of records of receipt and disposition of all controlled drugs in sufficient detail to enable accurate reconciliation and that the drug records are in order and that an account of all controlled drugs is maintained and periodically reconciled.*
- *42 CFR 483.75 (g)(2)(ii)- F867- QAA Activities*
- *42 CFR 483.95(c), F942- Abuse, Neglect, and Exploitation Training*
- *42 CFR 483.95(g), F946-Required In-Service Training for Nurse Aide*

DEFICIENCY CATEGORIZATION

In addition to actual or potential physical harm, always consider whether psychosocial harm has occurred when determining severity level (See Appendix P, Section IV, E, Psychosocial Outcome Severity Guide).

Examples of Severity Level 4 Noncompliance Immediate Jeopardy to Resident Health or Safety include, but are not limited to:

- *The facility failed to assure that a resident's personal property was safeguarded and that staff did not misappropriate resident's property. A resident, who had a medical condition in which she had loss of hair, owned two wigs which were personalized for her needs which she used consistently during the daytime hours. Staff documented that the resident was "crying loudly, shouting and was hysterical" and when investigated, she stated someone had stolen her wigs over the weekend. She stated she told staff and they discounted her complaints. The resident refused to leave her room or see anyone, was extremely agitated, and wanted the police called. During the facility investigation, two employees who had worked the evening shift over the weekend, were heard by other staff members, talking and laughing about how they had taken the resident's wigs.*

Examples of Severity Level 3 Noncompliance Actual Harm that is not Immediate Jeopardy include, but are not limited to:

- *The facility had failed to protect residents from misappropriation of resident property, had failed to immediately report and investigate alleged violations, and had failed to implement policies and procedures for reporting the possible crime to law enforcement. A resident reported to staff that she was missing a gold necklace. She had last seen the necklace in a nightstand drawer next to her bed. The resident was tearful, since she had received the necklace from her children who had purchased it for her 80th birthday. The resident was worried that she had carelessly lost the necklace and did not want her children to be angry at her. The resident discontinued attending activities, since she did not want to leave her room so that she could protect her belongings. During the facility's investigation, during an interview, CNA #1 stated that she had noticed that CNA #2 had a new necklace that looked familiar. CNA #1 said that CNA#2 quickly evaded questions as to how she had acquired the*

necklace, until she said that a new boyfriend had given it to her. CNA #1 stated that she did not want to cause any trouble and did not report anything about the necklace until a week later, when it was brought to the Director of Nursing's attention that a resident's necklace was missing. Also, during the investigation, the facility received more reports from staff of stolen jewelry from five other residents, but no staff reported any of the incidents to law enforcement or the State survey agency.

Examples of Severity Level 2 Noncompliance No Actual Harm with Potential for More Than Minimal Harm that is Not Immediate Jeopardy include, but are not limited to:

- *The facility had failed to protect a resident from misappropriation of resident property when a radio was stolen from a resident's room. The resident, who was cognitively impaired, also had severe confusion and was unable to communicate. The resident had an activity program for listening to classical music in his room. On Monday afternoon, it was reported that the activity staff came into the resident's room to provide the activity but were unable to locate the radio and subsequently reported the loss to the Administrator. Staff stated the radio had been in the room when they had left on Friday after the afternoon activity. The Administrator contacted the resident's son, and confirmed that the family had not removed the radio during a visit over the weekend and had no knowledge of where it might be. The facility replaced the radio. The Administrator reported the incident to the SA. Although the resident could not articulate what had occurred with the radio, the family wished to have the music therapy continue as the resident had a lifelong interest in classical music and they felt, even though the resident could no longer communicate and was confused, that the music provided a sense of comfort. The facility completed the investigation, and identified that a temporary staff member had stolen the radio. The temporary staff member was not allowed to work in the facility again.*

Severity Level 1: No Actual Harm with Potential for Minimal Harm
The failure of the facility to prevent misappropriation of resident property and exploitation is more than minimal harm. Therefore, Severity Level 1 does not apply for this regulatory requirement.

F603
§483.12
The resident has the right to be free from abuse, *neglect, misappropriation of resident property, and exploitation as defined in this subpart. This includes but is not limited to freedom* from corporal punishment, involuntary seclusion *and any physical or chemical restraint not required to treat the resident's medical symptoms.*

§483.12(a) **The facility must—**

§483.12(a)(1) **Not use verbal, mental, sexual, or physical abuse, corporal punishment, or involuntary seclusion;**

INTENT
*Each resident has the right to be free from **involuntary seclusion**.*

Effective November 28, 2017

DEFINITIONS

"**Involuntary seclusion**" is defined as separation of a resident from other residents or from her/his room or confinement to her/his room (with or without roommates) against the resident's will, or the will of the *resident* representative.

GUIDANCE

***NOTE**: During a situation in which a resident's behavior has escalated and immediate interventions are required for the safety of the resident, staff and/or other residents), the facility must immediately consult with the resident's physician about the behavioral symptoms and the resident's designated representative; and provide necessary supervision of the resident to ensure that the resident and other residents are protected.*

Involuntary seclusion may take many forms, including but not limited to the confinement, restriction or isolation of a resident. Involuntary seclusion may be a result of staff convenience, a display of power from the caregiver over the resident, or may be used to discipline a resident for wandering, yelling, repeatedly requesting care or services, using the call light, disrupting a program or activity, or refusing to allow care or services such as showering or bathing to occur.

Involuntary seclusion includes, but is not limited to, the following:

- *A resident displays disruptive behaviors, such as yelling, screaming, distracting others (such as standing and obstructing others viewing abilities for the TV or programs) and staff remove and seclude the resident in a separate location such as in an office area or his/her room, leaving and closing the door and without providing interventions to address the behavioral symptoms;*
- *In an attempt to isolate a resident in order to prevent him/her from leaving an area, the resident(s) is involuntarily confined to an area by staff placing furniture, carts, chairs in front of doorways or areas of egress;*
- *Staff hold a door shut, from the opposite side of the door, in order to prevent egress;*
- *Staff place a resident in a darkened room, office, or area secluded from other staff and residents for convenience or as punishment;*
- *A resident is physically placed in an area without access to call lights, and/or other methods of communication creating an environment of seclusion and isolation for the resident; and*
- *A resident placed in a secured area of the facility, but does not meet the criteria for the unit and is not provided with access codes or other information for independent egress.*

Considerations Involving Secured/Locked Areas

If a resident resides in a secured/locked area that restricts a resident's movement throughout the facility, the facility must ensure that the resident is free from involuntary seclusion.

A resident in a secured/locked area would not be considered to be involuntarily secluded if all of the following are met:

- *The facility has identified the clinical criteria for placing a resident in the secured/locked area;*
  Placement in a secured/locked area is not:

1. *Used for staff convenience or discipline;*
2. *Based on the resident's diagnosis alone since the determination for placement in the area must be made on an individualized basis; and/or*
3. *Based on a request from the resident's representative or family member without clinical justification;*

For example, if the POA requests placement in the secured/locked area but the resident declines placement and placement does not meet the clinical criteria and is not in the best interest of the resident, then placement of the resident in the secured/locked area would be involuntary seclusion.

- *The facility involves the resident/representative in care planning, including the decision for placement in a secured/locked area and the development of interventions based upon the resident's comprehensive assessment and needs; and*
- *The facility provides immediate access and visitation by family, resident representative or other individuals, subject to reasonable clinical and safety restrictions and the resident's right to deny or withdraw consent.*

It is expected that each resident's record would include:

- *Documentation of the clinical criteria met for placement in the secured/locked area by the resident's physician along with information provided by members of the interdisciplinary team;*
- *Documentation that reflects the resident/representative's involvement in the decision for placement in the secured/locked area;*
- *Documentation that reflects whether placement in the secured/locked area is the least restrictive approach that is reasonable to protect the resident and assure his/her health and safety;*
- *Documentation by the interdisciplinary team of the impact and/or reaction of the resident, if any, regarding placement on the unit; and*
- *Ongoing documentation of the review and revision of the resident's care plan as necessary, including whether he/she continues to meet the criteria for remaining in the secured/locked area, and if the interventions continue to meet the needs of the resident.*

***NOTE**: A resident who chooses to live in the secured/locked unit (e.g., the spouse of a resident who resides in the area), and does not meet the criteria for placement, must have access to the method of opening doors independently. The chosen method for opening doors (e.g., distribution of access code information) is not specified by CMS. Staff should be aware of which residents have access to opening doors and monitor their use of the access to ensure other residents' safety.*

***NOTE**: See also Tags at Resident Rights for guidance related to justice-involved individuals.*

Transmission Based Precautions

When used appropriately, transmission-based precautions (i.e., isolation due to infection) is not to be considered involuntary seclusion. The facility's policies must identify the type and duration of the transmission-based precautions required, depending upon the infectious agent or organism involved; and the precautions should be the least restrictive possible for the resident

based on his/her clinical situation. Furthermore, the resident's record must contain the rationale for the selected transmission-based precautions. However, once the resident is no longer a risk for transmitting the infection, the removal of transmission-based precautions is required in order to avoid unnecessary involuntary seclusion. See also 42 CFR 483.65 – Infection Control (Tag F880).

INVESTIGATIVE PROTOCOL FOR INVOLUNTARY SECLUSION
USE
Use this protocol for investigating:

- *An alleged violation of involuntary seclusion during a standard survey and abbreviated surveys (complaint investigations, onsite investigations of self-reported incidents, and/or revisits); and*
- *An allegation of involuntary seclusion involving a resident who resides in a secured/locked area or who is/was on temporary transmission-based precautions.*

If a surveyor determines that an act of involuntary seclusion has occurred or is occurring, he/she must immediately report this to the Administrator, or his/her designated representative if the Administrator is not present. The survey team should determine whether the facility then takes appropriate action in accordance with the requirements at F607, F609, and F610, including implementing safeguards to prevent further potential involuntary seclusion.

Review of Facility Policies and Procedures
Obtain and review the facility's policies and procedures related to the allegation under investigation.

Observations
Observe the physical environment in which the alleged involuntary seclusion may have occurred. This may include observations of the following, which include, but are not limited to:

- *Room configuration;*
- *Location of the alleged involuntary seclusion in relation to supervised areas; and*
- *Objects that may have been used to obstruct residents.*

Observe whether staff members make remarks and behave in a manner that may indicate concerns with staff treatment of residents.

Interview:
Alleged Victim/Resident Representative and Witness Interviews
Interview the alleged victim/resident representative to determine as much information regarding the alleged involuntary seclusion that he/she may be able to provide. Interview the alleged victim privately; however, the alleged victim may request that another person be present. If so, be aware that the alleged victim may not be comfortable speaking openly in the presence of another person, and another interview may be necessary to follow up on any discrepancies identified. A resident with a cognitive impairment and/or mental illness may mistakenly be assumed to be an incompetent witness. In those situations, interview the alleged victim, to the extent possible, and corroborate statements with other observations, interviews and record

review. During the interview, observe the resident's emotions and tone, as well as any nonverbal expressions or gesturing to a particular body area, in response to the questions.

Interview witnesses, including but not limited to, the assigned staff, staff in the immediate area, staff from the shifts prior to or after the alleged involuntary seclusion; the victim's roommate (if any), other residents, and/or visitors. Make every attempt to maintain the confidentiality of witnesses. It may not be appropriate to interview the person who reported the allegation first, as that may unintentionally identify the person. The surveyor may ask the witness to re-create or re-enact the alleged incident, to better understand the sequence of events.
Interview the alleged victim/resident representative and witnesses to determine:

- *What happened, when, where, and how often;*
- *Whether he/she can identify the alleged perpetrator and any witnesses;*
- *What occurred prior to, during and immediately following the alleged involuntary seclusion;*
- *Whether he/she reported the allegation to anyone within the facility or to an outside agency (e.g., other staff, ombudsman); if so, to whom, when and what was the response;*
- *For the alleged victim,*
  - *Whether he/she feels safe, is afraid of anyone, or is fearful of retaliation; and*
  - *Whether the alleged victim has had past encounters with the alleged perpetrator.*

Staff Interview
Review staff schedules to determine who was working at the time of the alleged involuntary seclusion. Interview staff from any department who has direct contact with the resident(s), as appropriate, to collect information about:

- *Whether he/she had knowledge of the alleged involuntary seclusion and what actions, if any, he/she took in response to the allegation;*
- *Any changes in the alleged victim's behavior as a result of the alleged involuntary seclusion;*
- *How the alleged perpetrator and alleged victim related to one another prior to and after the incident;*
- *Whether the alleged perpetrator had exhibited inappropriate behaviors to the alleged victim or other residents in the past, such as using derogatory language, rough handling, or ignored residents while giving care;*
- *Whether he/she reported the alleged involuntary seclusion to management/administrative staff, or any State or local agencies, such as Adult Protective Services or local law enforcement, and if so, to whom was the alleged involuntary seclusion reported and when;*
- *If not reported, what prevented him/her from reporting;*
- *If he/she reported the allegation, whether he/she feels that retaliation has occurred as a result of reporting the allegation, and if so, what actions were taken against staff; and*
- *Whether he/she has received training related to involuntary seclusion from the facility.*

***NOTE**: If the staff member was a witness, refer also to the questions above under Witness Interview.*

Alleged Perpetrator Interview:
The alleged perpetrator may or may not be in the facility or may refuse to be interviewed. If the alleged perpetrator is a staff member, the staff member may have been suspended or re-assigned until the investigation is completed and in some situations, the facility may have terminated the employment of the individual. If possible, interview the alleged perpetrator either in person or by phone to determine:

- *What position he/she holds and how long the alleged perpetrator has worked in the facility;*
- *What type of orientation, training, work assignments, and supervision he/she receives;*
- *Whether he/she was present in the facility at the time of the alleged involuntary seclusion;*
- *What information he/she can provide regarding the alleged involuntary seclusion such as what happened, why was the resident separated/secluded, how often does it occur;*
- *What is his/her relationship to the alleged victim; and*
- *If he/she has any other information that he/she wishes to share in regard to the investigation.*

Other Health Care Professionals Interview
Interview the director of nursing, social worker, and physician/practitioner, as necessary, to determine:

- *Whether he/she was notified by staff of the alleged involuntary seclusion and if so, the response;*
- *Whether he/she conducted an assessment of the resident for potential injuries and/or changes in mental status, and if identified, what interventions or treatment (e.g., counseling) were provided and when; and*
- *If a resident is under transmission-based precautions, the reason why the resident is under transmission-based precautions and when transmission-based precautions are to be removed.*

Record Review-Resident
It may be necessary to obtain copies of any relevant information in the resident's record. Review the alleged victim's record to obtain necessary information, as applicable, such as:

- *The diagnosis and physician orders including medications;*
- *The RAI, to include the resident's cognitive status, functional status (independent ambulation, transfer status, uses a wheelchair, using an assistance device or requires staff assistance for ADL's);*
- *Care plan and interventions/goals;*
- *Physician's, nurse's, social worker's and other staff members progress notes, as applicable;*
- *Social and psychological history; and*
- *Hospital transfer/discharge information, if applicable (**NOTE**: the surveyor may follow up with an interview with the treating practitioner at the hospital).*

Review interdisciplinary notes within the timeframe of the alleged involuntary seclusion for documentation that supports, clarifies, or verifies the allegation. Determine if the record reflects:

- *The date/time of the allegation and/or the date/time when the allegation was first discovered and reported; and*
- *Any change in the alleged victim's mood and demeanor before and after the alleged incident, such as, but not limited to: Distrust, fear (e.g., fear of being left alone), angry outbursts, tearfulness, agitation, trembling, cowering, panic attacks, withdrawal from social interaction, changes is sleeping patterns, or symptoms similar to PTSD symptoms.*

Record Review-Alleged Perpetrator's Personnel File Review, if Staff
If staff is identified as the alleged perpetrator, review the staff member's personnel file for information related to:
The allegation being investigated or history of other allegations;

- *Adverse personnel actions taken;*
- *Screening that occurred prior to and during employment; and*
- *Training and orientation related to abuse and neglect prevention.*

Additional Activities for Investigating Possible Involuntary Seclusion for Residents in Secured/Locked Areas
If a resident lives in an area that restricts free movement throughout the facility, the survey team must determine the following:

- *Whether the facility has developed and implemented policies and procedures related to secured/locked areas, including criteria for placement and ongoing assessment to assure that the resident meets the criteria;*
- *Whether the facility attempted alternatives prior to placement in a secured/locked area; if so, what alternatives, and what the resident's response was to the alternative interventions;*
- *Why the resident is placed in the secured/locked area;*
- *Whether the resident/resident representative was involved in the placement decision; whether the resident/resident representative agreed with the decision or not; if not, how did the facility address this; and*
- *Whether the secured/locked area is accessible to other residents in the facility and visitors, and if so, how.*

Facility Investigator Interview
If the facility has investigated the alleged involuntary seclusion, identify the staff member responsible for the initial reporting and the overall investigation of the alleged involuntary seclusion. This may be the administrator in some facilities. Obtain a copy of the investigation report, if any.

***NOTE**: Refer to F609 for further investigation if the facility does not have a copy of the investigation report available.*

Interview the facility investigator to determine:

- *When he/she was notified of the allegation and by whom;*
- *When and what actions were taken to protect the alleged victim(s) while the investigation was in process;*
- *Steps taken to investigate the allegation and a timeline of events that occurred;*

- *What happened as a result of the investigation;*
- *When and who received the results of the investigation; and*
- *Whether there is any related information regarding the allegation that may not be included in the investigation report.*

Administrator Interview

The administrator is responsible for the overall implementation of the facility policies/procedures, including to prohibit involuntary seclusion. This includes the obligation to report, investigate, protect the alleged victim, and take corrective actions, as necessary, based upon the outcome of the investigation. Note that some of this information may have already been obtained from the facility investigator.

Interview the administrator to determine:

- *When he/she was notified of the alleged involuntary seclusion, and when the initial report was made to the required agencies;*
- *Who was/is responsible for the investigation, whether it has been completed and the outcome, or whether the investigation is ongoing;*
- *When the results of the investigation were reported to the administrator and to the required agencies;*
- *How the alleged victim and other residents at risk were protected during the investigation;*
- *If the alleged violation is verified, what corrective actions are being taken;*
- *Whether any changes were necessary to the facility's policies and procedures;*
- *Whether the alleged perpetrator had previous warnings or incidents at the facility; and*
- *What information has been provided to staff and residents related to involuntary seclusion, including reporting requirements.*

Interview with Person Responsible for Quality Assurance

Interview the person responsible for quality assurance activities. Determine how the committee is providing monitoring and oversight of potential and/or actual reported allegations of involuntary seclusion. Evaluate whether the committee has made recommendations such as policy revision and/or training to prohibit involuntary seclusion.

KEY ELEMENTS OF NONCOMPLIANCE

To cite deficient practice at F603, the surveyor's investigation will generally show that the facility separated or secluded a resident against the resident's will or the resident representative's will without clinical justification.

POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION

During the investigation, the surveyor may have determined that concerns may also be present with related outcome, process and/or structure requirements. The surveyor is cautioned to investigate these related requirements before determining whether non-compliance may be present. Some examples of related requirements that should be considered include the following:

- *42 CFR 483.10, 483.10(a)(1)-(2), 483.10(b)(1)-(2), F550- Resident Rights and Dignity*
- *42 CFR 483.10(c)(1),(4),(5), F552- Right to be Informed/Make Treatment Decisions*

Effective November 28, 2017

- *42 CFR 483.10(c)(2)-(3), F553 - Right to Participate Planning Care*
- *42 CFR 483.10(g)(14), F580-Notify of Changes (Injury/Decline/Room,Etc)*
- *42 CFR 483.10(j), F585- Grievances*
- *42 CFR 483.12(a)(3)-(4), F606 - Not Employ/Engage Staff with Adverse Actions*
- *42 CFR 483.12(b)(1)-(4), F607 – Develop/Implement Abuse/Neglect, etc. Policies*
- *42 CFR 483.12(b)(5), F608 - Reporting of Reasonable Suspicion of a Crime*
- *42 CFR 483.12(c)(1), (4), F609 – Reporting of Alleged Violations*
- *42 CFR 483.12(c)(2) - (4), F610 – Alleged Violations-Investigate/Prevent/Correct*
- *42 CFR 483.20(b)(1)-(2)(i),(2)(iii), F636-Comprehensive Assessments & Timing*
- *42 CFR 483.20(b)(2)(ii), F637-Comprehensive Assess After Significant Change*
- *42 CFR 483.21(b)(1), F656- Develop/Implement Comprehensive Care Plan*
- *42 CFR 483.21(b)(2), F657- Care Plan Development and Revision*
- *42 CFR 483.24, F675 - Quality of Life*
- *42 CFR 483.95(c), F942- Abuse, Neglect, and Exploitation Training*
- *42 CFR 483.95(g), F946-Required In-Service Training for Nurse Aide*
- *Life safety code requirements*
    - *If there are concerns with life safety code requirements, the survey team should notify its SA supervisor that a life safety code concern has been identified and may require a life safety code survey.*

DEFICIENCY CATEGORIZATION

In addition to actual or potential physical harm, always consider whether psychosocial harm has occurred when determining severity level (See Appendix P, Section IV, E, Psychosocial Outcome Severity Guide).

Examples of Severity Level 4 Noncompliance Immediate Jeopardy to Resident Health or Safety include, but is not limited to:

- *The facility failed to assure that a resident was free from involuntary seclusion. The resident with a history of suicidal ideation and displaying behavioral symptoms which included episodic periods of yelling and screaming, especially towards the end of the day and during the night. According to the resident's record, after dinner last evening, the resident was placed by staff in her recliner with a tray attached by the nurse's station. It was documented and corroborated by staff interviews that they heard the resident yell and scream loudly, pounding on her tray. Several residents began complaining about the noise. A nurse aide transferred the resident to a wheelchair, and placed the resident, who was at risk for suicidal ideation, in a housekeeping supply room, which was used for storage of chemicals. The nurse aide closed the door and went back to the floor. The resident began crying loudly, banging on the doors and yelling for help. Another staff person thought that she heard a resident yelling, but was busy completing tasks for another resident. Afterwards, she heard the yelling continue, found the resident, and removed the resident from the room, the resident was sweating profusely, her face was reddened, and was shaking and sobbing incoherently. Upon interview, the nurse aide who had secluded the resident stated that she did not have the time to deal with the yelling, and she had to get other residents to bed. She moved the resident to the supply room to quiet her down.*

Effective November 28, 2017

Examples of Severity Level 3 Noncompliance Actual Harm that is not Immediate Jeopardy include, but is not limited to:

- *The facility failed to assure that a resident was free from involuntary seclusion. A resident was admitted to a secured area at the request of his representative. After admission, the resident requested the security codes in order to go in and out of the area, but staff refused to provide the codes. The resident then requested to be transferred, but staff refused his request. The staff then contacted the resident's attending physician, who made the determination that was not any clinical reason for the resident to be located in the secured area; once the physician made this determination , he notified the facility, which immediately transferred the resident to a room not located in the secured area. During interview with the resident, he stated that he was still angry that he had been placed in the secured area against his will for his first day in the facility, and felt afraid to leave his room except for meals or else staff would place him again in the secured area, even though staff attempted to regain his trust.*

Examples of Severity Level 2 Noncompliance No Actual Harm with Potential for More Than Minimal Harm that is Not Immediate Jeopardy include, but is not limited to:

- *The facility failed to assure that a resident was free from involuntary seclusion. Based on resident and staff interviews, it was stated that a nurse aide was transporting him to an activity. The resident, who was dependent on staff for mobility in his wheelchair, said that he was annoyed that he was late to the activity. He began to insult the nurse aide. The nurse aide transported the resident in his wheelchair to an unused shower room, instead of to the activity room and the nurse aide told the resident that when he stopped insulting her, she would take him to the activity. The nurse aide stood outside the door to supervise the resident and when the resident became quiet, she took the resident back to the activity. Afterwards, the resident reported what had happened to the activity director and said that he did not want the aide working with him anymore. During interview, the resident stated that this was the only time something like this happened.*

Severity Level 1: No Actual Harm with Potential for Minimal Harm

The failure of the facility to prevent involuntary seclusion is more than minimal harm. Therefore, Severity Level 1 does not apply for this regulatory requirement.

F604

§483.10(e) Respect and Dignity.

The resident has a right to be treated with respect and dignity, including:

§483.10(e)(1) **The right to be free from any physical or chemical restraints imposed for purposes of discipline or convenience, and not required to treat the resident's medical symptoms,** ***consistent with §483.12(a)(2).***

§483.12

The resident has the right to be free from abuse, ***neglect, misappropriation of resident property, and exploitation as defined in this subpart. This includes but is not limited to freedom*** **from corporal punishment, involuntary seclusion** ***and any physical or chemical restraint not required to treat the resident's medical symptoms.***

Effective November 28, 2017

§483.12(a) The facility must—

§483.12(a)(2) Ensure that the resident is free from physical or chemical restraints imposed for purposes of discipline or convenience and that are not required to treat the resident's medical symptoms. When the use of restraints is indicated, the facility must use the least restrictive alternative for the least amount of time and document ongoing re-evaluation of the need for restraints.

INTENT

The intent of this requirement is for each resident to attain and maintain his/her highest practicable well-being in an environment that:

- *P*rohibits the use of physical restraints for discipline or convenience*;*
- *Prohibits the use of physical restraints to unnecessarily inhibit a resident's freedom of movement or activity; and*
- *L*imits *physical* restraint use to circumstances in which the resident has medical symptoms that *may* warrant the use of restraints*.*

When a physical restraint is used, the facility must:

- *Use the least restrictive restraint for the least amount of time; and*
- *Provide ongoing re-evaluation of the need for the physical restraint.*

DEFINITIONS

"**Convenience**" is defined as *the result of* any action *that has the effect of altering* a resident's behavior *such that the resident requires* a lesser amount of effort *or care,* and *is* not in the resident's best interest.

"**Discipline**" is defined as any action taken by the facility for the purpose of punishing or penalizing residents.

"**Freedom of movement**" means any change in place or position for the body or any part of the body that the person is physically able to control.

*"**Manual method**" means to hold or limit a resident's voluntary movement by using body contact as a method of physical restraint.*

"**Medical symptom**" is defined as an indication or characteristic of a physical or psychological condition.

*"**Position change alarms**" are alerting devices intended to monitor a resident's movement. The devices emit an audible signal when the resident moves in certain ways.*

"**Physical restraint**" *is* defined as any manual method, physical or mechanical device*, equipment, or* material that *meets all of the following criteria:*

- *Is* attached or adjacent to the resident's body*;*
- *C*annot *be* remove*d* easily *by the resident; and*

- *R*estricts *the resident's* freedom of movement or normal access to *his/her* body.

"Removes easily" means that the manual method, *physical or mechanical* device, equipment, or material, can be removed intentionally by the resident in the same manner as it was applied by the staff.

GUIDANCE
As described under Definitions, a physical restraint is any manual method, physical or mechanical device/equipment or material that limits a resident's freedom of movement and cannot be removed by the resident in the same manner as it was applied by staff. The resident's physical condition and his/her cognitive status may be contributing factors in determining whether the resident has the ability to remove it. For example, a bed rail is considered to be a restraint if the resident is not able to put the side rail down in the same manner as the staff. Similarly, a lap belt is considered to be a restraint if the resident cannot intentionally release the belt buckle.

Examples of facility practices that meet the definition of a *physical* restraint include, but are not limited to:

- Using *bed* rails that keep a resident from voluntarily getting out of bed;
- Placing a chair or bed close *enough* to a wall that *the resident is prevented* from rising out of the chair or voluntarily getting out of bed*;*
- *Placing a resident on a concave mattress so that the resident cannot independently get out of bed;*
- Tucking in *a sheet tightly so that the resident cannot get out of bed,* or *fastening* fabric or clothing so that a resident's *freedom of* movement is restricted*;*
- Placing a resident in a chair*, such as a beanbag or recliner,* that prevents a resident from rising *independently*;
- Using devices in conjunction with a chair, such as trays, tables, *cushions,* bars or belts, that the resident cannot remove *and* prevent*s* the resident from rising*;*
- *Applying leg or arm restraints, hand mitts, soft ties or vests that the resident cannot remove;*
- *Holding down a resident in response to a behavioral symptom or during the provision of care if the resident is resistive or refusing the care;*
- *Placing a resident in an enclosed framed wheeled walker, in which the resident cannot open the front gate or if the device has been altered to prevent the resident from exiting the device; and*
- *Using a position change alarm to monitor resident movement, and the resident is afraid to move to avoid setting off the alarm.*

Physical Risks and Psychosocial Impacts Related to Use of Restraints
Research and standards of practice show that physical restraints have many negative side effects and risks that far outweigh any benefit from their use. Physical restraints may increase the risk of one or more of the following:

- *Decline in physical functioning including an increased dependence in activities of daily living (e.g., ability to walk), impaired muscle strength and balance, decline in range of motion, and risk for development of contractures;*
- *Respiratory complications;*
- *Skin breakdown around the area where the restraint was applied or skin integrity issues related to the use of the restraint (i.e., pressure ulcers/injuries);*
- *Urinary/bowel incontinence or constipation;*
- *Injury from attempts to free him/herself from the restraint; and*
- *Accidents such as falls, strangulation, or entrapment.*

Psychosocial impact related to the use of physical restraints may include one or more of the following:

- *Agitation, aggression, anxiety, or development of delirium;*
- *Social* withdrawal, depression, or reduced social contact *due to the* loss of autonomy*;*
- *Feelings of shame;*
- *Loss of dignity, self-respect, and identity;*
- *Dehumanization;*
- *Panic, feeling threatened or fearful; and*
- *Feelings of imprisonment or restriction of freedom of movement.*

Assessment, Care Planning, and Documentation for the Use of a Physical Restraint

The regulation limits the use of any physical restraint to circumstances in which the resident has medical symptoms that warrant the use of restraints. There must be documentation identifying the medical symptom being treated and an order for the use of the specific type of restraint. However, the *practitioner's* order *alone (without supporting clinical documentation)* is not sufficient to warrant the use of the restraint. *The facility is accountable for the process to meet the minimum requirements of the regulation including appropriate assessment, care planning by the interdisciplinary team, and documentation of the medical symptoms and use of the physical restraint for the least amount of time possible and provide ongoing re-evaluation.*

The resident or resident representative may request the use of a physical restraint; however, the nursing home is responsible for evaluating the appropriateness of the request, and must determine if the resident has a medical symptom that must be treated and must include the practitioner in the review and discussion. If there are no medical symptoms identified that require treatment, the use of the restraint is prohibited. Also, a resident, or the resident representative, has the right to refuse treatment; however, he/she does not have the right to demand a restraint be used when it is not necessary to treat a medical symptom.

Facilities are responsible for knowing the effects devices have on its residents. If a device has a restraining effect on a resident, and is not administered to treat a medical symptom, the device is acting as a physical restraint. The restraining effects to the resident may have been caused intentionally or unintentionally by staff, and would indicate an action of discipline or convenience. In the case of an unintentional physical restraint, the facility did not intend to restrain a resident, but a device is being used that has that same effect, and is not being used to treat a medical symptom. These effects may result in convenience for the staff, as the resident may require less effort than previously required.

Effective November 28, 2017

The use of a restraint must be individualized and be based upon the resident's condition and medical symptoms that must be treated. While a physical restraint may be used to treat an identified medical symptom for one resident, the use of the same type of restraint may not be appropriate to treat other residents with the same medical symptom. If a resident is identified with a physical restraint, the facility must be able to provide evidence that ensures:

- *The resident's medical symptom that requires the use of a physical restraint has been identified;*
- *A practitioner's order is in place for the use of the specific physical restraint based upon the identified medical symptom;*

  ***NOTE**: If a resident is recently admitted to the facility and a restraint was used in a previous health care setting, the facility must still conduct an assessment to determine the existence of medical symptoms that warrant the continued use of the restraint.*

- *Interventions, including less restrictive alternatives were attempted to treat the medical symptom but were ineffective;*
- *The resident/representative was informed of potential risks and benefits of all options under consideration including using a restraint, not using a restraint, and alternatives to restraint use;*

  ***NOTE:** The resident, or resident representative (if applicable), has the right to refuse the use of a restraint and may withdraw consent to use of the restraint at any time. If so, the refusal must be documented in the resident's record. The facility is expected to assess the resident and determine how resident's needs will be met if the resident refuses/declines treatment.*

- *The length of time the restraint is anticipated to be used to treat the medical symptom, the identification of who may apply the restraint, where and how the restraint is to be applied and used, the time and frequency the restraint should be released, and who may determine when the medical symptom has resolved in order to discontinue use of the restraint;*
- *The type of specific direct monitoring and supervision provided during the use of the restraint, including documentation of the monitoring;*
- *The identification of how the resident may request staff assistance and how needs will be met during use of the restraint, such as for re-positioning, hydration, meals, using the bathroom and hygiene;*
- *The resident's record includes ongoing re-evaluation for the need for a restraint and is effective in treating the medical symptom; and*
- *The development and implementation of interventions to prevent and address any risks related to the use of the restraint (See also the Long-Term Care Facility Resident Assessment Instrument User's Manual, Version 3.0, Chapter 3, Section P-Restraints for further guidance and 42 CFR 483.25(d) [F689] for concerns related to ensuring the resident receives adequate supervision to prevent accidents).*

NOTE: Falls do not constitute self-injurious behavior or a medical symptom that warrants the use of a physical restraint. Although restraints have been traditionally used as a falls prevention

approach, they have major, serious drawbacks and can contribute to serious injuries. There is no evidence that the use of physical restraints, including, but not limited to, *bed* rails and position change alarms, will prevent or reduce falls. Additionally, falls that occur while a person is physically restrained often result in more severe injuries (e.g., strangulation, entrapment).

The use of handcuffs, manacles, shackles, other chain-type restraint devices, or other restrictive devices are not considered safe, appropriate health care restraint interventions for use by a nursing home. This would not include arrests made onsite if a resident is taken into custody and is removed from the premises by law enforcement.

***NOTE**: For more information regarding requirements for providing services to justice-involved individuals in facilities, see also F550-Resident's Rights and S&C-16-21- https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-16-21.pdf).*

Convenience and/or Discipline

A facility must not impose physical restraints for purposes of discipline or convenience. The facility is prohibited from obtaining permission from the resident, or resident representative, for the use of restraints when the restraint is not necessary to treat the resident's medical symptoms. Anecdotally, it has been reported that staff will inform a resident, or the resident representative, that a restraint will be beneficial to the resident to prevent a fall or to safeguard the resident who may be wandering into other resident's rooms. However, in these instances, the surveyor should consider whether the restraint was used for the sake of staff convenience.

Reasons for using restraints for staff convenience or discipline may include:

- *Staff state that a resident was placed in a restraint because staff are too busy to monitor the resident, and their workload includes too many residents to provide monitoring;*
- *Staff believe that the resident does not exercise good judgment, including that he/she forgets about his/her physical limitations in standing, walking, or using the bathroom alone and will not wait for staff assistance;*
- *Staff state that family have requested that the resident be restrained, as they are concerned about the resident falling especially during high activity times, such as during meals, when the staff are busy with other residents;*
- *Staff have identified to management that there is not enough staff on a particular shift or during the weekend and staffing levels were not changed;*
- *Staff state that new staff and/or temporary staff do not know the resident, how to approach, and/or how to address behavioral symptoms or care needs so they apply physical restraints;*
- *Lack of staff education regarding the alternatives to the use of restraints as a method for preventing falls and accidents;*
- *Staff have negative feelings or a lack of respect towards the resident, and restrain the resident to teach him/her a lesson;*
- *In response to a resident's wandering behavior, staff become frustrated and restrain a resident to a wheelchair; and*
- *When a resident is confused and becomes combative when care is provided and staff hold the resident's arms and legs down to complete the care (**NOTE**: This example differs*

from an emergency situation where staff briefly hold a resident for the sole purpose of providing necessary immediate medical care ordered by a practitioner).

Situations where a facility uses a physical restraint, or device acting as a physical restraint, that is not for treating a medical symptom, whether intentionally or unintentionally by staff, would indicate an action of discipline or convenience. An example that illustrates unintentional use of a physical restraint for staff convenience is when a staff member places a resident with limited mobility in a beanbag chair while other residents receive assistance during high activity times.

Determination of Use of Restraints for a Period of Imminent Danger to the Safety and Well-Being of the Resident

Some facilities have identified that a situation occurred in which the resident(s) is in "imminent danger" and there was fear for the safety and well-being of the resident(s) due to violent behavior, such as physically attacking others. In these situations, the order from the practitioner and supporting documentation for the use of a restraint must be obtained either during the application of the restraint, or immediately after the restraint has been applied. The failure to immediately obtain an order is viewed as the application of restraint without an order and supporting documentation. Facilities may have a policy specifying who can initiate the application of restraint prior to obtaining an order from the practitioner.

If application of a restraint occurs, the facility must:

- *Determine that a physical restraint is a measure of last resort to protect the safety of the resident or others;*
- *Provide ongoing direct monitoring and assessment of the resident's condition during use of the restraint;*
- *Provide assessment by the staff and practitioner to address other interventions that may address the symptoms or cause of the situation (e.g., identification of an infection process or delirium, presence of pain);*
- *Ensure that the resident and other residents are protected until the resident's behavioral symptoms have subsided, or until the resident is transferred to another setting;*
- *Discontinue the use of the restraint as soon as the imminent danger ends; and*
- *Immediately notify the resident representative of the symptoms and temporary intervention implemented.*

Documentation must reflect what the resident was doing and what happened that presented the imminent danger, interventions that were attempted, response to those interventions, whether the resident was transferred to another setting for evaluation, whether the use of a physical restraint was ordered by the practitioner, and the medical symptom(s) and cause(s) that were identified.

Determination of Use of Bed Rails as a Restraint

Facilities must use a person-centered approach when determining the use of bed rails, which would include conducting a comprehensive assessment, and identifying the medical symptom being treated by using bed rails. Bed rails may have the effect of restraining one individual but not another, depending on the individual resident's conditions and circumstances.

Effective November 28, 2017

Residents who are cognitively impaired are at a higher risk of entrapment and injury or death caused by restraints. Residents *in a bed with bed rails have attempted* to exit through, between, *under,* over, or around bed rails *or have attempted to crawl over the foot board, which places them* at risk *of serious* injury or death. Serious injury from a fall is more likely from a bed with raised *bed rails* than from a bed where *bed* rails are not used. *In many cases, the risk of using the bed rails may be greater than the risk of not using them as the risk of restraint-related injury and death is significant. For example, a resident who has no voluntary movement may still exhibit involuntary movements. Involuntary movements, resident weight, and gravity's effects may lead to the resident's body shifting toward the edge of the bed, increasing the risk for entrapment, when bed rails are used. Also refer to 42 CFR 483.25(n) – Bed Rails (tag F700).*

The *use of* partial *bed rails* may assist *an independent* resident to enter and exit the bed independently and would not be considered a physical restraint. *To determine if a bed rail is being used as a restraint, the resident must be able to easily and voluntarily get in and out of bed when the equipment is in use. If the resident cannot easily and voluntarily release the bed rails, the use of the bed rails may be considered a restraint.*

Determination of the Use of Position Change Alarms as Restraints

Position change alarms are any physical or electronic device that monitors resident movement and alerts the staff when movement is detected. Types of position change alarms include chair and bed sensor pads, bedside alarmed mats, alarms clipped to a resident's clothing, seatbelt alarms, and infrared beam motion detectors. Position change alarms do not include alarms intended to monitor for unsafe wandering such as door or elevator alarms.

While position change alarms may be implemented to monitor a resident's movements, for some residents, the use of position change alarms that are audible to the resident(s) may have the unintended consequence of inhibiting freedom of movement. For example, a resident may be afraid to move to avoid setting off the alarm and creating noise that is a nuisance to the resident(s) and staff, or is embarrassing to the resident. For this resident, a position change alarm may have the potential effect of a physical restraint.

Examples of negative potential or actual outcomes which may result from the use of position change alarms as a physical restraint, include:

- *Loss of dignity;*
- *Decreased mobility;*
- *Bowel and bladder incontinence;*
- *Sleep disturbances due to the sound of the alarm or because the resident is afraid to move in bed thereby setting off the alarm; and*
- *Confusion, fear, agitation, anxiety, or irritation in response to the sound of the alarm as residents may mistake the alarm as a warning or as something they need to get away from.*

PROCEDURES §483.12 and (a)(2)-Physical Restraints

The process to review concerns are outlined in the Physical Restraints Critical Element Pathway (Form CMS-20077).

***NOTE**: A resident may have a device in place that the facility has stated can be removed by the resident. For safety reasons, do not request that the resident remove the restraint, but rather, request that staff ask the resident to demonstrate how he/she releases the device without staff providing specific instructions for the removal.*

Use observations, interviews, and record review to gather and corroborate information related to:

- *The use of the physical restraint, including whether the facility identified a device as a restraint, why it is used, how long it has been used, duration of use, alternatives attempted;*
- *What information was provided to the resident regarding the use of the restraint and whether the use of the restraint reflects the resident's preferences and choices;*
- *Whether the physical restraint is used for, or has the effect of, staff convenience or discipline; or*
- *Physical and psychosocial outcomes from the use of the restraint.*

Use the Physical Restraints Critical Element (CE) Pathway, along with the above Guidance:

- *When a resident's clinical record reflects the use of a physical restraint;*
- *If the survey team observes a position change alarm, or other device or practice that restricts or potentially restricts a resident's freedom of movement (physically or psychologically);*
- *If the resident or other individuals report that a restraint is being used on the resident; or*
- *If an allegation of inappropriate use of a physical restraint is received.*

KEY ELEMENTS OF NONCOMPLIANCE

*To cite deficient practice at F604, the surveyor's investigation will generally show that the facility has failed, in one or more areas, to do **any one** or more of the following:*

- *Ensure that the resident is free from physical restraints imposed for discipline or staff convenience;*
- *Identify the medical symptom being treated when using a device or a facility practice that meets the definition of physical restraint;*
- *Define and implement interventions according to standards of practice during the use of a physical restraint that is used for treatment of a medical symptom;*
- *Provide the least restrictive restraint for the least time possible;*
- *Providing ongoing monitoring and evaluation for the continued use of a physical restraint to treat a medical symptom; or*
- *Develop and implement interventions for reducing or eventually discontinuing the use of the restraint when no longer required to treat a resident's medical symptoms.*

POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION

During the investigation, the surveyor may have determined that concerns may also be present with related outcome, process and/or structure requirements. The surveyor is cautioned to investigate these related requirements before determining whether non-compliance may be present. Some examples of related requirements that should be considered include the following:

- *42 CFR 483.10, 483.10(a)(1)-(2), 483.10(b)(1)-(2), F550- Resident Rights and Dignity*

Effective November 28, 2017

- *42 CFR 483.10(c)(2)-(3), F553 - Right to Participate Planning Care*
- *42 CFR 483.21(b)(1), F656- Develop/Implement Comprehensive Care Plan*
- *42 CFR 483.24, F675 - Quality of Life*
- *42 CFR 483.25(d), F689 - Accidents*
- *42 CFR 483.25(n)(1)-(4), F700- Special Care: Bedrails*
  42 CFR 483.35, 483.35(a), and 483.35(c)- F725 and F726 – Sufficient and Competent Staff
- *42 CFR 483.40(b)-(b)(1), F742- Treatment/Svc for Mental/Psychosocial Concerns*
- *42 CFR 483.70(h), F841-Responsibilities of Medical Director*
- *42 CFR 483.75 (g)(2)(ii)- F867- QAA Activities*

DEFICIENCY CATEGORIZATION

In addition to actual or potential physical harm, always consider whether psychosocial harm has occurred when determining severity level (See Appendix P, Section IV, E, Psychosocial Outcome Severity Guide).

Examples of Severity Level 4 Noncompliance Immediate Jeopardy to Resident Health or Safety include, but are not limited to:

- *The facility failed to identify the resident's medical symptom that warranted the use of a restraint. It was identified that a resident had repeated falls in his room usually after meals, when he attempted to transfer from his wheelchair to the bed. The clinical record documented that the resident repeatedly requested to be assisted to lie down after eating. Staff recorded that the belt restraint was being applied to prevent falls as he had fallen several times when attempting to stand up from the wheelchair after meals and lie down. Although the resident verbalized distress at being tied down in the wheelchair, staff stated they had informed the resident that they would put the resident in bed as soon as they finished taking care of the other residents in the dining room. It was documented that after staff left the room, the resident had attempted to stand up with the lap belt in place in the wheelchair, and as a result, the wheelchair tipped over and he sustained a fracture of his hand and had hit his head, resulting in hospitalization and treatment for multiple head and face lacerations and a subdural hematoma.*
- *The facility failed to identify bed rails as a physical restraint, failed to assess the resident for use of a bed rail, and failed to ensure that the bed rails did not pose a risk of injury from falls. A moderately cognitively impaired resident was admitted to the facility who required extensive assistance with bed mobility and transfer, and was not ambulatory. The staff recorded on admission that the resident was at high risk for falls and as a result, placed full bed rails on all open sides of the bed. No assessment was conducted related to the use of bed rails, or the use of restraints. Documentation in the record revealed that the resident crawled to the foot of her bed while the full bed rails were in a raised position, attempted to stand and walk, and fell off the right side of the bed. The resident was hospitalized for surgical repair of a femoral neck fracture.*

Examples of Severity Level 3 Noncompliance Actual Harm that is not Immediate Jeopardy include, but are not limited to:

- *The facility failed to assure that a restraint was an intervention to treat a medical symptom and was not being used for staff convenience. Facility staff had placed a*

resident in a bean bag chair from which he could not rise. Based on staff interview, the resident was ambulatory, but had fallen in the past when attempting to stand up. The facility staff did not recognize that the bean bag was a physical restraint; thus, the staff did not conduct any assessment to identify any medical symptoms that would necessitate a restraint. Staff stated that they placed the resident in the bean bag chair while caring for other residents. The resident reported being placed and left in the bean bag chair every day in the afternoon and was not able to stand to walk to his room or to activities. The resident said that he felt humiliated that he is not able to get out of the chair himself, when he wants to, especially since he enjoys talking with the other residents. The surveyor observed the resident struggling to get up, but was not able.

- *The facility failed to assure that the use of a physical restraint was used to treat a resident's medical symptoms, and was not being used for staff convenience. A resident was admitted with a diagnosis of dementia, and had been hospitalized due to a head injury related to a fall at her home. The physician admission orders included an order for a lap belt to be used when the resident was up in the wheel chair; however, there was no identification of the medical symptom that necessitated the use of the lap belt. In a phone interview with the physician, he indicated that staff had requested the lap belt order due to the resident's falls. Based on observation, the resident sat in the day room in a wheel chair with the lap belt in place through the morning, from the breakfast service through the end of the noon meal. Staff did not provide repositioning, assistance with using the bathroom, or release of the lap belt for mobility. After lunch, the resident was transported to her room in the wheelchair with the lap belt in place; however, the lap belt was not removed and the resident remained in the same position through the afternoon without opportunities for repositioning, assistance with using the bathroom, or release of the lap belt for mobility. The resident was observed to be moving about restlessly, pulling at the lap belt, and calling out for help without staff response or intervention. When staff prompted the resident to release the belt, the resident was not able. Observation of the resident's skin when put to bed after the PM shift arrived, revealed reddened areas on the coccyx, urine soaked incontinence product with visible skin maceration. Staff interviewed stated that the lap belt was being used as a falls prevention intervention. They stated, and the record corroborated that there had been a decline in the resident's mobility, and continence since admission.*

Examples of Severity Level 2 Noncompliance No Actual Harm with Potential for More Than Minimal Harm that is Not Immediate Jeopardy include, but are not limited to:

- *The facility failed to assure that a physical restraint used for one resident was for the treatment of medical symptoms. Record review and observation revealed that the resident was alert and responded to her name, but was identified as mildly cognitively impaired and had fallen at home prior to her admission several weeks before. Observations revealed that a seat belt was used intermittently when the resident was in the wheelchair, but the resident had not attempted to rise, nor had attempted to remove the seatbelt. Staff stated that they thought the resident could release the seatbelt, although an assessment had not been completed regarding the use of the seatbelt. There was no documentation of an assessment for the use of the seat belt, whether the resident could release the seat belt or of identification of medical symptoms that would require the*

use of the seat belt while in the wheelchair. The resident's record reflected no decline in functional status.

- *The facility failed to ensure that the use of a concave mattress was being used in the treatment of medical symptoms and not for staff convenience. A resident, who could independently transfer self from bed to wheelchair and to bathroom, was observed to have a concave mattress. During resident interview, the resident stated that it was hard to get out of bed. The resident's record indicated no history of falls or injuries. During interview, the nurse assigned to the resident verified that the concave mattress was used to prevent the resident from exiting the bed independently. The resident's record did not include any information in the assessment, physician's orders, or care plan related to the concave mattress.*

Severity Level 1: No Actual Harm with Potential for Minimal Harm
The failure of the facility to assure residents are free from physical restraints not required to treat the resident's symptoms is more than minimal harm. Therefore, Severity Level 1 does not apply for this regulatory requirement.

F605
§483.10(e) Respect and Dignity.
The resident has a right to be treated with respect and dignity, including:

§483.10(e)(1) **The right to be free from any physical or chemical restraints imposed for purposes of discipline or convenience, and not required to treat the resident's medical symptoms,** ***consistent with §483.12(a)(2).***

§483.12
The resident has the right to be free from abuse, ***neglect, misappropriation of resident property, and exploitation as defined in this subpart. This includes but is not limited to freedom*** **from corporal punishment, involuntary seclusion** ***and any physical or chemical restraint not required to treat the resident's medical symptoms.***

§483.12(a) The facility must—

§483.12(a)(2) Ensure that the resident is free from physical or chemical restraints imposed for purposes of discipline or convenience and that are not required to treat the resident's medical symptoms. When the use of restraints is indicated, the facility must use the least restrictive alternative for the least amount of time and document ongoing re-evaluation of the need for restraints.

INTENT
The intent of this requirement is for each person to attain and maintain his/her highest practicable well-being in an environment that prohibits the use of *chemical* restraints*:*

- *F*or discipline or convenience; *and*
- *Not required to treat a resident's medical symptoms.*

Effective November 28, 2017

When a medication is indicated to treat a medical symptom, the facility must:

- *Use the least restrictive alternative for the least amount of time;*
- *Provide ongoing re-evaluation of the need for the medication; and*
- *Not use the medication for discipline or convenience.*

***NOTE**: The surveyor's review of medication use is not intended to constitute the practice of medicine. However, surveyors are expected to investigate the basis for decisions and interventions affecting residents.*

DEFINITIONS

"**Chemical restraint**" is defined as any drug that is used for discipline or staff convenience and not required to treat medical symptoms.

"**Convenience**" is defined as *the result of* any action *that has the effect of altering* a resident's behavior *such that the resident requires* a lesser amount of effort *or care,* and *is* not in the resident's best interest.

"**Discipline**" is defined as any action taken by facility staff for the purpose of punishing or penalizing residents.

*"**Indication for use**" is defined as the identified, documented clinical rationale for administering a medication that is based upon an assessment of the resident's condition and therapeutic goals and is consistent with manufacturer's recommendations and/or clinical practice guidelines, clinical standards of practice, medication references, clinical studies or evidence-based review articles that are published in medical and/or pharmacy journals.*

*"**Medical symptom**" is defined as an indication or characteristic of a medical, physical or psychological condition.*

GUIDANCE

The indication for use for any medication ordered for a resident must be identified and documented in the resident's record. (Also refer to F757 and/or F758.) When any medication restricts the resident's movement or cognition, or sedates or subdues the resident, and is not an accepted standard of practice for a resident's medical or psychiatric condition, the medication may be a chemical restraint. Even if use of the medication follows accepted standards of practice, it may be a chemical restraint if there was a less restrictive alternative treatment that could have been given that would meet the resident's needs and preferences or if the medical symptom justifying its use has subsided. The facility is accountable for the process to meet the minimum requirements of the regulation including appropriate assessment, care planning by the interdisciplinary team, and documentation of the medical symptoms and use of a less restrictive alternative for the least amount of time possible and provide ongoing re-evaluation.

***NOTE**: A medication may have been required to treat a medical symptom, and as a result, the medical symptom is no longer present. In some cases, the clinical goal of the continued use of the medication is to stabilize the symptoms of the disorder so that the resident can function at the highest level possible. In other words, the clinical goal is to have no symptoms of the disorder.*

Although the symptom may no longer be present, the disease process is still present. For example, diseases may include:

- *Chronic psychiatric illness such as schizophrenia or schizoaffective disorder, bipolar disorder, depression, or post-traumatic stress disorder;*
- *Neurological illness such as Huntington's disease or Tourette's syndrome; and*
- *Psychosis and psychotic episodes.*

In such instances, if the medication is reduced or discontinued, the symptoms may return. Reducing or eliminating the use of the medication may be contraindicated and must be individualized. If the medication is still being used, the clinical record must reflect the rationale for the continued administration of the medication. If no rationale is documented, this may meet the criteria for a chemical restraint, such as for staff convenience (See also F758 for concerns related to unnecessary use of a psychotropic medication and lack of gradual dose reduction).

Determination of Medical Symptoms

The clinical record must reflect whether the staff and practitioner have identified, to the extent possible, and addressed the underlying cause(s) of distressed behavior, either before or while treating a medical symptom. Potential underlying causes for expressions and/or indications of distress may include, but are not limited to:

- *Delirium;*
- *Pain;*
- *The presence of an adverse consequence associated with the resident's current medication regimen; and*
- *Environmental factors, such as staffing levels, over stimulating noise or activities, under stimulating activities, lighting, hunger/thirst, alteration in the resident's customary location or daily routine, physical aggression leading to altercations, temperature of the environment, and crowding.*

***NOTE**: If it is determined that the administration of a medication is being used to treat a medical symptom, the survey team should review to assure that the use of the medication is supported by adequate indication and rationale for use, and is used at the correct dose and duration, and with adequate monitoring. (See also F741, F757, and F758 for concerns related to non-pharmacological approaches of redirecting or addressing behavior)*

Determination of Indication for Medication Use

The clinical record must reflect the following:

- *Whether there is an adequate indication for use for the medication (e.g., a psychotropic medication is not administered unless the medication is used to treat a specific condition);*
- *Whether an excessive dose and/or duration of the medication was administered to the resident;*
- *Whether there is adequate monitoring for the effectiveness of the medication in treating the specific condition and for any adverse consequences resulting from the medication;*
- *Whether a resident who uses a psychotropic drug(s) is receiving gradual dose reduction and behavioral interventions, unless clinically contraindicated; and*

- *Whether a resident who receives a psychotropic drug(s) pursuant to a PRN (pro re nata, or as needed) order is not administered the medication unless the medication is necessary to treat a diagnosed specific symptom, as documented in the clinical record.*

If the practitioner orders a medication to be administered on a PRN time-limited basis for the provision of medical treatment to address an emergency medical condition (e.g., delirium), this would not be considered to be a chemical restraint. The dosage cannot exceed what is prescribed by the practitioner, and if the resident does not respond to the initial administration of the PRN medication, the practitioner must be contacted, regarding re-assessment of the resident's medical condition and evaluation of interventions. The administration of a PRN medication must be discontinued when the resident does not need the medication for treatment of the medical condition (also see §483.45(e) F758 for limitations on psychotropic and antipsychotic medication PRN orders). If staff continue to utilize a PRN medication that subdues or sedates a resident, and is not treating a medical condition, this would be considered to be a chemical restraint for staff convenience or discipline.

Risks and Psychosocial Impacts Related to Use of Chemical Restraints

A medication that is used for discipline or convenience and is not required to treat medical symptoms, may cause the resident to be:

- *Subdued, sedated, or withdrawn;*
- *Asleep during hours that he/she would not ordinarily be asleep; or*
- *Limited in his/her functional capacity.*

Additional effects resulting from sedating or subduing a resident may include, but are not limited to, the following:

- *Loss of autonomy, dignity, self-respect and orientation;*
- *Confusion, cognitive decline, withdrawal, depression;*
- *Decreased activity levels, including social activities;*
- *Decline in skin integrity;*
- *Decline in continence level;*
- *Decline in physical functioning including an increased dependence in activities of daily living (e.g., ability to walk), impaired muscle strength and balance, decline in range of motion, and risk for development of contractures, increased risk of falls; and*
- *Weight loss if missing meals.*

Facilities are responsible for knowing the effects medications have on their residents. If a medication has a sedating or subduing effect on a resident, and is not administered to treat a medical symptom, the medication is acting as a chemical restraint. The sedating/subduing effects to the resident may have been caused intentionally or unintentionally by staff, and would indicate an action of discipline or convenience. In the case of an unintentional chemical restraint, the facility did not intend to sedate or subdue a resident, but a medication is being administered that has that effect, and is not the least restrictive alternative to treat the medical symptom. These effects may result in convenience for the staff, as the resident may require less effort than previously required. Even if a medication was initially administered for a medical symptom, the continued administration of a medication in the absence of a medical symptom, that sedates a resident or otherwise makes it easier to care for them, is a chemical restraint.

Other examples of facility practices that indicate that a medication (ordered by a practitioner) is being used as a chemical restraint for staff convenience or discipline include, but are not limited to:

- *Staff indicate that a medication is being administered based on the resident's representative's request to administer a medication to "calm down" the resident;*
- *Staff have recommended to the practitioner that a resident be administered a medication in order to prevent a resident from displaying behaviors such as wandering into other resident's rooms:*
- *Staff administer a medication to quiet the resident because the resident continually calls out, without attempting alternative interventions;*
- *Staff become frustrated with a resident who continually requests staff assistance (such as for toileting), or continually puts on the call light, and administer a medication to sedate or subdue the resident);*
- *Staff administer a medication that subdues or sedates a resident when insufficient staffing levels do not allow for the resident's needs to be met;*
- *Staff administer a medication to sedate or subdue the resident, and/or to restrict the resident to a seated or lying position, since the resident continually wanders into other resident's rooms or attempts to leave the unit; and*
- *Staff become upset with a resident who resists receiving a bath and pinches staff. The staff had not re-assessed the resident nor revised interventions regarding how to provide bathing care in order to meet the resident's needs. Instead, staff administer a medication that is used to subdue the resident prior to providing the bath, but the medication is not used to treat an identified medical symptom.*

INVESTIGATIVE PROTOCOL FOR CHEMICAL RESTRAINTS USE

Use this protocol to investigate whether the facility is using a medication as a chemical restraint when:

- *An allegation of use of a chemical restraint is received; or*
- *The survey team determines noncompliance with F757 and/or F758, and the resident was or is receiving an unnecessary medication that restricts movement, or sedates or subdues the resident*

***NOTE**: If the survey team identifies an unnecessary medication that is acting as a chemical restraint (sedating or subduing a resident), the noncompliance is cited at F605 – Chemical Restraints and not cited at F757 – Unnecessary Medications. Both tags shall not be cited for the same noncompliance.*

PROCEDURES

The survey team must first use use the Interpretive Guidance (Refer to F757 and F758) and Critical Element Pathway for Unnecessary Medications, Psychotropic Medications, and Medication Regimen Review (Form CMS-20082) to determine whether the medication is used to treat a medical symptom.

Review the assessment, care plan, practitioner orders, and consulting pharmacist reviews to identify facility interventions and to guide observations to be made. Corroborate observations by interview and record review.

Gather information regarding the resident's mental, physical, functional, and psychosocial status and the medication-related therapeutic goals identified in the care plan as the basis for further review.

Observation

Record observations regarding any potential environmental causes of distress to the resident, such as staffing levels, over stimulating noise or activities, under stimulating activities, lighting, hunger/thirst, physical aggression leading to altercations, temperature of the environment, and crowding. In addition, observe for any alteration to the resident's customary location or daily routine.

Record any visible physical and psychosocial reaction to the potential use of a medication, such as:

- *Drowsiness, somnolence, excessive sedation, and hallucinations;*
- *Neurologic consequences such as akathisia, neuroleptic malignant syndrome (NMS), parkinsonism, tardive dyskinesia; and/or*
- *Confusion, agitation, anxiety, nervousness;*
- *Social isolation, withdrawal, loss of self-esteem; and/or*
- *Lack of participation in individualized activities, according to the resident's care plan.*

Interviews

Interview the resident, and/or resident representative, to the degree possible, to identify:

- *Prior to administration of the medication:*
  - *Whether other interventions have been attempted; if so, what alternatives; and what the response was;*
  - *Whether staff provided information regarding why the medication was being used;*
  - *The risks and/or benefits of using the medication; and*
  - *When and for how long the medication was going to be used.*
- *Who requested the medication to be used and why;*
- *Describe the effect of the medication on the resident's functioning, participation in individual and/or group activities, and how it makes them feel; and*
- *Describe any changes in the resident's ability to understand, sleeping patterns, or social involvement since receiving the medication.*

Interview direct care staff and/or licensed personnel (e.g. nursing, social worker), as appropriate, on various shifts that provide care to the resident to determine:

- *Why the medication is being administered and what effect (physical and/or psychosocial) it has on the resident;*
- *Depending on whether distressed behavior is expressed, how do staff respond and what individualized, person-centered interventions are attempted;*
- *Prior to administration of the medication, whether other interventions have been attempted; if so, what alternatives; and how the interventions met or failed to meet the resident's needs;*
- *How long the medication has been administered, and when it began;*
- *Prior to administration of the medication, what is determined to be the underlying cause(s) of the medical symptom that is being treated; how is the cause(s) treated;*

- *Who and how the facility monitors for adverse consequences related to the administration of the medication;*
- *How is it determined that the medical symptom is no longer present and who determines this;*
- *If the medication continues to be administered and the medical symptom is no longer present, what is the clinical rationale for continuing the use of the medication and where is this documented;*
- *How staff are assigned to monitor, care for, and be familiar with residents' behaviors (e.g., the number, location, and consistency of staff assigned across different shifts/units);*
- *Who supervises the overall delivery of care to the residents to assure care planned interventions are implemented and how supervision occurs (to assure that a chemical restraint is not used for staff convenience); and*
- *Whether staff have discussed concerns with the Director of Nurses and Administrator regarding the behavioral symptoms of specific residents and the monitoring of interventions, and whether staff have requested more resources or changes to resident assignments, and the response to the concerns.*

Interview the practitioner regarding concerns identified during the investigation, including when the staff contacted him/her, what concerns they identified regarding the resident's behavior, the response provided, including whether other interventions were attempted prior to the use of a medication, what medical symptom is being treated with the medication, whether the medication is considered to be the least restrictive (in type, dose, and duration) that may be used to treat the symptom, and the plan for discontinuing and/or revising interventions.
Interview the pharmacist to identify when he/she conducted the last medication regimen review for the resident; if the medication was administered prior to the last review and it was not identified as a concern, whether he/she can provide information regarding the indication for use of the medication; if the medication was administered prior to the last review and it was identified as a concern, , whether he/she notified the practitioner, Director of Nurses, and/or medical director and what was the response; and what is the facility's process for notifying the pharmacist when initiating a medication for a change in the resident's condition, such as when there are expressions or indications of distress, or other changes in a resident's psychosocial status.

Interview the social worker to determine any patterns of behaviors that may impact the resident's safety or care provided, whether he/she was aware of interventions attempted, how attempts met or did not meet the resident's needs, whether he/she was aware of what medications are administered to the resident, whether he/she has identified any changes in the resident's behavior or activity level after administration of the medication, and why he/she believes the medication is being administered.
Interview the Director of Nurses to identify his/her knowledge regarding the behavioral symptoms of specific residents and the monitoring of interventions. Also, interview the Director of Nurses and Administrator to identify whether staff have requested more resources or changes to resident assignments, and the response to the concerns.

Record Review

Review the assessment, care plan, practitioner orders, progress notes, and consulting pharmacist reviews. Determine whether there was a decline in the resident's functional and/or psychosocial status related to the medication that was administered. If so, the surveyor must determine whether the decline can be attributed to disease progression or administration of an unnecessary medication. Determine if documentation in the resident's record reflects:

Prior to administration of the medication, whether other interventions have been attempted; if so, what alternatives; and how the interventions met or failed to meet the resident's needs;

- *Prior to administration of the medication, whether the facility identified, to the extent possible, and addressed the underlying cause(s) of the medical symptom;*
- *Indication for use for the medication(s), including the medical symptom(s) being treated;*
- *Whether the record reflects any adverse consequences after administration of the medication;*
- *Whether the record reflects whether there was a change in functioning and/or activity after administration of the medication;*
- *If a medication used to treat medical symptoms was appropriate at one time, determine if it was discontinued once it was no longer necessary, or if a clinical rationale to continue the medication is documented; and*
- *Whether the medication is administered on a PRN basis on particular days or shifts or when certain staff is caring for the resident and the symptoms for which the medication is prescribed are not documented.*

Facility Review

It may be necessary to interview the medical director regarding medications that are not required to treat the resident's medical symptoms result in the resident being subdued, sedated, or withdrawn or limited in his/her functional capacity.

Determine whether the Quality Assessment & Assurance committee is aware of psychotropic medication used to address resident behavioral symptoms, whether there is sufficient, qualified staff trained to provide interventions for behavioral symptoms, and supervision of staff to assure that medications are only used to treat a medical symptom and do not have the effect of convenience or discipline.

KEY ELEMENTS OF NONCOMPLIANCE

*To cite deficient practice at F605, the surveyor's investigation will generally show that the facility has failed, in one or more areas, to do **any one** or more of the following:*

- *Assure that the resident is free from restraints imposed for discipline or staff convenience (convenience can be caused intentionally or unintentionally by staff);*
- *Identify medical symptoms that were being treated with the use of a chemical restraint;*
- *If a chemical restraint is in use, the facility:*
  - *Provides the least restrictive alternative for the least time possible, including and as appropriate, developing and implementing a plan for gradual dose reduction, in the absence of identified and documented clinical contraindications;*
  - *Monitors and evaluates the resident's response to the medication; and*

- *Discontinues the use of the medication when the medical symptom is no longer being treated, unless reducing or eliminating the use of the medication may be clinically contraindicated.*

POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION

During the investigation, the surveyor may have determined that concerns may also be present with related outcome, process and/or structure requirements. The surveyor is cautioned to investigate these related requirements before determining whether non-compliance may be present. Some examples of related requirements that should be considered include the following:

- *42 CFR 483.10, 483.10(a)(1)-(2), 483.10(b)(1)-(2), F550- Resident Rights and Dignity*
- *42 CFR 483.10(c)(2)-(3), F553 - Right to Participate Planning Care*
- *42 CFR 483.21(b)(1), F656- Develop/Implement Comprehensive Care Plan*
- *42 CFR 483.35, 483.35(a), and 483.35(c)- F725 and F726 – Sufficient and Competent Staff*
- *42 CFR 483.40(b)-(b)(1), F742- Treatment/Svc for Mental/Psychosocial Concerns*
- *42 CFR 483.45(c), F756-Drug Regimen Review, Report Irregular, Act On*
- *42 CFR 483.45(d), F757- Drug Regimen is Free From Unnecessary Drugs*
- *42 CFR 483.45, F758- Psychotropic Medications*
- *42 CFR 483.70(h), F841-Responsibilities of Medical Director*
- *42 CFR 483.75 (g)(2)(ii)- F867- QAA Activities*

DEFICIENCY CATEGORIZATION

In addition to actual or potential physical harm, always consider whether psychosocial harm has occurred when determining severity level (See Appendix P, Section IV, E, Psychosocial Outcome Severity Guide).

Examples of Severity Level 4 Noncompliance Immediate Jeopardy to Resident Health or Safety includes, but is not limited to:

- *The facility administered a medication to a resident for staff convenience without a medical symptom identified. The resident was admitted to a secured area of the facility two months prior to the survey. During observations the resident was observed lying in a reclining chair, sleeping and staff had difficulty arousing the resident for meals. The staff had to provide one to one assistance to assist the resident to eat. The resident was unable to hold the utensils, and was being fed a pureed meal. The resident required a two-person assist to transfer from bed to chair and required total assistance for activities of daily living. The resident's record revealed that on admission, the resident was independent in mobility and ambulation and did not require assistance to eat. Staff interviewed stated that they had difficulty monitoring the resident as they were taking care of other residents. They stated that there were no identified interventions or activities to address these behaviors. As a result, staff requested a medication from the physician for the wandering behavior. The physician was interviewed and stated that the medication was being administered for wandering, but that he was not aware that the resident was sedated and the resident's decline in walking and activities of daily living. There was no other evidence in the resident's record or from interviews with staff and the physician that indicate a medical reason for the decline and sedating effect.*

- *The facility failed to assure that a medication it administered to a resident was being used to treat a medical symptom and not for staff convenience. The resident was admitted for post-surgical rehabilitation of a fractured hip. During an interview, the resident's representative stated that prior to admission, the resident had been alert, was able to recognize her family members, was used to sitting with the family after the evening meal at home, and, although pleasantly confused, enjoyed a warm bath prior to bedtime and slept through the night. However, after admission, there had been a significant change in the resident's status. The resident's record reflected that the resident, after admission, was immediately put to bed after the evening meal every day; subsequently, the resident began yelling out for help, wanted to get out of bed, and disrupted other residents' sleep. During an interview with the practitioner, staff had contacted him and requested an antipsychotic medication to keep the resident quiet during the night hours as she was disruptive and agitated. The practitioner ordered an antipsychotic medication twice a day, but did not provide documentation of a medical symptom being treated with the medication. Observations throughout the survey revealed the resident seated in a wheelchair, subdued or sleeping, sucking on her hand, mumbling to self, and not aware of surroundings or visitors. Staff interviewed corroborated that there had been a decline in the resident's condition since the administration of the medication. Due to the significant change in the resident's status related to the initiation and use of a chemical restraint, serious harm occurred to the resident.*

Examples of Severity Level 3 Noncompliance Actual Harm that is not Immediate Jeopardy include, but is not limited to:

- *The facility administered a medication that was not being used to treat medical symptoms, the facility did not attempt any less restrictive interventions, and the medication was used for the convenience of staff. As a result of this noncompliance, the resident was sedated into the morning hours. The resident was unable to be aroused sufficiently to eat breakfast in the dining room where he normally eats meals, and now required assistance by staff to eat breakfast. The resident was observed to attend and participate in his other meals and activities for the rest of the day. The record did not indicate any falls or any decline in other activities of daily living. The resident, diagnosed with Alzheimer's disease, had displayed night time behaviors that frustrated other residents and nursing staff, such as wandering into other resident's rooms, and rummaging through drawers and closets. To address the resident's behavior, staff contacted the attending physician to discuss the issue and request a long-acting anti-anxiety medication. No other attempts of non-pharmacological interventions were identified or implemented prior to the use of the chemical restraint. Staff stated that they did not have the time to implement other interventions. The resident's record did not indicate a medical symptom being treated, nor a reduction of the medication when the resident's functional status declined.*

Examples of Severity Level 2 Noncompliance No Actual Harm with Potential for More Than Minimal Harm that is Not Immediate Jeopardy include, but are not limited to:

- *The facility failed to assure that an antianxiety medication was being administered to treat a medical symptom and not for the convenience of staff. Although the resident has*

not experienced falls or other adverse consequences in relation to the administration of the medication, the potential exists for more than minimal harm with the continued use of the anti-anxiety medication in the absence of a medical symptom. Interviews and record review revealed that the facility was giving a resident anti-anxiety medication prior to the resident taking showers occasionally on weekends. Staff indicated that the resident had occasionally declined showers not because she was anxious, but because she found bed baths to be more relaxing than the shower environment. The staff interviewed stated that the nurse aides, who worked the daytime weekend shift, were upset about the resident refusing the shower as they did not have time to come back and shower the resident at another time not realizing that this was not the resident's preference. The weekend nurse contacted the physician for a medication to alleviate the resident's "anxiety to taking a shower." A nursing assistant who was assigned to provide the resident's care during the week, stated that sometimes the resident does not want to take a shower and on those occasions, she would give the resident a bed bath. The nursing assistant said the resident is not resistive or combative.

Severity Level 1: No Actual Harm with Potential for Minimal Harm
The failure of the facility to assure residents are free from chemical restraints is more than minimal harm. Therefore, Severity Level 1 does not apply for this regulatory requirement.

F606
§483.12(a) **The facility must—**

§483.12(a)(3) **Not employ *or otherwise engage* individuals who—**
- ***(i) H*****ave been *f*ound guilty of *abuse, neglect, exploitation, misappropriation of property, or mistreatment* by a court of law;**
- ***(ii)*** **Have had a finding entered into the State nurse aide registry concerning abuse, neglect, *exploitation,* mistreatment of residents or misappropriation of their property; *or***
- ***(iii) Have a disciplinary action in effect against his or her professional license by a state licensure body as a result of a finding of abuse, neglect, exploitation, mistreatment of residents or misappropriation of resident property.***

§483.12(a)(4) **Report to the State nurse aide registry or licensing authorities any knowledge it has of actions by a court of law against an employee, which would indicate unfitness for service as a nurse aide or other facility staff.**

INTENT
The facility must not hire an employee or engage an individual who was found guilty of abuse, neglect, exploitation, or mistreatment or misappropriation of property by a court of law; or who has a finding in the State nurse aide registry concerning abuse, neglect, exploitation, mistreatment of residents or misappropriation of resident property, or has had a disciplinary action in effect taken against his/her professional license. The facility must report knowledge of actions by a court of law against an employee that indicates the employee is unfit for duty.

Effective November 28, 2017

DEFINITIONS

"Found guilty … by a court of law" applies to situations where the defendant pleads guilty, is found guilty, or pleads *no contest to charges of abuse, neglect, exploitation, misappropriation of property, or mistreatment.*

"Finding" is defined as a determination made by the State that validates allegations of abuse, neglect, *exploitation,* mistreatment of residents, or misappropriation of their property.

"Mistreatment," *as defined at §483.5, means "inappropriate treatment or exploitation of a resident."*

GUIDANCE

Employment

NOTE*: For purposes of this guidance, "staff" includes employees, the medical director, consultants, contractors, volunteers. Staff would also include caregivers who provide care and services to residents on behalf of the facility, students in the facility's nurse aide training program, and students from affiliated academic institutions, including therapy, social, and activity programs.*

Facilities must be thorough in their investigations of the histories of prospective staff. In addition to inquiry of the State nurse aide registry or licensing authorities, the facility should check information from previous and/or current employers and make reasonable efforts to uncover information about any past criminal prosecutions. It has been reported that former nurse aides with a finding of abuse, neglect, misappropriation of resident property, exploitation, or mistreatment may seek employment in other departments of a facility, such as maintenance or laundry services/department, or at another nursing home in a non-nursing capacity.

Some States may have additional requirements for criminal background checks and State law may prohibit persons convicted of certain crimes from working in a long-term care facility. The State Survey Agency may use its own authority for assuring facility compliance such as the use of the National Background Check Program or specific State licensure requirements that may address criminal background checks. In addition, some facilities may have more stringent hiring restrictions than what is required by State or Federal law.

If a facility has not developed and/or implemented policies and procedures related to screening procedures prior to employment, a finding of noncompliance should be considered at F607, not F606. If it is determined that the facility employed or engaged an individual, either directly or under contract, who was found guilty by a court of law of abuse, neglect, misappropriation of property, exploitation or mistreatment, or had a finding entered into the State nurse aide registry or has a disciplinary action in effect against his/her professional license concerning abuse, neglect, mistreatment of residents or misappropriation of resident property, a finding of noncompliance must be cited at F606. In this situation, there may also be a citation at F607 if the facility failed to develop and/or implement policies and procedures related to staff screening.

Effective November 28, 2017

Reporting to the State Nurse Aide Registry or Licensing Authorities
A nurse aide found guilty of neglect, abuse, *mistreatment,* misappropriation of property, *or exploitation by a court of law, must have his/her name entered into the State* nurse aide registry. A licensed staff member found guilty of the above must be reported to *his/her* licensing board. Further, if a facility determines that actions by a court of law against an employee are such that they indicate that the individual is unsuited to work in a nursing home, then the facility must report that individual to the *State* nurse aide registry (if a nurse aide) or to the State licensing authorities (if a licensed staff member). *Examples of convictions that may indicate unfitness to work in a nursing home include, but are not limited to,* child abuse, sexual assault, *theft*, *and* assault with a deadly weapon.

***NOTE**: In addition, according to 42 CFR 483.156(c)(1)(iv)(A) to (c)(1)(iv)(D) Registry of Nurse Aides, the SA must include the following information on any finding by the State survey agency of abuse, neglect, or misappropriation of property by the individual:*

- *Documentation of the State's investigation, including the nature of the allegation and the evidence that led the State to conclude that the allegation was valid;*
- *The date of the hearing, if the individual chose to have one, and its outcome; and*
- *A statement by the individual disputing the allegation, if he or she chooses to make one.*

This information must be included in the registry within 10 working days of the finding and must remain in the registry permanently, unless the finding was made in error, the individual was found not guilty in a court of law, or the State is notified of the individual's death.

Refer to the CE Pathways for Abuse (Form CMS-20059) and Neglect (Form CMS-20130) and the Investigative Protocols for tags F602 and F603.

KEY ELEMENTS OF NONCOMPLIANCE
*To cite deficient practice at F606, the surveyor's investigation will generally show that the facility did **any** one or more of the following:*

- *Hire or engage an individual who, unless the individual in question has appealed their disqualification from employment in a nursing home and that appeal has been successful under State or federal law:*
  - *Has been found guilty of abuse, neglect, exploitation, misappropriation of property, or mistreatment by a court of law; **or***
  - *Has had a finding entered into the State nurse aide registry concerning abuse, neglect, exploitation, mistreatment of residents, or misappropriation of their property; **or***
  - *Has had a disciplinary action in effect against his/her professional license by a state professional licensure body as a result of a finding of abuse, neglect, exploitation, mistreatment of residents, or misappropriation of resident property; **or***
- *Failed to report to the State nurse aide registry or licensing authorities any knowledge of actions taken by a court of law that would indicate unfitness as a staff member of a nursing home.*

F607
§483.12(b) **The facility must develop and implement written policies and procedures that:**

Effective November 28, 2017

***§483.12(b)(1) P*rohibit *and prevent* abuse, neglect, *and exploitation* of residents and misappropriation of resident property,**

§483.12(b)(2) Establish policies and procedures to investigate any such allegations, and

§483.12(b)(3) Include training as required at paragraph §483.95,

§483.12(b)(4) Establish coordination with the QAPI program required under §483.75. [§483.12(b)(4) will be implemented beginning November 28, 2019 (Phase 3)]

INTENT

This regulation was written to provide protections for the health, welfare and rights of each resident residing in the facility. In order to provide these protections, the facility must develop written policies and procedures to prohibit and prevent abuse, neglect, exploitation of residents, and misappropriation of resident property. These written policies must include, but are not limited to, the following components:

- *Screening;*
- *Training;*
- *Prevention;*
- *Identification;*
- *Investigation;*
- *Protection; and*
- *Reporting/response.*

In order to ensure that the facility is doing all that is within its control to prevent such occurrences, these policies must be implemented (i.e., carried out), otherwise, the policies and procedures would not be effective. The facility is expected to provide oversight and monitoring to ensure that its staff, who are agents of the facility, implement these policies during the provision of care and services to each resident residing in the facility. A facility cannot disown the acts of its staff, since the facility relies on them to meet the Medicare and Medicaid requirements for participation by providing care in a safe environment.

***NOTE**: For purposes of this guidance, "staff" includes employees, the medical director, consultants, contractors, volunteers. Staff would also include caregivers who provide care and services to residents on behalf of the facility, students in the facility's nurse aide training program, and students from affiliated academic institutions, including therapy, social, and activity programs.*

GUIDANCE

The facility must develop and implement policies and procedures that include the *following* seven components:

I. Screening:

The facility must have written procedures for screen*ing* potential employees for a history of abuse, neglect, *exploitation, or misappropriation of resident property in order to prohibit abuse,*

neglect, and exploitation of resident property, and consistent with the applicable requirements at §483.12(a)(3). This includes attempting to obtain information from previous employers and/or current employers, and checking with the appropriate licensing boards and registries. *See F729 for requirements related to registry verification and multi-State registry verification.*

Additionally, a facility's services may be furnished under arrangement, with a registry, contracted, or temporary agency staff, or students from affiliated academic institutions. The facility's policies must also address how pre-screening occurs for prospective consultants, contractors, volunteers, caregivers and students in its nurse aide training program and students from affiliated academic institutions, including therapy, social, and activity programs. The facility should require these individuals to be subject to the same scrutiny prior to placement in the facility, whether screened by the facility itself, the third-party agency, or academic institution. The facility should maintain documentation of the screening that has occurred.

The facility must have written procedures for screening that may include, but are not limited to:

- *For prospective employees, reviewing:*
  - *The employment history (e.g., dates of employment position or title), particularly where there is a pattern of inconsistency;*
  - *Information from former employers, whether favorable or unfavorable; and/or*
  - *Documentation of status and any disciplinary actions from licensing or registration boards and other registries.*

In addition, a facility must develop and implement policies and procedures to prohibit and prevent both abuse and neglect. This would include screening prospective residents to determine whether the facility has the capability and capacity to provide the necessary care and services for each resident admitted to the facility. The facility's written procedures may include, but are not limited to:

- *For prospective residents, reviewing:*
  - *An assessment of the individual's functional and mood/behavioral status;*
  - *Medical acuity; and*
  - *Special needs (e.g., mechanical ventilation care, dialysis, hospice).*

The facility can then determine whether – in consideration of current staffing patterns, staff qualifications, competency and knowledge, clinical resources, physical environment, and equipment- it can safely and competently provide the necessary care to meet the resident's needs. For example, a resident may have a prior history of distressed behaviors such as unsafe wandering, physically aggressive behaviors including sexually aggressive behaviors, or mental/psychiatric illnesses. In order to provide protections and a safe environment for the resident and other residents, the facility must determine whether it has sufficient competent and qualified staff in order to meet the needs of the resident. If the individual is admitted, pre-admission screening information may provide information that may be used as part of the initial assessment and care planning data.

II. Training:

The facility must have written policies and procedures that include training new and existing nursing home staff and in-service training for nurse aides in the following topics which include:

- *Prohibiting and preventing all forms of abuse, neglect, misappropriation of resident property, and exploitation;*
- *Identifying* what constitutes abuse, neglect*, exploitation,* and misappropriation of resident property*;*
- *Recognizing signs of abuse, neglect, exploitation and misappropriation of resident property, such as physical or psychosocial indicators;*
- *Reporting abuse, neglect, exploitation, and misappropriation of resident property, including injuries of unknown sources, and to whom and when* staff *and others must* report their knowledge related to *any alleged violation* without fear of reprisal*; and*
- *Understanding behavioral symptoms of residents that may increase the risk of abuse and neglect and how to respond. These symptoms, include, but are not limited to, the following:*
  - *A*ggressive and/or catastrophic reactions of residents;
  - *Wandering or elopement-type behaviors;*
  - *Resistance to care;*
  - *Outbursts or yelling out; and*
  - *Difficulty in adjusting to new routines or staff.*

NOTE*: The provision of training on abuse prohibition alone does not relieve the nursing home of its responsibility to assure that the resident is free from abuse. The nursing home must provide ongoing oversight and supervision of staff in order to assure that its policies are implemented as written.*

NOTE*: Federal regulations at 42 CFR §§ 483.95(c) and 483.95(g) specify that a facility must develop, implement, and maintain a training program that includes staff training related to abuse, neglect, and exploitation. If the facility fails to develop and implement policies and procedures that include training as required at 42 CFR 483.95(c) and (g)(2), then F607 would be cited. Refer to tag F943 if there are concerns related to the development, implementation and maintenance of an effective training program for all new and existing staff, which includes training on activities that constitute abuse, neglect, exploitation, and misappropriation of resident property; procedures for reporting incidents; and dementia management. Refer to tag F947 for concerns related to the provision of in-service training, which must include dementia management training and resident abuse prevention training.*

III. Prevention:

The facility must have and implement written policies and procedures to prevent and prohibit all types of abuse, neglect, misappropriation of resident property, and exploitation that achieves (but is not limited to):

- *Establishing a safe environment that supports, to the extent possible, a resident's consensual sexual relationship and by establishing policies and protocols for preventing sexual abuse, such as the identify when, how, and by whom determinations of capacity to consent to a sexual contact will be made and where this documentation will be recorded; and the resident's right to establish a relationship with another individual, which may include the development of or the presence of an ongoing sexually intimate relationship;*
- Identify*ing,* correct*ing and* interven*ing* in situations in which abuse, neglect, *exploitation,* and/or misappropriation of resident property is more likely to occur. This includes *the*

implementation of policies that address the deployment of *trained and qualified, registered, licensed, and certified* staff on each shift in sufficient numbers to meet the needs of the residents, and assure that the staff assigned have knowledge of the individual residents' care needs *and behavioral symptoms, if any (see also F727 related to proficiency of nurse aides);*

- *Assuring that residents are free from neglect by having the structures and processes to provide needed care and services to all residents, which includes, but is not limited to, the provision of a facility assessment to determine what resources are necessary to care for its residents competently;*
- The *identification, ongoing* assessment, care planning *for appropriate interventions,* and monitoring of residents with needs and behaviors which might lead to conflict or neglect, such as:
  - *Verbally aggressive behavior, such as screaming, cursing, bossing around/demanding, insulting to race or ethnic group, intimidating;*
  - *Physically aggressive behavior, such as hitting, kicking, grabbing, scratching, pushing/shoving, biting, spitting, threatening gestures, throwing objects;*
  - *Sexually aggressive behavior such as saying sexual things, inappropriate touching/grabbing;*
  - *Taking, touching, or rummaging through other's property;*
  - *Wandering into other's rooms/space;*
  - *R*esidents with a history of self-injurious behaviors*;*
  - *R*esidents with communication disorders *or who speak a different language; and*
  - *Residents* that require *extensive* nursing care and/or are totally dependent on staff *for the provision of care.*
- *Ensuring the health and safety of each resident with regard to visitors such as family members or resident representatives, friends, or other individuals subject to the resident's right to deny or withdraw consent at any time and to reasonable clinical and safety restrictions;*
- *Providing residents and representatives, information on how and to whom they may report concerns, incidents and grievances without the fear of retribution; and providing feedback regarding the concerns that have been expressed. (See F585 for further information regarding grievances).*

The facility may also develop and implement policies and procedures, which achieve the following:

- Identify*ing,* correct*ing and* interven*ing* in situations in which abuse, neglect, *exploitation,* and/or misappropriation of resident property is more likely to occur. This includes an analysis of *and implementation of policies that address at a minimum:*
  - Features of the physical environment that may make abuse, neglect, *exploitation, and misappropriation of resident property* more likely to occur, such as secluded areas of the facility; and
  - The *identification of who is responsible for the* supervision of staff *on all shifts and how supervision will occur in order* to identify inappropriate staff behaviors, such as using derogatory language, rough handling, ignoring residents while giving care, and directing residents who need assistance with the bathroom to urinate or defecate in their beds.

- *Providing staff information on how and to whom they may report concerns, such as insufficient staffing or a shortage in supplies, without the fear of retribution; and providing feedback regarding the concerns that have been expressed.*

IV. Identification:
The facility must have written procedures to assist staff in identifying abuse, neglect, and exploitation of residents, and misappropriation of resident property. This would include identifying the different types of abuse- mental/verbal abuse, sexual abuse, physical abuse, and the deprivation by an individual of goods and services.

Because some cases of abuse are not directly observed, understanding resident outcomes of abuse could assist in identifying whether abuse is occurring or has occurred. Possible indicators of abuse include, but are not limited to:

- *An injury that is suspicious because the source of the injury is not observed or the extent or location of the injury is unusual, or because of the number of injuries either at a single point in time or over time; and*
- *Sudden or unexplained changes in the following behaviors and/or activities such as fear of a person or place, or feelings of guilt or shame.*

V. Investigation:
The facility must have written procedures for investigating abuse, neglect, misappropriation, and exploitation that include:

***NOTE**: See also Section VI regarding protection of the alleged victim.*

- *Identifying staff responsible for the investigation;*
- *Exercising caution in handling evidence that could be used in a criminal investigation (e.g., not tampering or destroying evidence);*
- Investigating different types of *alleged violations;*
- *Identifying and interviewing all involved persons, including the alleged victim, alleged perpetrator, witnesses, and others who might have knowledge of the allegations;*
- *Focusing the investigation on determining if abuse, neglect, exploitation, and/or mistreatment has occurred, the extent, and cause; and*
- *Providing complete and thorough documentation of the investigation.*

VI. Protection:
The facility must have written procedures that ensure that all residents are protected from physical and psychosocial harm during and after the investigation. This must include:

- *Responding immediately to protect the alleged victim and integrity of the investigation;*
- *Examining the alleged victim for any sign of injury, including a physical examination or psychosocial assessment if needed;*
- *Increased supervision of the alleged victim and residents;*
- *Room or staffing changes, if necessary, to protect the resident(s) from the alleged perpetrator;*
- *Protection from retaliation; and*
- *Providing emotional support and counseling to the resident during and after the investigation, as needed.*

VII. Reporting/Response:
The facility must have written procedures that must include:

- *Immediately reporting all alleged violations to the Administrator, state agency, adult protective services and to all other required agencies (e.g., law enforcement when applicable) within specified timeframes;*
- *Assuring that reporters are free from retaliation or reprisal;*
- *R*eporting to the State nurse aide registry or licensing authorities any knowledge it has of any actions by a court of law which would indicate an employee is unfit for service;
- *Taking all necessary actions as a result of the investigation, which may include, but are not limited to, the following:*
  - Analyz*ing* the occurrence*(s)* to determine *why abuse, neglect, misappropriation of resident property or exploitation occurred, and* what changes are needed to prevent further occurrences;
  - *Defining how care provision will be changed and/or improved to protect residents receiving services;*
  - *Training of staff on changes made and demonstration of staff competency after training is implemented;*
  - *Identification of staff responsible for implementation of corrective actions;*
  - *The expected date for implementation; and*
  - *Identification of staff responsible for monitoring the implementation of the plan.*

Refer to the CE Pathways for Abuse (Form CMS-20059) and Neglect (Form CMS-20130) and the Investigative Protocols for tags F602 and F603.

KEY ELEMENTS OF NONCOMPLIANCE
To cite deficient practice at F607, the surveyor's investigation will generally show that the facility has failed to do one or more of the following:

- *Develop and implement written policies and procedures that prohibit and prevent abuse, neglect and exploitation of residents and misappropriation of resident property and includes the screening of prospective employees and residents;* ***or***
- *Develop and implement written policies and procedures for the investigation of allegations of abuse, neglect and exploitation of residents and misappropriation of resident property and includes the staff identification of abuse, neglect, exploitation, and misappropriation of resident property, protection of residents during investigations, and the reporting of allegations and investigative findings and taking corrective actions;* ***or***
- *Develop and implement written policies and procedures that include training as required at §483.95.*

F608
§483.12(b) The facility must develop and implement written policies and procedures that:

§483.12(b)(5) Ensure reporting of crimes occurring in federally-funded long-term care facilities in accordance with section 1150B of the Act. The policies and procedures must include but are not limited to the following elements.

Effective November 28, 2017

(i) Annually notifying covered individuals, as defined at section 1150B(a)(3) of the Act, of that individual's obligation to comply with the following reporting requirements.

(A) Each covered individual shall report to the State Agency and one or more law enforcement entities for the political subdivision in which the facility is located any reasonable suspicion of a crime against any individual who is a resident of, or is receiving care from, the facility.

(B) Each covered individual shall report immediately, but not later than 2 hours after forming the suspicion, if the events that cause the suspicion result in serious bodily injury, or not later than 24 hours if the events that cause the suspicion do not result in serious bodily injury.

(ii) Posting a conspicuous notice of employee rights, as defined at section 1150B(d)(3) of the Act.

(iii) Prohibiting and preventing retaliation, as defined at section 1150B(d)(1) and (2) of the Act.

INTENT

The intent is for the facility to develop and implement policies and procedures that:

- *Ensure reporting of crimes against a resident or individual receiving care from the facility occurring in nursing homes within prescribed timeframes to the appropriate entities, consistent with Section 1150B of the Act;*
- *Ensure that all covered individuals, such as the owner, operator, employee, manager, agent or contractor report reasonable suspicion of crimes, as required by Section 1150B of the Act;*
- *Provide annual notification for covered individuals of these reporting requirements;*
- *Post a conspicuous notice of employee rights, including the right to file a complaint; and*
- *Assure that any covered individual who makes a report to be made, or is in the process of making a report, is not retaliated against.*

DEFINITIONS

"Covered individual" *is anyone who is an owner, operator, employee, manager, agent or contractor of the facility (See section 1150B(a)(3) of the Act).*

"Crime"*: Section 1150B(b)(1) of the Act provides that a "crime" is defined by law of the applicable political subdivision where the facility is located. A political subdivision would be a city, county, township or village, or any local unit of government created by or pursuant to State law.*

"Law enforcement," *as defined in section 2011(13) of the Act, is the full range of potential responders to elder abuse, neglect, and exploitation including: police, sheriffs, detectives, public safety officers; corrections personnel; prosecutors; medical examiners; investigators; and coroners.*

"Serious bodily injury" *means an injury involving extreme physical pain; involving substantial risk of death; involving protracted loss or impairment of the function of a bodily member, organ, or mental faculty; requiring medical intervention such as surgery, hospitalization, or physical*

rehabilitation; or an injury resulting from criminal sexual abuse (See section 2011(19)(A) of the Act).

"Criminal sexual abuse": *In the case of "criminal sexual abuse" which is defined in section 2011(19)(B) of the Act (as added by section 6703(a)(1)(C) of the Affordable Care Act), serious bodily injury/harm shall be considered to have occurred if the conduct causing the injury is conduct described in section 2241 (relating to aggravated sexual abuse) or section 2242 (relating to sexual abuse) of Title 18, United States Code, or any similar offense under State law. In other words, serious bodily injury includes sexual intercourse with a resident by force or incapacitation or through threats of harm to the resident or others or any sexual act involving a child. Serious bodily injury also includes sexual intercourse with a resident who is incapable of declining to participate in the sexual act or lacks the ability to understand the nature of the sexual act.*

GUIDANCE

NOTE*: Once an individual suspects that a crime has been committed, facility staff must exercise caution when handling materials that may be used for evidence or for a criminal investigation. It has been reported that some investigations were impeded due to washing linens or clothing, destroying documentation, bathing or cleaning the resident before the resident has been examined, or failure to transfer a resident to the emergency room for examination including obtaining a rape kit, if appropriate.*

NOTE*: Please refer to the facility's obligations under "Reporting Reasonable Suspicion of a Crime in a Long-Term Care Facility: Section 1150B of the Social Security Act," (See S&C Memo: 11-30-NH, revised January 20, 2012, http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/downloads/scletter11_30.pdf).*

Required Policies and Procedures for Reporting Suspicions of a Crime

The following table describes the different reporting requirements that are addressed under 42 CFR 483.12:

	F608 ***42 CFR 483.12(b)(5) and Section 1150B of the Act***	***F609*** ***42 CFR 483.12(c)***
What	*Any reasonable suspicion of a crime against a resident*	*1) All alleged violations of abuse, neglect, exploitation or mistreatment, including injuries of unknown source and misappropriation of resident property* *2) The results of all investigations of alleged violations*
Who is required to report	*Any covered individual, including the owner, operator, employee, manager, agent or contractor of the facility*	*The facility*

Effective November 28, 2017

	F608 ***42 CFR 483.12(b)(5) and Section 1150B of the Act***	***F609*** ***42 CFR 483.12(c)***
To whom	*State Survey Agency (SA) and one or more law enforcement entities for the political subdivision in which the facility is located (i.e., police, sheriffs, detectives, public safety officers; corrections personnel; prosecutors; medical examiners; investigators; and coroners)*	*The facility administrator and to other officials in accordance with State law, including to the SA and the adult protective services where state law provides for jurisdiction in long-term care facilities*
When	*Serious bodily injury- Immediately but not later than 2 hours* after forming the suspicion* *No serious bodily injury- not later than 24* hours*	*All alleged violations-Immediately but not later than* *1) 2 hours- if the alleged violation involves abuse or results in serious bodily injury* *2) 24 hours- if the alleged violation does not involve abuse and does not result in serious bodily injury.*

** - Reporting requirements under this regulation are based on real (clock) time, not business hours*

A facility's policies and procedures for reporting under 42 CFR 483.12(b)(5) should specify the following components, which include, but are not limited to:

- *Identification of who in the facility is considered a covered individual;*
- *Identification of crimes that must be reported;*

  NOTE*: Each State and local jurisdiction may vary in what is considered to be a crime and may have different definitions for each type of crime. Facilities should consult with local law enforcement to determine what is considered a crime.*

- *Identification of what constitutes "serious bodily injury;"*
- *The timeframe for which the reports must be made; and*
- *Which entities must be contacted, for example, the State Survey Agency and local law enforcement.*

There are instances where an alleged violation of abuse, neglect, misappropriation of resident property and exploitation would be considered to be reasonable suspicion of a crime. In these cases, the facility is obligated to report to the administrator, to the state survey agency, and to other officials in accordance with State law (see F609). Regardless, covered individuals still have the obligation to report the reasonable suspicion of a crime to the State Survey Agency and local law enforcement.

Some facilities may have policies and procedures where the administrator could coordinate timely reporting to the State Survey Agency and law enforcement on behalf of covered individuals who choose to the report to the administrator. Risks to the covered individual for reporting to the administrator could be mitigated if an individual has clear assurance that the administrator is reporting it and submitting a collective report would not cause delays in reporting according to specified timeframes. Reports should be documented and the administrator should keep a record of the documentation. It remains the responsibility of each covered individual to ensure that his/her individual reporting responsibility is fulfilled, so it is advisable for any multiple-person report to include identification of all individuals making the report. In addition, a facility cannot prohibit or circumscribe a covered individual from reporting directly to law enforcement even if it has a coordinated internal system.

Surveyors must review whether the facility has included in its policies and procedures examples of crimes that would be reported. Examples of situations that would likely be considered crimes in all subdivisions would include but are not limited to:

- *Murder;*
- *Manslaughter;*
- *Rape;*
- *Assault and battery;*
- *Sexual abuse;*
- *Theft/Robbery;*
- *Drug diversion for personal use or gain;*
- *Identify theft; and*
- *Fraud and forgery.*

There are political subdivisions that have other examples for which instances of elder mistreatment are considered to be crimes. Because all reasonable suspicions of crimes must be reported, regardless of whether it is perpetrated by facility staff, residents, or visitors, it would be especially beneficial for the facility to work with local law enforcement in determining what would not be reported (e.g., all cases of resident to resident conflict may not rise to the level of abuse and may not be appropriate to report to local law enforcement).

Annual Notification of Reporting Obligations to Covered Individuals

The facility must develop and implement written procedures that include, but are not limited to, notifying covered individuals annually of their obligations to report reasonable suspicion of crimes in the facility. Policies and procedures should include, but are not limited to the following:

- *Identification of who are the covered individuals in the facility;*
- *How covered individuals are notified of the reporting requirements. Notification must include the following:*
  - *Each covered individual's independent obligation to report the suspicion of a crime against a resident directly to local law enforcement and the State Survey Agency;*
  - *The timeframe requirements for reporting reasonable suspicion of crimes:*

    - *If the events that cause the reasonable suspicion result in serious bodily injury to a resident, the covered individual must report the suspicion immediately, but not later than 2 hours after forming the suspicion;*
    - *If the events that cause the reasonable suspicion do not result in serious bodily injury to a resident, the covered individual shall report the suspicion not later than 24 hours after forming the suspicion.*
- *Penalties associated with failure to report:*
  - *If a covered individual fails to report within mandated timeframes, the covered individual will be subject to a civil money penalty of not more than $200,000; and the covered individual may be excluded from participation in any Federal health care program (as defined in section 1128B(f)).*
  - *If a covered individual fails to report within mandated timeframes and the violation exacerbates the harm to the victim of the crime or results in harm to another individual, the covered individual will be subject to a civil money penalty of not more than $300,000; and the Secretary may make a determination in the same proceeding to exclude the covered individual from participation in any Federal health care program (as defined in section 1128B(f)).*
- *The mechanism for documenting that all covered individuals have been notified annually of their reporting obligations. Documentation may include a copy of a notice or letter sent to covered individuals with confirmation that it was received or a completed training/orientation attendance sheet documenting the individual completed training on reporting obligations.*

Retaliation

In order to encourage reporting of the suspicion of a crime, facilities should develop and implement policies and procedures that promote a culture of safety and open communication in the work environment. This may be accomplished through prohibiting retaliation against an employee who reports a suspicion of a crime. Actions that constitute retaliation against staff include:

- *When a facility discharges, demotes, suspends, threatens, harasses, or denies a promotion or other employment-related benefit to an employee, or in any other manner discriminates against an employee in the terms and conditions of employment because of lawful acts done by the employee.*
- *When a facility files a complaint or a report against a nurse or other employee with the state professional licensing agency because of lawful acts done by the nurse or employee for reporting a reasonable suspicion of a crime to law enforcement.*

An example of retaliation would be if a staff member, on behalf of or as an agent of the facility, harasses an employee who had reported a suspected crime.

In addition to developing policies prohibiting retaliation for reporting suspicions of a crime, the facility must develop and implement policies and procedures for posting notice in a conspicuous location informing covered individuals of their right to file a complaint with the State Survey Agency if they believe the facility has retaliated against an employee or individual who reported a suspected crime and how to file such a complaint.

The sign may be posted in the same area that the facility posts other required employee signs, such as labor management posters. Size and type requirements for the sign should be no less than the minimum required for the other required employment-related signs.

INVESTIGATIVE PROTOCOL FOR REPORTING OF REASONABLE SUSPICION OF A CRIME

USE

Use this protocol during any survey, if based on a complaint or an investigation of abuse, neglect, misappropriation of resident property, or exploitation, the facility did not report a reasonable suspicion of a crime or an allegation of retaliation was received. Refer to the CE Pathways for Abuse (Form CMS-20059) and Neglect (Form CMS-20130) and the Investigative Protocols for tags F602, and F603, which gathers information about what information was or was not reported by covered individuals and whether retaliation may have occurred.

The protocol below investigates whether the facility developed and implemented policies and procedures related to:

Ensuring the reporting reasonable suspicion of crimes,

- *Notifying covered individuals of their reporting responsibilities,*
- *Prohibiting and preventing retaliation, and*
- *Posting notification of employee rights.*

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PROCEDURES

If the surveyor discovers an incident that has criminal implications and has not been reported by the facility, the facility should be encouraged to make the report to the appropriate agencies. If the facility refuses, the surveyor should consult with his/her supervisor immediately, since the State Agency may need to assume this responsibility.

***NOTE**: For those covered individuals who did not report the reasonable suspicion of a crime, discuss with the State Survey Agency and next steps for referral for follow-up and possible sanctions.*

Facility Policies and Procedures

Obtain and review the facility's policies and procedures to determine whether the facility is in compliance with the requirements at 1150B for:

- *Ensuring the reporting reasonable suspicion of crimes,*
- *Notifying covered individuals of their reporting responsibilities,*
- *Prohibiting and preventing retaliation, and*
- *Posting notification of employee rights.*

Observations

Observe whether the facility has posted notification of employee rights and whether the notification includes all of the required components. Note the location of the notification, in relation to whether it is likely to be noticed by all employees.

Interview of State Professional Licensing Authorities
If there is an allegation of retaliation against of an employee, the surveyor should contact the appropriate State licensing board, to determine whether the facility had filed a complaint or report against the employee, and if so, what information was provided in the complaint or report.

Interview Staff
Interview staff who may have knowledge of the alleged incident to determine how did staff follow facility policies and procedures, such as what actions were taken when there was a suspected crime, when he/she may have last received training and/or notification regarding the reporting of suspected crimes, and whether there are any barriers to reporting. For an allegation of retaliation, interview staff about what occurred, how the facility retaliated against staff, and when.

Interview – Administrator
Interview the Administrator to determine the following:

- *How the Administrator oversees the implementation of policies and procedures for reporting of suspected crimes;*
- *For an allegation of retaliation:*
  - *Whether any actions were taken against an employee, and if so, what actions and why;*
  - *Whether the facility had submitted a report to the State professional licensing agency, and if so, why.*

Review of In-service Training/Orientation Records
Obtain and review documentation of training to determine whether covered individuals were notified annually of their responsibility to report allegations of crimes in the facility.

Review of Employee Personnel Records
If there is an allegation of retaliation against of the employee, obtain a copy of the employee's personnel records to determine if the facility may have taken any action against the employee which may be related to an employee's report of a suspected crime.

KEY ELEMENTS OF NONCOMPLIANCE
To cite deficient practice at F608, the surveyor's investigation will generally show that the facility failed to develop and implement policies and procedures for any one or more of the following:

- *Ensure the reporting of suspected crimes, within mandated timeframes (i.e., immediately but not later than two hours if the suspected crime resulted in serious bodily injury, within 24 hours for all other cases);*
- *Notify covered individuals annually of their reporting obligations;*
- *Post signage of employee rights related to retaliation against the employee for reporting a suspected crime; or*
- *Prohibit and prevent retaliation.*

Effective November 28, 2017

DEFICIENCY CATEGORIZATION

In addition to actual or potential physical harm, always consider whether psychosocial harm has occurred when determining severity level (See Appendix P, Section IV, E, Psychosocial Outcome Severity Guide).

Examples of Severity Level 4 Noncompliance Immediate Jeopardy to Resident Health or Safety include, but are not limited to:

- *The facility failed to develop and implement policies and procedures for covered individuals to identify and report a suspected crime to local law enforcement and the SA, resulting in failure to protect a resident from further potential criminal activity by an alleged perpetrator. A resident, with a cognitive impairment who was dependent on staff for care, reported to family members that she was "touched down there" and identified the alleged perpetrator. Family members reported this to the licensed staff person on duty; however, the staff told the family that the resident was confused. Staff did not report the family's allegation to anyone and failed to provide protection for the resident allowing ongoing access to the resident by the alleged perpetrator. The resident had emotional changes including crying and agitation and cowered with fear whenever the alleged perpetrator approached the resident recurring fear whenever the perpetrator approached the resident. The resident subsequently developed a sexually transmitted disease (STD). Based on interviews with various staff members, these covered individuals were not aware of their reporting responsibilities for a suspected crime, and assumed that this did not need to be reported because the resident was confused.*

Examples of Severity Level 3 Noncompliance Actual Harm that is not Immediate Jeopardy include, but are not limited to:

- *The facility failed to implement policies and procedures for covered individuals to report to law enforcement, the suspicion of a crime related to drug diversion. A resident was prescribed opioid pain medication to manage severe pain following recent surgery for a fractured hip. A resident had requested that staff review his pain medication as it was not effective over the weekend. The resident informed staff that he was unable to attend weekend daytime activities due to discomfort and lack of sleep from having pain at night. The resident stated that he received a different colored pill during the weekend, but it did not seem to work like the medication that was given during the weekdays. The facility's investigation revealed that the same staff nurse worked on each of the weekend night shifts when the resident was identified to have unrelieved pain. This staff nurse had access to the controlled medications for residents on that unit. During interview with the nurse aide who worked on the same shift as the nurse, the nurse aide stated that she saw the nurse coming out of the resident's room with the medication cup, and the nurse had told her that the resident was sleeping and she would give the medication later. The nurse aide reported that she then saw the nurse take the medication herself. She stated that she was afraid to report what she had seen since she did not want to jump into any conclusions or cause any trouble for the nurse. Interviews with other staff revealed they were not aware of facility policies or of their obligations to report a suspected crime including possible drug diversion.*

Effective November 28, 2017

Examples of Severity Level 2 Noncompliance No Actual Harm with Potential for More Than Minimal Harm that is Not Immediate Jeopardy include, but are not limited to:

- *The facility failed to provide annual notification to staff on their obligations to report suspected crimes and to post signage of employee rights related to retaliation against the employee for reporting a suspected crime. Based on interviews with five staff members, the staff were not knowledgeable about their obligations to report suspected crimes to law enforcement and to the State Survey Agency, without fear of retaliation. The staff were not aware of the time frames for reporting a suspected crime and did not recall receiving training on reporting.*

Severity Level 1: No Actual Harm with Potential for Minimal Harm
The failure of the facility to meet the requirements under this Federal requirement is more than minimal harm. Therefore, Severity Level 1 does not apply for this regulatory requirement.

F609
§483.12(c) In response to allegations of abuse, neglect, exploitation, or mistreatment, the **facility must*:***

§483.12(c)(1) E**nsure that all alleged violations involving abuse, neglect, *exploitation* or mistreatment, including injuries of unknown source and misappropriation of resident property, are reported immediately, *but not later than 2 hours after the allegation is made, if the events that cause the allegation involve abuse or result in serious bodily injury, or not later than 24 hours if the events that cause the allegation do not involve abuse and do not result in serious bodily injury,* to the administrator of the facility and to other officials (including to the State Survey *Agency and adult protective services where state law provides for jurisdiction in long-term care facilities*) in accordance with State law through established procedures.**

***§483.12(c)(4) Report* the results of all investigations to the administrator or his or her designated representative and to other officials in accordance with State law, including to the State Survey *Agency,* within 5 working days of the incident, and if the alleged violation is verified appropriate corrective action must be taken.**

INTENT
The facility must report alleged violations related to mistreatment, exploitation, neglect, or abuse, including injuries of unknown source and misappropriation of resident property and report the results of all investigations to the proper authorities within prescribed timeframes.

NOTE*: In cases where a deficiency is identified and CMS imposes a civil money penalty based on the noncompliance, CMS will reduce the amount of the penalty by 50%, if all of the following apply (See 42 CFR 488.438):*

- *The facility self-reported the noncompliance to CMS or the State before it was identified by CMS or the State and before it was reported to CMS or the State by means of a complaint lodged by a person other than an official representative of the nursing home;*
- *Correction of the self-reported noncompliance occurred on whichever of the following occurs first:*

- *15 calendar days from the date of the circumstance or incident that later resulted in a finding of noncompliance; or*
- *10 calendar days from the date the civil money penalty was imposed;*

- *The facility waives its right to a hearing under 42 CFR 488.436;*
- *The noncompliance that was self-reported and corrected did not constitute a pattern of harm, widespread harm, immediate jeopardy, or result in the death of a resident;*
- *The civil money penalty was not imposed for a repeated deficiency that was the basis of a civil money penalty that previously received a reduction; and*
- *The facility has met mandatory reporting requirements for the incident or circumstance upon which the civil money penalty is based, as required by Federal and State law.*

DEFINITIONS

"**Abuse**," *is defined at §483.5 as "*the willful infliction of injury, unreasonable confinement, intimidation, or punishment with resulting physical harm, pain or mental anguish. *Abuse* also includes the deprivation by an individual, including a caretaker, of goods or services that are necessary to attain or maintain physical, mental, and psychosocial well-being. *Instances of abuse of all residents, irrespective of any mental or physical condition, cause physical harm, pain or mental anguish. It includes verbal abuse, sexual abuse, physical abuse, and mental abuse including abuse facilitated or enabled through the use of technology."*

"Alleged violation" *is a situation or occurrence that is observed or reported by staff, resident, relative, visitor or others but has not yet been investigated and, if verified, could be noncompliance with the Federal requirements related to mistreatment, exploitation, neglect, or abuse, including injuries of unknown source, and misappropriation of resident property.*

*"**Exploitation**," as defined at §483.5, means "taking advantage of a resident for personal gain, through the use of manipulation, intimidation, threats, or coercion."*

"Immediately" means as soon as possible, in the absence of a shorter State time frame requirement, *but not later than 2 hours after the allegation is made, if the events that cause the allegation involve abuse or result in serious bodily injury, or not later than 24 hours if the events that cause the allegation do not involve abuse and do not result in serious bodily injury*.

"Injuries of unknown source" – An injury should be classified as an "injury of unknown source" when **both** of the following criteria are met:

- The source of the injury was not observed by any person or the source of the injury could not be explained by the resident; **and**
- The injury is suspicious because of the extent of the injury or the location of the injury (e.g., the injury is located in an area not generally vulnerable to trauma) or the number of injuries observed at one particular point in time or the incidence of injuries over time.

"**Misappropriation of resident property**," *as defined at §483.5,* means "the deliberate misplacement, exploitation, or wrongful, temporary, or permanent use of a resident's belongings or money without the resident's consent."

"Mistreatment," *as defined at §483.5, is "inappropriate treatment or exploitation of a resident."*

Effective November 28, 2017

"**Neglect**," *as defined at §483.5,* means "*the* failure *of the facility, its employees or service providers* to provide goods and services *to a resident that are* necessary to avoid physical harm, *pain,* mental *anguish or emotional distress."*

"**Sexual abuse**," *is defined at §483.5 as "non-consensual sexual contact of any type with a resident."*

GUIDANCE
REPORTING ALLEGED VIOLATIONS
It is the responsibility of the facility to ensure that all staff are aware of reporting requirements and to support an environment in which staff and others report all alleged violations of mistreatment, exploitation, neglect, or abuse, including injuries of unknown source, and misappropriation of resident property. Protection of residents can be compromised or impeded if individuals are fearful of reporting, especially if the alleged abuse has been carried out by a staff member. During investigations, some staff have stated that he/she was aware, or had knowledge, that the incident had occurred, but did not report because he/she did not think it met the definition of abuse, neglect, mistreatment, exploitation, or misappropriation of resident property. Anecdotal reports have indicated that failure to report an alleged violation may be due to, but not limited to, the following:

- *An individual's allegation is not believed due to a history of reporting false allegations;*
- *Staff fear of retaliation, or fear losing his/her job;*
- *Sympathy for co-workers, for example, not wanting to cause trouble for the co-worker;*
- *Communication, cultural, or language issues; or*
- *Residents/resident representatives may fear retaliation.*

An individual (e.g., a resident, visitor, facility staff) who reports an alleged violation to facility staff does not have to explicitly characterize the situation as "abuse," "neglect," "mistreatment," or "exploitation" in order to trigger the Federal requirements at §483.12(c). Rather, if facility staff could reasonably conclude that the potential exists for noncompliance with the Federal requirements related to mistreatment, exploitation, neglect, or abuse, including injuries of unknown source, and misappropriation of resident property, then it would be considered to be reportable and require action under §483.12(c). For example, if a resident is abused but does not allege abuse, the resident's failure or inability to provide information about the occurrence is immaterial when the abuse may be substantiated by other supporting evidence. Another example is when a nurse aide witnesses an act of abuse but fails to report the alleged violation, the failure to report does not support a conclusion that the abuse did not occur and the facility would not meet the reporting requirements.

All alleged violations, whether oral or in writing, must be immediately reported to the administrator of the facility and to other officials in accordance with State law through established procedures (including to the State survey and certification agency and adult protective services where State law provides for jurisdiction in long-term care facilities). Conformance with this provision requires that each State Agency has a means to collect reports, even during off-duty hours (e.g., answering machine, voice mail, fax, electronic transmission, etc.). The facility must have documentation of the report, including what was reported and the date and time when the report was made to the SA.

The definition of "immediately" means as soon as possible in the absence of a shorter State time frame requirement, but not later than 2 hours after the allegation is made, if the events that cause the allegation involve abuse or result in serious bodily injury, or not later than 24 hours if the events that cause the allegation do not involve abuse and do not result in serious bodily injury.

If an alleged violation has been identified and reported to the administrator/designee, the facility must immediately report it and provide protection for the identified resident(s) prior to conducting the investigation of the alleged violation. In some situations, the facility may initially evaluate an occurrence to determine whether it meets the definition of an "alleged violation." For example, upon discovery of an injury, the facility must immediately take steps to evaluate whether the injury meets the definition of an "injury of unknown source," Similarly, if a resident states that his or her belongings are missing, the facility may make an initial determination whether the item has been misplaced in the resident's room, in the laundry, or elsewhere before reporting misappropriation of property. However, if the alleged violation meets the definition of abuse, neglect, exploitation or mistreatment, the facility should not make an initial determination whether the allegation is credible before reporting the allegation.

***NOTE**: At the conclusion of the investigation, and no later than 5 working days of the incident, the facility must report the results of the investigation and if the alleged violation is verified, take corrective action, in accordance with §483.12(c)(4).*

The phrase **"in accordance with State law"** modifies the word "officials" only. State law may stipulate that alleged violations and the results of the investigations be reported to additional State officials beyond those specified in Federal regulations. This phrase does not modify what **types** of alleged violations must be reported or the time frames in which the reports are to be made. States may not eliminate the obligation for any of the alleged violations (i.e., mistreatment, neglect, abuse, injuries of unknown source, *exploitation,* and misappropriation of resident property) to be reported, nor can the State establish longer time frames for reporting than mandated in the regulations at §§483.1*2*(c)*(1)* and (4). No State can override the obligation of the nursing home to fulfill the requirements under §483.1*2*(c), as long as the Medicare/Medicaid certification is in place.

Some States may have different reporting requirements that could go beyond the Federal requirements or are more specific than the Federal requirements. For example, some States require that all falls be reported to the SA. The SA should continue to manage and investigate these cases under its state licensure authority. If the State determines that these occurrences do meet the definition of abuse, neglect, mistreatment, or injuries of unknown source, as outlined in this guidance, the SA must assess whether the nursing home has met the requirements for reporting and investigating these cases in accordance with 42 C.F.R. §483.12(c).

There may be instances where a report is required under 42 CFR 483.12(c) [F609], but not under 42 CFR 483.12(b)(5)/Section 1150B of the Act[F608]. The following table describes the different requirements:

Effective November 28, 2017

	F608 ***42 CFR 483.12(b)(5)*** ***and Section 1150B of the Act***	***F609*** ***42 CFR 483.12(c)***
What	*Any reasonable suspicion of a crime against a resident*	*1) All alleged violations of abuse, neglect, exploitation or mistreatment, including injuries of unknown source and misappropriation of resident property* *2) The results of all investigations of alleged violations*
Who is required to report	*Any covered individual, including the owner, operator, employee, manager, agent or contractor of the facility*	*The facility*
To whom	*SA and one or more law enforcement entities for the political subdivision in which the facility is located (i.e., police, sheriffs, detectives, public safety officers; corrections personnel; prosecutors; medical examiners; investigators; and coroners)*	*The facility administrator and to other officials in accordance with State law, including to the SA and the adult protective services where state law provides for jurisdiction in long-term care facilities*
When	*Serious bodily injury- Immediately but not later than 2 hours after forming the suspicion* *No serious bodily injury- not later than 24 hours*	*All alleged violations-Immediately but not later than* *3) 2 hours- if the alleged violation involves abuse <u>or</u> results in serious bodily injury* *4) 24 hours- if the alleged violation does not involve abuse <u>and</u> does not result in serious bodily injury.* *Results of all investigations of alleged violations- within 5 working days of the incident*

** - Reporting requirements under this regulation are based on real (clock) time, not business hours*

Refer to the CE Pathways for Abuse (Form CMS-20059) and Neglect (Form CMS-20130) and the Investigative Protocols for tags F602 and F603.

Key Elements of Noncompliance

To cite deficient practice at F609, the surveyor's investigation will generally show that the facility failed to do any one or more of the following:

- *Identify a situation as an alleged violation involving abuse, neglect, exploitation or mistreatment, including injuries of unknown source and misappropriation of resident property;*
- *Report immediately an alleged violation involving abuse, neglect, exploitation or mistreatment, including injuries of unknown source and misappropriation of resident property to the administrator of the facility and to other officials, including to the State survey and certification agency and adult protective services in accordance with State law; or*
- *Report the results of all investigations within 5 working days to the administrator or his/her designated representative and to other officials in accordance with State law (including to the State survey and certification agency).*

F610
§483.12(c) In response to allegations of abuse, neglect, exploitation, or mistreatment, the* facility must*:

***§483.12(c)(2) H*ave evidence that all alleged violations are thoroughly investigated.**

***§483.12(c)(3) P*revent further potential abuse, neglect, exploitation, or mistreatment while the investigation is in progress.**

***§483.12(c)(4) Report* the results of all investigations to the administrator or his or her designated representative and to other officials in accordance with State law, including to the State Survey *Agency,* within 5 working days of the incident, and if the alleged violation is verified appropriate corrective action must be taken.**

INTENT
The facility must take the following actions in response to an alleged violation of abuse, neglect, exploitation or mistreatment:
- *Thoroughly investigate the alleged violation;*
- *Prevent further abuse, neglect, exploitation and mistreatment from occurring while the investigation is in progress; and*
- *Take appropriate corrective action, as a result of investigation findings.*

***NOTE**: Refer to F609 for the requirement to report the findings of the investigation within 5 working days.*

GUIDANCE
Facility's Investigation of Alleged Violations
For all alleged violations of abuse, neglect, exploitation, misappropriation of resident property, exploitation, and mistreatment, including injuries of unknown source, the surveyor reviews whether the facility maintains evidence that all alleged violations are thoroughly investigated. There is no specific investigation process that the facility must follow, but the facility must thoroughly collect evidence to allow the Administrator to determine what actions are necessary (if any) for the protection of residents. Depending upon the type of allegation received, it is expected that the investigation would include, but is not limited to:

- *Conducting observations of the alleged victim, including identification of any injuries as appropriate, the location where the alleged situation occurred, interactions and relationships between staff and the alleged victim and/or other residents, and interactions/relationships between resident to other residents;*
- *Conducting interviews with, as appropriate, the alleged victim and representative, alleged perpetrator, witnesses, practitioner, interviews with personnel from outside agencies such as other investigatory agencies, and hospital or emergency room personnel;*
- *Conducting record review for pertinent information related to the alleged violation, as appropriate, such as progress notes (Nurse, social services, physician, therapist, consultants as appropriate, etc.), financial records, incident reports (if used), reports from hospital/emergency room records, laboratory or x-ray reports, medication administration records, photographic evidence, and reports from other investigatory agencies.*

Even if an alleged violation was reported to law enforcement as a reasonable suspicion of a crime committed against a resident, the facility must still conduct its own internal investigation to the extent possible, in consultation with the law enforcement authority. When law enforcement is contacted the facility must not impede the investigation and must maintain any potential evidence (e.g., clothing, linens, etc.) as instructed by law enforcement. It has been reported that some investigations were impeded due to washing linens or clothing, destroying documentation, bathing or cleaning the resident before the resident has been examined, or failure to transfer a resident to the emergency room for examination including obtaining a rape kit, if appropriate.

Prevention

Depending on the nature of the alleged violation, the facility must immediately put effective measures in place to ensure that further potential abuse, neglect, exploitation, or mistreatment does not occur while the investigation is in process.

Examples of instances where the facility failed to provide protections include, but are not limited to:

- *The alleged perpetrator continues to have access to the alleged victim and/or other vulnerable residents;*
- *Retaliation occurs against a resident who reports an alleged violation;*
- *A resident who continually fondles other residents is moved to another unit, where he/she continues to exhibit the same behaviors to other residents;*
- *A resident with a history of striking is left unsupervised with a resident who has been targeted in the past and/or other residents; and*
- *The facility conducts an inadequate investigation and ceases temporary resident protection measures that were implemented as a result of the alleged violation.*

Examples of measures to protect residents include, but are not limited to:

- *Monitoring of the alleged victim and other residents at risk, such as conducting unannounced management visits at different times and shifts;*

- *Evaluation of whether the alleged victim feels safe and if the he/she does not feel safe, taking immediate steps to alleviate the fear, such as a room relocation, increased supervision, etc.;*
- *Immediate assessment of the alleged victim and provision of medical treatment as necessary;*
- *Immediate notification of the alleged victim's practitioner and the family or responsible party;*
- *Removal of access by the alleged perpetrator to the alleged victim and assurance that ongoing safety and protection is provided for the alleged victim and, as appropriate, other residents;*
- *Notification of the alleged violation to other agencies or law enforcement authorities; and*
- *Whether administrative staff, including the administrator, were informed and involved as necessary in the investigation.*

Corrective Actions
As a result of a facility's investigation, if an alleged violation is verified, the facility must take appropriate corrective action to protect residents. The facility should oversee the implementation of corrective action and evaluate whether it is effective. While some corrective actions may be limited in scope, facilities should determine whether more systemic actions may be necessary to prevent recurrence of the situation. In addition, the Quality Assessment & Assurance committee should monitor the reporting and investigation of the alleged violations, including assurances that residents are protected from further occurrences and that corrective actions are implemented as necessary.

Refer to the CE Pathways for Abuse (Form CMS-20059) and Neglect (Form CMS-20130) and the Investigative Protocols for tags F602 and F603.

KEY ELEMENTS OF NONCOMPLIANCE
*To cite deficient practice at F610, the surveyor's investigation will generally show that the facility failed to do **any** one or more of the following:*

- *Initiate an investigation of an alleged violation of abuse, neglect, exploitation, misappropriation of resident property, exploitation, and mistreatment, including injuries of unknown source; **or***
- *Complete a thorough investigation of the alleged violation; **or***
- *Maintain documentation that an alleged violation was thoroughly investigated; **or***
- *Prevent further potential abuse, neglect, exploitation, or mistreatment while the investigation of an alleged violation is in progress; **or***
- *Take corrective action following an investigation of an alleged violation, if the allegation was verified.*

F620
§483.15(a) Admissions policy.
§483.15(a)(1) The facility must establish and implement an admissions policy.

***§483.15*(a)(2) The facility must—**

(i) Not *request or* require residents or potential residents to waive their rights *as set forth in this subpart and in applicable state, federal or local licensing or certification laws, including but not limited to their rights* to Medicare or Medicaid; and
(ii) Not *request or* require oral or written assurance that residents or potential residents are not eligible for, or will not apply for, Medicare or Medicaid benefits.
(iii) Not request or require residents or potential residents to waive potential facility liability for losses of personal property.

***§483.15*(a)*(3)* The facility must not *request or* require a third party guarantee of payment to the facility as a condition of admission or expedited admission, or continued stay in the facility. However, the facility may *request and* require *a resident representative* who has legal access to a resident's income or resources available to pay for facility care to sign a contract, without incurring personal financial liability, to provide facility payment from the resident's income or resources.**

***§483.15*(a)*(4)* In the case of a person eligible for Medicaid, a nursing facility must not charge, solicit, accept, or receive, in addition to any amount otherwise required to be paid under the State plan, any gift, money, donation, or other consideration as a precondition of admission, expedited admission or continued stay in the facility. However,—**
(i) A nursing facility may charge a resident who is eligible for Medicaid for items and services the resident has requested and received, and that are not specified in the State plan as included in the term ''nursing facility services'' so long as the facility gives proper notice of the availability and cost of these services to residents and does not condition the resident's admission or continued stay on the request for and receipt of such additional services; and
(ii) A nursing facility may solicit, accept, or receive a charitable, religious, or philanthropic contribution from an organization or from a person unrelated to a Medicaid eligible resident or potential resident, but only to the extent that the contribution is not a condition of admission, expedited admission, or continued stay in the facility for a Medicaid eligible resident.

***§483.15*(a)(5) States or political subdivisions may apply stricter admissions standards under State or local laws than are specified in this section, to prohibit discrimination against individuals entitled to Medicaid.**

§483.15*(a)*(6) A nursing facility must disclose and provide to a resident or potential resident prior to time of admission, notice of special characteristics or service limitations of the facility.

§483.15*(a)*(7) A nursing facility that is a composite distinct part as defined in § 483.5 must disclose in its admission agreement its physical configuration, including the various locations that comprise the composite distinct part, and must specify the policies that apply to room changes between its different locations under paragraph (c)(9) of this section.

DEFINITIONS/ACRONYMS
"Composite distinct part": *A composite distinct part is a distinct part consisting of two or more noncontiguous components that are not located within the same campus, as that term is defined*

in §413.65(a)(2) of this chapter. Additional requirements specific to SNF/NF composite distinct parts are found at §483.5.

"Campus": *Campus is defined in §413.65(a)(2) and means the physical area immediately adjacent to the provider's main buildings, other areas and structures that are not strictly contiguous to the main buildings but are located within 250 yards of the main buildings, and any other areas determined on an individual case basis, by the CMS regional office, to be part of the provider's campus.*

"Distinct part": *A distinct part SNF or NF is physically distinguishable from the larger institution or institutional complex that houses it, meets the requirements of this paragraph and of paragraph (b)(2) of this section, and meets the applicable statutory requirements for SNFs or NFs in sections 1819 or 1919 of the Act, respectively. A distinct part SNF or NF may be comprised of one or more buildings or designated parts of buildings (that is, wings, wards, or floors) that are: In the same physical area immediately adjacent to the institution's main buildings; other areas and structures that are not strictly contiguous to the main buildings but are located within close proximity of the main buildings; and any other areas that CMS determines on an individual basis, to be part of the institution's campus. A distinct part must include all of the beds within the designated area, and cannot consist of a random collection of individual rooms or beds that are scattered throughout the physical plant. The term "distinct part" also includes a composite distinct part that meets the additional requirements of paragraph (c) of this section. Additional requirements specific to SNF/NF distinct parts are found at 483.5.*

GUIDANCE
§483.15(a)(1) and (2) Admissions Policy/Preconditions of Admission
All facilities must establish and implement a policy or policies addressing resident admission to the facility. First, the admissions policy must comply with the provisions at §483.15(c)(1) which stipulate the limited conditions for transfer or discharge. The provisions at §§483.15 (a)(2) –(5), further prohibit the waiver of certain rights and preconditions for admission to, and continued stay in the facility. Additionally, under §§483.15(a)(6) – (7), the admissions policy must identify information that must be disclosed to residents and potential residents, such as notice of special facility characteristics, any service limitations of the facility, if applicable. Additionally, it requires that the facility's admission agreement disclose its physical composition, including any composite distinct part locations, and must specify the policies that apply to room changes in a composite distinct part (see additional guidance below). The facility must also have a process for how it will disclose required information to residents and potential residents.

The provision*s at §§483.15(a)(2)(i) and (ii)* prohibit both direct and indirect request*s to residents or potential residents to waive any rights under the LTC requirements and under applicable federal, state, local licensing or certification laws, including but not limited to the* waiver of rights to Medicare or Medicaid. A direct request for waiver, for example, *would* require residents to sign admissions documents explicitly promising or agreeing not to apply for Medicare or Medicaid. An indirect request for waiver *would* include, *for example*, requiring the resident to pay private rates for a specified period of time, such as two years (*e.g.,* "private pay duration of stay contract") before Medicaid will be accepted as a payment source for the resident.

Effective November 28, 2017

Facilities must not seek or receive any kind of assurances that residents *or potential residents* are not eligible for, or will not apply for, Medicare or Medicaid benefits.

Lastly, residents must not be asked to waive facility responsibility for the loss of their personal property or be unable to use personal property because it is only permitted in the facility if safeguarded by the facility in a manner that makes the property essentially inaccessible to the resident. These waivers effectively take away the residents' right to use personal possessions and relieve facilities from their responsibility to exercise due care with respect to residents' personal property. Compliance requires facilities to develop policies and procedures to safeguard residents' personal possessions without effectively prohibiting a resident's use of personal possessions. This provision is not intended to make facilities automatically liable for every loss regardless of whether or not the facility is aware of the extent of personal property brought into the facility. Examples of reasonable facility policies may include 1) establishing a process to document high value personal property (particularly cash, valuables, and medical/assistive devices) brought in by residents; and 2) establishing a process to work with residents and their representatives/family to ensure safety as well as availability to the resident of cash and/or items over a certain dollar value, including medical/assistive devices. For concerns related to whether the facility takes reasonable care to protect each resident's property from loss or theft or the resident's right to be free from misappropriation of property, see F584, §483.10(i) Safe Environment and F602, §483.12 Misappropriation of Resident Property.

§483.15(a)(3) Third Party Guarantee of Payment

The facility *must* not *request or* require a third *party* to accept personal responsibility for paying the facility bill out of his or her own funds *as a condition of admission, expedited admission, or continued stay in the facility*. However, *the facility may request and require a resident representative with legal access to the resident's funds available to pay for facility care to access and* use the resident's money *or other assets* to pay for care, *as authorized by law*. *The facility may request and require this representative to sign a contract, without incurring personal liability, to provide the facility with payment from the resident's income or assets.* A third party guarantee is not the same as a third party payor, e.g., an insurance company; and this provision does not preclude the facility from obtaining information about Medicare or Medicaid eligibility or the availability of private insurance. The prohibition against third-party guarantees applies to all residents and prospective residents in all certified long term care facilities, regardless of payment source.

§483.15(a)(4)(i) and (ii), Medicaid – Preconditions for Admission

The *requirements at §483.15(a)(4)(i) and (ii) apply* only to *individuals eligible for Medicaid and therefore to* Medicaid certified nursing facilities *(NFs) or dually-certified SNF/NFs*.
Facilities may not charge for any service that is included in the definition of "nursing facility services" *which are* required to be provided as part of the daily rate *(See also §483.10(f)(11)(i))* .
Facilities may not accept additional payment from residents or their families as a prerequisite to admission or to continued stay in the facility. Additional payment includes*, but is not limited to,* deposits from residents *who are eligible for Medicaid* or their families, or any promise to pay private rates for a specified period of time.

NOTE: This regulation does not preclude a facility from charging a deposit fee to, or requiring a promissory note from, an individual whose stay is not covered by Medicaid. In instances where the deposit fee is refundable and remains as funds of the resident, the facility must have a surety bond that covers the deposit amount-- *(See also §483.10(f)(10)(vi)).*

A nursing facility is permitted to charge an applicant or resident *for services, while his or her* Medicaid eligibility is pending. *This charge may be* in the form of a deposit prior to admission and/or payment after admission. *Subject to the rules of the State in which the facility is located,* Medicaid eligibility will be made retroactive up to 3 months before the month of application if the applicant would have been eligible had he or she applied in any of the retroactive months.

***NOTE**: A resident cannot be discharged for nonpayment while their Medicaid eligibility is pending (See F622, Transfer and Discharge Requirements).*

In addition, the nursing facility must accept as payment in full the amounts determined by the state for all dates the resident was both Medicaid eligible and a nursing facility resident. Therefore, a nursing facility that charged a recipient for services between the first month of eligibility established by the state and the date notice of eligibility was received is obligated to refund*, within 30 days from receipt of funds from a third party payor*, any payments received for that period less the state's determination of any resident's share of the nursing facility's costs for that same period. A nursing facility must prominently display written information in the facility and provide explanation to applicants or residents *in a manner they can understand* about applying for Medicaid, including how to use Medicaid benefits, and how to receive refunds for previous payments covered by such benefits.

Under the post-eligibility process, if the resident *who is eligible for Medicaid* has income and is required to make a monthly payment to the nursing facility (which is a portion of the Medicaid payment amount), then the nursing facility is permitted to retain the amount it is legally owed. However, the nursing facility must not charge any administrative fees.

A nursing facility may charge a beneficiary *who receives Medicaid* for a service the beneficiary has requested and received, only if:

- That service is not defined in the State plan as a "nursing facility" service;
- The facility informs the resident and the resident's representative in advance that this is not a covered service to allow them to make an informed choice regarding the fee; and
- The resident's admission or continued stay is not conditioned on the resident's requesting and receiving that service.

§483.15(a)(5) State/Local Jurisdiction Admission Standards

Surveyors are expected to refer to state and/or local laws and regulations on admissions standards to prohibit discrimination against individuals entitled to Medicaid as applicable.

§483.15(a)(6) Facility Special Characteristics

Facilities may choose to offer specialized care or services, such as a rehabilitation, dementia, or a mechanical ventilation unit. To enable potential residents and resident representatives to make informed decisions in choosing a facility for admission, facilities must inform residents and

resident representatives and potential residents or representatives of any special characteristics or service limitations the facility may have prior to admission. For example, a facility may have a religious affiliation that guides its practices and routines which must be communicated to any potential resident.

Likewise, if a facility has limitations in the type of medical care it can provide, this information must be communicated prior to admission. For example, if the need for a specific type of care or service becomes necessary, knowledge of service limitations may make the need for transfer or discharge more predictable and understandable for the resident and/or his or her representative.

Disclosure of facility special characteristics does not relieve a facility of its responsibility to provide required nursing and other services for which it is licensed and certified to provide. To see the required services, refer to sections 1819(a) and 1819(b)(4)(A), and sections 1919(a) and 1919(b)(4)(A) of the Act.

§483.15(a)(7) Composite Distinct Part
If a facility does not have a composite distinct part, this provision does not apply. If there are concerns as to whether or not a facility meets the requirements for a composite distinct part according to §483.5(c), consult with the CMS Regional Office for clarification.

Prior to admission, facilities that have areas that meet the definition of a composite distinct part must disclose in their admission agreements to residents:

- *A description of the facility's physical configuration, including the locations for each part that comprise the composite distinct part.*
- *Policies governing room changes between its different locations.*

***NOTE**: If there is a deficiency specific to the requirement at §483.10(g)(15), do not cite at §483.10(g)(15), F580, but cite here at F620, regarding admission policies.*

INVESTIGATIVE PROTOCOL
Objectives
The objectives of this protocol are to determine whether the facility has failed to comply with the regulations at §§483.15(a)(1) – (7) above, regarding admission policies and payment.

Use
Use this protocol when concerns regarding admissions procedures arise during record review, interviews and/or in response to complaints.

PROCEDURES
Record Reviews
Review the facility admissions package, including admissions policies, and contracts to determine if they contain any of, but not limited to, the following:

- *Requirements or requests for residents to waive:*
  - *their rights to current or future enrollment in Medicare or Medicaid*
  - *claims of liability against the facility for loss of personal property*

- *Requirements or requests for a third party guarantee of payment as a condition of admission or expedited admission.*
- *Requirements for payment for services which are covered under Medicaid as a condition of admission, or continued stay.*

In addition, if the facility has any special characteristics or service limitations, review the admissions package to determine if they are and have been disclosed to residents and their representative prior to admission. For composite distinct part facilities, determine if the facility discloses and has disclosed its various locations that make up the composite distinct parts and its policies for room changes between its different locations.

For concerns regarding a facility charging for services that may be covered by the State Medicaid plan, surveyors are expected to review State covered services. Compare with the list of items for which the facility charges to determine if the facility is charging for covered services.

Interviews

Ask resident and/or their representative if there were any preconditions or requirements for admission, such as a third party guarantee of payment, or requests for gifts, money, donations or other considerations.
Ask resident and/or their representative if there were any other preconditions or requirements, or limitations in care that they did not expect or know about prior to admission.
Ask resident and/or their representative if they were required to waive:

- *Their rights to Medicare or Medicaid, or future enrollment in either; and/or*
- *Claims of liability against the facility for loss of personal property.*

Interview staff about information that is provided to potential residents to help them make informed decisions.

F621
***§483.15(b)* Equal access to quality care.**
***§483.15(b)*(1) A facility must establish, maintain *and implement* identical policies and practices regarding transfer *and* discharge, *as defined in §483.5* and the provision of services for all individuals regardless of source of payment, *consistent with §483.10(a)(2)*;**

***§483.15(b)*(2) The facility may charge any amount for services furnished to non- Medicaid residents *unless otherwise limited by state law and* consistent with the notice requirement in *§483.10(g)(18)(i) and (g)(4)(i)* describing the charges; and**

***§483.15(b)*(3) The State is not required to offer additional services on behalf of a resident other than services provided in the State plan.**

§483.15(c)(9) Room changes in a composite distinct part. Room changes in a facility that is a composite distinct part (as defined in § 483.5) are subject to the requirements of § 483.10(e)(7) and must be limited to moves within the particular building in which the resident resides,

unless the resident voluntarily agrees to move to another of the composite distinct part's locations.

DEFINITIONS

"Composite Distinct Part": *A composite distinct part is a distinct part consisting of two or more noncontiguous components that are not located within the same campus, as defined in §413.65(a)(2) of this chapter. Additional requirements specific to SNF/NF composite distinct parts are found at §483.5.*

"Campus": *Campus is defined in §413.65(a)(2) and means the physical area immediately adjacent to the provider's main buildings, other areas and structures that are not strictly contiguous to the main buildings but are located within 250 yards of the main buildings, and any other areas determined on an individual case basis, by the CMS regional office, to be part of the provider's campus.*

"Distinct Part": *A distinct part SNF or NF is physically distinguishable from the larger institution or institutional complex that houses it, meets the requirements of this paragraph and of paragraph (b)(2) of this section, and meets the applicable statutory requirements for SNFs or NFs in sections 1819 or 1919 of the Act, respectively. A distinct part SNF or NF may be comprised of one or more buildings or designated parts of buildings (that is, wings, wards, or floors) that are: In the same physical area immediately adjacent to the institution's main buildings; other areas and structures that are not strictly contiguous to the main buildings but are located within close proximity of the main buildings; and any other areas that CMS determines on an individual basis, to be part of the institution's campus. A distinct part must include all of the beds within the designated area, and cannot consist of a random collection of individual rooms or beds that are scattered throughout the physical plant. The term "distinct part" also includes a composite distinct part that meets the additional requirements of paragraph (c) of this section. Additional requirements specific to SNF/NF distinct parts are found at 483.5.*

INTENT

To ensure residents are treated equally regarding transfer, discharge, and the provision of services, regardless of their payment source.

GUIDANCE

All *services, including but not limited to* nursing services, specialized rehabilitative services, *behavioral health services,* social services, dietary services, *and* pharmac*y* services, or activities*,* that are mandated by the law must be provided to residents according to *their* individual needs, as determined by assessments and care plans. "Identical policies and practices" concerning services means that facilities must not distinguish between residents based on their source of payment when providing services that are required to be provided under the law.

Notice Requirements for Changes to Medicare/Medicaid Coverage

Facilities must inform each resident in writing before or at admission, and periodically during their stay, such as when a change in coverage occurs, of the facility's available services and associated costs. The facility may charge any amount for services furnished to non- Medicaid

residents unless otherwise limited by state law. Section 483.10(f)(11) and F571 provide additional information regarding services and charges for which a facility may or may not charge the resident. Pursuant to §483.10(g)(18)(i) and F582, the facility must provide notice of changes in coverage for services to residents as soon as is reasonably possible.

Facility Requirements Regarding Room Changes in a Composite Distinct Part
If a facility does not have a composite distinct part this provision does not apply. If there are concerns as to whether or not a facility meets the requirements for a distinct or composite distinct part of a larger institution or institutional complex, consult with the CMS Regional Office for clarification.

Room changes within either a composite distinct part SNF or a distinct part SNF are subject to the requirements at §483.10(e)(7) and F560, which address the resident's right to refuse transfer/room change. For concerns regarding the resident's right to refuse such a transfer or room change, refer to 483.10(e)(7) and F560.

PROBES
Determine if residents are grouped in separate wings or floors for reasons other than care needs, *and if the quality of care is different between the different wings/floors*.
Ask nursing home administrator, social worker, charge nurses, unit managers, and/or Director of Nursing:

- *What factors led to decisions to place residents in different wings or floors (or locations if a SNF composed of composite distinct parts)?*
- *Do factors other than medical and nursing needs affect where residents are placed?*

Ask *representatives of the Office of the* State Long-Term Care Ombudsman if *they have information that could indicate the* facility treats residents differently in transfer, discharge and covered services based on source of payment.
If concerns arise regarding equal access to care, ask the resident or representative:

- *Were there any changes to care or services when their payor source changed, for example did they notice fewer staff available to meet their needs when their payor source was due to change or had changed?*
- *Did the resident receive notice of changes in charges for services?*
- *Were they asked to move or were they moved to a different location in the building when their payor source changed?*

F622
***§483.15*(c) Transfer and *d*ischarge-**
§483.15*(c)(1) *Facility requirements-

***(i)* The facility must permit each resident to remain in the facility, and not transfer or discharge the resident from the facility unless—**

***(A)* The transfer or discharge is necessary for the resident's welfare and the resident's needs cannot be met in the facility;**

***(B)* The transfer or discharge is appropriate because the resident's health has improved sufficiently so the resident no longer needs the services provided by the facility;**

(C) **The safety of individuals in the facility is endangered** *due to the clinical or behavioral status of the resident;*

(D) **The health of individuals in the facility would otherwise be endangered;**

(E) **The resident has failed, after reasonable and appropriate notice, to pay for (or to have paid under Medicare or Medicaid) a stay at the facility.** *Nonpayment applies if the resident does not submit the necessary paperwork for third party payment or after the third party, including Medicare or Medicaid, denies the claim and the resident refuses to pay for his or her stay.* **For a resident who becomes eligible for Medicaid after admission to a** *facility,* **the facility may charge a resident only allowable charges under Medicaid; or**

(F) The facility ceases to operate.

(ii) The facility may not transfer or discharge the resident while the appeal is pending, pursuant to § 431.230 of this chapter, when a resident exercises his or her right to appeal a transfer or discharge notice from the facility pursuant to § 431.220(a)(3) of this chapter, unless the failure to discharge or transfer would endanger the health or safety of the resident or other individuals in the facility. The facility must document the danger that failure to transfer or discharge would pose.

*§483.15***(c)(2) Documentation.**

When the facility transfers or discharges a resident under any of the circumstances specified in paragraphs *(c)(1)(i)(A)* **through** *(F)* **of this section,** *the facility must ensure that the transfer or discharge is documented in* **the resident's** *medical* **record** *and appropriate information is communicated to the receiving health care institution or provider.*

(i) Documentation in the resident's medical record must include:

(A) The basis for the transfer per paragraph (c)(1)(i) of this section.

(B) In the case of paragraph (c)(1)(i)(A) of this section, the specific resident need(s) that cannot be met, facility attempts to meet the resident needs, and the service available at the receiving facility to meet the need(s).

(ii) The documentation *required by paragraph (c)(2)(i) of this section* **must be made by—**

(A) The resident's physician when transfer or discharge is necessary under paragraph *(c) (1) (A)* **or** *(B)* **of this section; and**

(B) A physician when transfer or discharge is necessary under paragraph *(c)(1)(i)(C) or (D)* **of this section.**

(iii) Information provided to the receiving provider must include a minimum of the following:

(A) Contact information of the practitioner responsible for the care of the resident.

(B) Resident representative information including contact information

(C) Advance Directive information

(D) All special instructions or precautions for ongoing care, as appropriate.

(E) Comprehensive care plan goals;

(F) All other necessary information, including a copy of the resident's discharge summary, consistent with §483.21(c)(2) as applicable, and any other documentation, as applicable, to ensure a safe and effective transition of care.

Effective November 28, 2017

INTENT

To specify the limited conditions under which a skilled nursing facility or nursing facility may initiate transfer or discharge of a resident, the documentation that must be included in the medical record, and who is responsible for making the documentation. Additionally, these requirements specify the information that must be conveyed to the receiving provider for residents being transferred or discharged to another healthcare setting.

DEFINITIONS

"Facility-initiated transfer or discharge": *A transfer or discharge which the resident objects to, did not originate through a resident's verbal or written request, and/or is not in alignment with the resident's stated goals for care and preferences.*

"Resident-initiated transfer or discharge": *Means the resident or, if appropriate, the resident representative has provided verbal or written notice of intent to leave the facility (leaving the facility does not include the general expression of a desire to return home or the elopement of residents with cognitive impairment).*

"Transfer and Discharge": *Includes movement of a resident to a bed outside of the certified facility whether that bed is in the same physical plant or not. Transfer and discharge does not refer to movement of a resident to a bed within the same certified facility. Specifically, transfer refers to the movement of a resident from a bed in one certified facility to a bed in another certified facility when the resident expects to return to the original facility. Discharge refers to the movement of a resident from a bed in one certified facility to a bed in another certified facility or other location in the community, when return to the original facility is not expected.*

GUIDANCE

NOTE*: The provisions at §§483.15(c)(1)and (2)(i)-(ii), only apply to transfers or discharges that are initiated by the facility, not by the resident. Section 483.15(c)(2)(iii) applies to both facility and resident initiated transfers (for information required at discharge, refer to F661, Discharge Summary).*

These regulations limit the circumstances under which a facility can initiate a transfer or discharge, thus protecting nursing home residents from involuntary discharge.

*In the following limited circumstances, facilities may initiate transfers or discharges**:***

1. *The discharge or transfer is necessary for the resident's welfare and the facility cannot meet the resident's needs.*
2. *The resident's health has improved sufficiently so that the resident no longer needs the care and/or services of the facility.*
3. *The resident's clinical or behavioral status (or condition) endangers the safety of individuals in the facility.*
4. *The resident's clinical or behavioral status (or condition) otherwise endangers the health of individuals in the facility.*
5. *The resident has failed, after reasonable and appropriate notice to pay, or have paid under Medicare or Medicaid, for his or her stay at the facility.*
6. *The facility ceases to operate.*

Surveyors must ensure that for discharges related to circumstances 1, 3, or 4 above, the facility has fully evaluated the resident, and does not base the discharge on the resident's status at the time of transfer to the acute care facility. See additional guidance at F626, §483.15(e)(1), Permitting Residents to Return. Facility-initiated transfers and discharges must meet all transfer and discharge requirements at §§483.15(c)(1) - (5).

Section 483.15(c)(1)(i) provides that "The facility must permit each resident to remain in the facility, and not transfer or discharge the resident from the facility unless…." This means that once admitted, for most residents (other than short-stay rehabilitation residents) the facility becomes the resident's home. Facilities are required to determine their capacity and capability to care for the residents they admit. Therefore, facilities should not admit residents whose needs they cannot meet based on the Facility Assessment. (See F838, Facility Assessment). There may be rare situations, such as when a crime has occurred, that a facility initiates a discharge immediately, with no expectation of the resident's return.

Resident-initiated transfers or discharges occur when the resident or, if appropriate, his/her representative has given written or verbal notice of their intent to leave the facility. A resident's expression of a general desire or goal to return to home or to the community or the elopement of a resident who is cognitively-impaired should not be taken as a notice of intent to leave the facility.

Discharges following completion of skilled rehabilitation may not always be a resident-initiated discharge. In cases where the resident may not object to the discharge, or has not appealed it, the discharge could still be involuntary and must meet all requirements of this regulation.

Surveyors must determine whether a transfer or discharge is resident or facility-initiated. The medical record should contain documentation or evidence of the resident's or resident representative's verbal or written notice of intent to leave the facility, a discharge care plan, and documented discussions with the resident or, if appropriate, his/her representative, containing details of discharge planning and arrangements for post-discharge care (See F660, Discharge Planning Process, and F661, Discharge Summary). Additionally, the comprehensive care plan should contain the resident's goals for admission and desired outcomes, which should be in alignment with the discharge if it is resident-initiated.

If a surveyor has concerns about whether a resident-initiated transfer or discharge was actually a facility-initiated transfer or discharge, the surveyor should investigate further through interviews and record review.

***NOTE**: In reviewing complaints for facility-initiated discharges that do not honor a resident's right to return following a hospitalization or therapeutic leave, surveyors would review both transfer and discharge requirements because the situation begins as a transfer and then changes to a discharge when the facility decides it will not permit the resident to return.*
If transfer is due to a significant change in the resident's condition, but not an emergency requiring an immediate transfer, then prior to any action, the facility must conduct and document the appropriate assessment to determine if revisions to the care plan would allow the

facility to meet the resident's needs. (See §483.20(b)(2)(ii), F637 for information concerning assessment upon significant change.)

A resident's declination of treatment does not constitute grounds for discharge, unless the facility is unable to meet the needs of the resident or protect the health and safety of others. The facility must be able to demonstrate that the resident or, if applicable, resident representative, received information regarding the risks of refusal of treatment, and that staff conducted the appropriate assessment to determine if care plan revisions would allow the facility to meet the resident needs or protect the health and safety of others.

Nonpayment as Basis for Discharge

Non-payment for a stay in the facility occurs when:

- *The resident has not submitted the necessary paperwork for third party (including Medicare/Medicaid) payment; or*
- *After the third party payor denied the claim and the resident refused to pay.*

It is the responsibility of the facility to notify the resident of their change in payment status, and the facility should ensure the resident has the necessary assistance to submit any third party paperwork. In situations where a resident representative has failed to pay, the facility may discharge the resident for nonpayment; however, if there is evidence of exploitation or misappropriation of the resident's funds by the representative, the facility should take steps to notify the appropriate authorities on the resident's behalf, before discharging the resident.
For a resident who becomes eligible for Medicaid after admission to a facility, the facility may charge a resident only allowable charges under Medicaid. Additionally, conversion from a private pay rate to payment at the Medicaid rate does not constitute non-payment.

Emergent Transfers to Acute Care

Residents who are sent emergently to the hospital are considered facility-initiated transfers because the resident's return is generally expected.

*Residents who are sent to the emergency room, **must** be permitted to return to the facility, unless the resident meets one of the criteria under which the facility can initiate discharge. In a situation where the facility initiates discharge while the resident is in the hospital following emergency transfer, the facility must have evidence that the resident's status is not based on his or her condition at the time of transfer) meets one of the criteria at §§483.15(c)(i)(A) through (D).*

483.15(c)(1)(ii) Discharge pending appeal

When a resident chooses to appeal his or her discharge from the facility, the facility may not discharge the resident while the appeal is pending. Additionally, if a resident's initial Medicaid application is denied but appealed, the resident is not considered to be in nonpayment status. Thus, an appeal suspends a finding of nonpayment. Appeal procedures vary by State.

If the resident, or if applicable, their representative, appeals his or her discharge while in a hospital, facilities must allow the resident to return pending their appeal, unless there is evidence that the facility cannot meet the resident's needs, or the resident's return would pose a

danger to the health or safety of the resident or others in the facility. If there are concerns related to a facility's determination that it cannot meet a resident's needs, surveyors should assess whether the facility has admitted residents with similar needs. A facility's determination to not permit a resident to return while an appeal of the resident's discharge is pending must not be based on the resident's condition when originally transferred to the hospital.

Required Documentation

To demonstrate that any of the cirmcumstances permissible for a facility to initiate a transfer or discharge as specified in 1 – 6 above have occurred, the medical record must show documentation of the basis for transfer or discharge. This documentation must be made before, or as close as possible to the actual time of transfer or discharge.

For circumstances 1 and 2 above for permissible facililty-initiated transfer or discharge, the ***resident's physician*** *must document information about the basis for the transfer or discharge. Additionally, for circumstance 1 above, the inability to meet the resident's needs, the documentation made by the* ***resident's physician must*** *include:*

- *The specific resident needs the facility could not meet;*
- *The facility efforts to meet those needs; and*
- *The specific services the receiving facility will provide to meet the needs of the resident which cannot be met at the current facility.*

In circumstances 3 and 4 above, documentation regarding the reason for the transfer or discharge must be provided by a physician, not necessarily the attending physician.

NOTE*: Documentation of the transfer or discharge may be completed by a non-physician practitioner (NPP) in accordance with State law.*

Information Conveyed to Receiving Provider

The regulations at §483.15(c)(2)(iii) address information that must be conveyed to the receiving provider when a resident is transferred or discharged. The specific information which must be conveyed depends upon whether the resident is transferred (expected to return), or is discharged (not expected to return). If the resident is being transferred, and return is expected, the following information must be conveyed to the receiving provider:

- *Contact information of the practitioner who was responsible for the care of the resident;*
- *Resident representative information, including contact information;*
- *Advance directive information;*
- *Special instructions and/or precautions for ongoing care, as appropriate, which must include, if applicable, but are not limited to:*
  - *Treatments and devices (oxygen, implants, IVs, tubes/catheters);*
  - *Precautions such as isolation or contact;*
  - *Special risks such as risk for falls, elopement, bleeding, or pressure injury and/or aspiration precautions;*
- *The resident's comprehensive care plan goals; and*
- *All information necessary to meet the resident's needs, which includes, but may not be limited to:*

- *Resident status, including baseline and current mental, behavioral, and functional status, reason for transfer, recent vital signs;*
- *Diagnoses and allergies;*
- *Medications (including when last received); and*
- *Most recent relevant labs, other diagnostic tests, and recent immunizations.*

- *Additional information, if any, outlined in the transfer agreement with the acute care provider (See §483.70(j) for additional information).*

***NOTE**: It may not be possible to convey all care plan information prior to urgent transfers, however, this information must be conveyed as close as possible to the actual time of transfer.*

For residents being discharged (return not expected), the facility must convey all of the information listed above, along with required information found at §483.21(c)(2) Discharge Summary, F661. Communicating this information to the receiving provider is one way the facility can reduce the risk of complications and adverse events during the resident's transition to a new setting.

Facilities may choose their own method of communicating transfer or discharge information, such as a universal transfer form or an electronic health record summary, as long as the method contains the required elements. The transferring or discharging facility may transmit the information electronically in a secure manner which protects the resident's privacy, as long as the receiving facility has the capacity to receive and use the information. Communication of this required information should occur as close as possible to the time of transfer or discharge.

INVESTIGATIVE PROTOCOL
Use the Critical Element (CE) Pathways for Community Discharge, or Hospitalization, as appropriate, along with the above interpretive guidelines when determining if the facility meets the requirements for, or investigating concerns related to the facility transfer or discharge requirements.

Summary of Investigative Procedure
*Briefly review the most recent comprehensive assessment, comprehensive care plan, progress notes, and orders to identify the basis for the transfer or discharge; during this review, identify the extent to which the facility has developed and implemented interventions to avoid transferring or discharging the resident, in accordance with the resident's needs, goals for care and professional standards of practice. This information will guide observations and interviews to be made in order to corroborate concerns identified. **NOTE**: Always observe for visual cues of psychosocial distress and harm (see Appendix P, Guidance on Severity and Scope Levels and Psychosocial Outcome Severity Guide).*

F623
***§483.15*(c)(3) Notice before transfer.**
Before a facility transfers or discharges a resident, the facility must—
(i) Notify the resident and the *resident's* representative*(s)* of the transfer or discharge and the reasons for the move in writing and in a language and manner they

understand. ***The facility must send a copy of the notice to a representative of the Office of the State Long-Term Care Ombudsman.***

(ii) Record the reasons ***for the transfer or discharge*** **in the resident's** ***medical*** **record** ***in accordance with paragraph (c)(2) of this section*****; and**

(iii) Include in the notice the items described in paragraph ***(c)(5)*** **of this section.**

§483.15**(c)(4) Timing of the notice.**

(i) Except ***as*** **specified in paragraphs** ***(c)(4)(ii) and (c)(8)*** **of this section, the notice of transfer or discharge required under this section must be made by the facility at least 30 days before the resident is transferred or discharged.**

(ii) Notice must be made as soon as practicable before transfer or discharge when—

(A) The safety of individuals in the facility would be endangered under paragraph ***(c)(1)(i)(C)*** **of this section;**

(B) The health of individuals in the facility would be endangered, under ***paragraph (c)(1)(i)(D)*** **of this section;**

(C) The resident's health improves sufficiently to allow a more immediate transfer or discharge, under paragraph ***(c)(1)(i)(B)*** **of this section;**

(D) An immediate transfer or discharge is required by the resident's urgent medical needs, under paragraph ***(c)(1)(i)(A)*** **of this section; or**

(E) A resident has not resided in the facility for 30 days.

§483.15**(c)(5) Contents of the notice. The written notice specified in paragraph** ***(c)(3)*** **of this section must include the following:**

(i) The reason for transfer or discharge;

(ii) The effective date of transfer or discharge;

(iii) The location to which the resident is transferred or discharged;

(iv) A statement of the resident's appeal ***rights, including the name, address (mailing and email), and telephone number of the entity which receives such requests; and information on how to obtain an appeal form and assistance in completing the form and submitting the appeal hearing request;***

(v) The name, address ***(mailing and email)*** **and telephone number of** ***the Office of the*** **State** ***L*****ong-*****T*****erm** ***C*****are** ***O*****mbudsman;**

(vi) For nursing facility residents with ***intellectual and*** **developmental disabilities** ***or related disabilities,*** **the mailing** ***and email*** **address and telephone number of the agency responsible for the protection and advocacy of individuals** ***with developmental disabilities*** **established under Part C of the Developmental Disabilities Assistance and Bill of Rights Act** ***of 2000 (Pub. L. 106-402, codified at 42 U.S.C. 15001 et seq.);*** **and**

(vii) For nursing facility residents ***with a*** **mental** ***disorder or related disabilities*****, the mailing** ***and email*** **address and telephone number of the agency responsible for the protection and advocacy of individuals** ***with a mental disorder*** **established under the Protection and Advocacy for Mentally Ill Individuals Act.**

Effective November 28, 2017

§483.15(c)(6) Changes to the notice.
If the information in the notice changes prior to effecting the transfer or discharge, the facility must update the recipients of the notice as soon as practicable once the updated information becomes available.

§483.15(c)(8) Notice in advance of facility closure
In the case of facility closure, the individual who is the administrator of the facility must provide written notification prior to the impending closure to the State Survey Agency, the Office of the State Long-Term Care Ombudsman, residents of the facility, and the resident representatives, as well as the plan for the transfer and adequate relocation of the residents, as required at § 483.70(l).

DEFINITIONS
"Facility-initiated transfer or discharge": *A transfer or discharge which the resident objects to, did not originate through a resident's verbal or written request, and/or is not in alignment with the resident's stated goals for care and preferences.*

"Resident-initiated transfer or discharge": *Means the resident or, if appropriate, the resident representative has provided verbal or written notice of intent to leave the facility (leaving the facility does not include the general expression of a desire to return home or the elopement of residents with cognitive impairment).*

"Transfer and Discharge": *Includes movement of a resident to a bed outside of the certified facility whether that bed is in the same physical plant or not. Transfer and discharge does not refer to movement of a resident to a bed within the same certified facility. Specifically, transfer refers to the movement of a resident from a bed in one certified facility to a bed in another certified facility when the resident expects to return to the original facility. Discharge refers to the movement of a resident from a bed in one certified facility to a bed in another certified facility or other location in the community, when return to the original facility is not expected.*

GUIDANCE
The requirements at 483.15(c)(3)-(6) only apply to facility-initiated transfers and discharges, not resident-initiated transfers and discharges. This guidance will address the requirement to send a notice in situations where the facility initiates a transfer or discharge, including discharges that occur while the resident remains in the hospital after emergency transfer.

Facility-initiated transfers and discharges generally occur when the facility determines it should not, or cannot provide needed care or services to a resident in accordance with F622, Transfer and Discharge Requirements. Whether or not a resident agrees with the facility's decision, the requirements at 483.15(c)(3)-(6) apply whenever a facility initiates the transfer or discharge.

A resident-initiated transfer or discharge is one in which the resident has provided written or verbal notice of their intent to leave the facility, which is documented in the resident's record. A resident's expression of a general desire to return home or to the community or elopement of a resident who is cognitively impaired should not be taken as a notice of intent to leave. When a resident initiates his or her transfer or discharge, the medical record should contain

documentation or evidence of the resident's or resident representative's verbal or written notice of intent to leave the facility, a discharge care plan, and documented discussions with the resident or if appropriate his/her representative, containing details of discharge planning, and arrangements for post-discharge care (See F660, Discharge Planning Process). Additionally, the comprehensive care plan should contain the resident's goals for admission and desired outcomes, which should be in alignment with the discharge if it is resident initiated. Therapeutic leave is a type of resident-initiated transfer. However, if the facility makes a determination to not allow the resident to return, the transfer becomes a facility-initiated discharge.

Notice of Transfer or Discharge and Ombudsman Notification
For facility-initiated transfer or discharge of a resident, the facility must notify the resident and the resident's representative(s) of the transfer or discharge and the reasons for the move in writing and in a language and manner they understand. Additionally, the facility must send a copy of the notice of transfer or discharge to the representative of the Office of the State Long-Term Care (LTC) Ombudsman. The intent of sending copies of the notice to a representative of the Office of the State LTC Ombudsman is to provide added protection to residents from being inappropriately discharged, provide residents with access to an advocate who can inform them of their options and rights, and to ensure that the Office of the State LTC Ombudsman is aware of facility practices and activities related to transfers and discharges. Notice to the Office of the State LTC Ombudsman must occur before or as close as possible to the actual time of a facility-initiated transfer or discharge. The medical record must contain evidence that the notice was sent to the Ombudsman. While Ombudsman Programs vary from state to state, facilities must know the process for ombudsman notification in their state.

Facility-Initiated Transfers and Discharges
In situations where the facility has decided to discharge the resident while the resident is still hospitalized, the facility must send a notice of discharge to the resident and resident representative, and must also send a copy of the discharge notice to a representative of the Office of the State LTC Ombudsman. Notice to the Office of the State LTC Ombudsman must occur at the same time the notice of discharge is provided to the resident and resident representative, even though, at the time of initial emergency transfer, sending a copy of the ***transfer*** *notice to the ombudsman only needed to occur as soon as practicable as described below.*

For any other types of facility-initiated discharges, the facility must provide notice of discharge to the resident and resident representative along with a copy of the notice to the Office of the State LTC Ombudsman at least 30 days prior to the discharge or as soon as possible. The copy of the notice to the ombudsman must be sent at the same time notice is provided to the resident and resident representative.

Emergency Transfers*--When a resident is temporarily transferred on an emergency basis to an acute care facility, this type of transfer is considered to be a facility-initiated transfer and a notice of transfer must be provided to the resident and resident representative as soon as practicable, according to 42 CFR 483.15(c)(4)(ii)(D). Copies of notices for emergency transfers must also still be sent to the ombudsman, but they may be sent when practicable, such as in a list of residents on a monthly basis.*

Effective November 28, 2017

Resident-Initiated Transfers and Discharges

A resident-initiated transfer or discharge means the resident or, if appropriate, the resident representative has provided verbal or written notice of intent to leave the facility. The medical record must contain documentation or evidence of the resident's or resident representative's verbal or written notice of intent to leave the facility. While a resident's expression of a general desire or goal to return home or to the community or the elopement of a resident who is cognitively impaired should be taken into consideration for the purposes of discharge planning and community placement, it should not be taken as notice of intent to leave the facility and does not constitute a resident-initiated transfer or discharge. For resident-initiated transfers or discharges, sending a copy of the notice to the ombudsman is not required because the notice requirement does not apply to resident-initiated transfers or discharges.

Surveyors must determine whether a transfer or discharge is resident or facility-initiated. The medical record should contain documentation or evidence of the resident's or resident representative's verbal or written notice of intent to leave the facility, a discharge care plan, and documented discussions with the resident or, if appropriate, his/her representative, containing details of discharge planning and arrangements for post-discharge care (See F660, Discharge Planning Process, and F661, Discharge Summary). Additionally, the comprehensive care plan should contain the resident's goals for admission and desired outcomes, which should be in alignment with the discharge if it is resident-initiated. If a surveyor has concerns about whether a resident-initiated transfer or discharge was actually a facility-initiated transfer or discharge, the surveyor should investigate further through interviews and record review.

Contents of the Notice

The facility's notice must include *the following:*

- The *specific* reason for the *transfer or* discharge, *including the basis per §§483.15(c)(1)(i)(A)-(F)*;
- The effective date of the *transfer or* discharge;
- The location to which the resident is to be *transferred or* discharged;
- An explanation of the right to appeal to the State;
- *The name, address (mail and email), and telephone number of the State entity which receives appeal hearing requests;*
- *Information on how to request an appeal hearing;*
- *Information on obtaining assistance in completing and submitting the appeal hearing request; and*
- The name, address, and phone number of the *representative of the Office of the* State Long-Term Care ombudsman.

For residents with intellectual and developmental *disabilities and/or mental illness*, *the notice must include* the name, *mail and e-mail* address*es* and phone number of the *state protection and advocacy* agency responsible for advocating for these *populations.*

Timing of the Notice

Generally, this notice must be provided at least 30 days prior to the *transfer or discharge*. Exceptions to the 30-day requirement apply when the *transfer or discharge* is effected because:

- *The resident's welfare is at risk, and his or her needs cannot be met in the facility (i.e., emergency transfer to an acute care facility); or*
- *The health or safety of others in the facility is e*ndangered.

In these cases, the notice must be provided as soon as practicable *and* ***notice to the ombudsman*** *in these situations can be sent when practicable, such as a list of residents on a monthly basis.*

Changes to the Notice
If information in the notice changes, the facility must update the recipients of the notice as soon as practicable with the new information to ensure that residents *and their representatives* are aware of and can respond appropriately. *For significant changes, such as a change in the destination, a new notice must be given that clearly describes the change(s) and resets the transfer or discharge date, in order to provide 30 day advance notification.*

Notice in Advance of Facility Closure:
Refer to 483.70(l), F845 for guidance related to evaluating Notice in Advance of Facility Closure.

F624
***§483.15(*c)(7) Orientation for *t*ransfer or *d*ischarge.**
A facility must provide and document sufficient preparation and orientation to residents to ensure safe and orderly transfer or discharge from the facility. *This orientation must be provided in a form and manner that the resident can understand.*

DEFINITIONS
"Transfer and Discharge": *Includes movement of a resident to a bed outside of the certified facility whether that bed is in the same physical plant or not. Transfer and discharge does not refer to movement of a resident to a bed within the same certified facility. Specifically, transfer refers to the movement of a resident from a bed in one certified facility to a bed in another certified facility when the resident expects to return to the original facility. Discharge refers to the movement of a resident from a bed in one certified facility to a bed in another certified facility or other location in the community, when return to the original facility is not expected.*

GUIDANCE
The guidance at this tag generally addresses the immediate orientation and preparation necessary for a transfer, such as to a hospital emergency room or therapeutic leave where discharge planning is not required because the resident will return, or for an emergent or immediate discharge where a complete discharge planning process is not practicable.

For concerns related to how the facility planned for a discharge that meets a resident's health and safety needs, as well as their preferences and goals in circumstances which permit a complete discharge planning process, please refer to F660, Discharge Planning.

Sufficient preparation *and orientation* means the facility informs the resident where he or she is going, and takes steps under its control to *minimize anxiety*.

Examples of preparation and orientation may include explaining to a resident why they are going to the emergency room or other location or leaving the facility; working with family or resident's representative to assure that the resident's possessions (as needed or requested by the resident) are not left behind or lost; and ensuring that staff handle transfers and discharges in a manner that minimizes anxiety or depression and recognizes characteristic resident reactions identified by the resident's assessment and care plan.

The facility must orient and prepare the resident regarding his or her transfer or discharge in a form and manner that the resident can understand. The form and manner of this orientation and preparation must take into consideration factors that may affect the resident's ability to understand, such as educational level, language and/or communication barriers, and physical and mental impairments. The facility must also document this orientation in the medical record, including the resident's understanding of the transfer or discharge.

Other tags for consideration would be:

- *F622, Transfer and Discharge Requirements, specifically the clinical information that must be conveyed to the receiving provider, if the transfer or discharge is to another healthcare setting; and*
- *F843, Transfer Agreement, for concerns related to timely transfer to the acute care facility.*

PROCEDURES

- *Review nursing notes and any other relevant documentation to see if appropriate orientation and preparation of the resident prior to transfer and discharge has occurred.*
- *Through record review and interviews, determine if the resident received sufficient preparation prior to transfer or discharge, and if they understood the information provided to them.*
- *Were the resident's needed/requested possessions transferred with the resident to the new location?*
- *Ask resident or his or her representative if they understand why the transfer or discharge occurred.*

F625
***§483.15(*d) Notice of *b*ed-*h*old policy and *return*—**

***§483.15*(d)(1) Notice before transfer. Before a nursing facility transfers a resident to a hospital or *the* resident *goes* on therapeutic leave, the nursing facility must provide written information to the resident *or resident representative* that specifies—**

(i) The duration of the *state* bed-hold policy, if any, during which the resident is permitted to return and resume residence in the nursing facility;

(ii) The reserve bed payment policy in the state plan, under § 447.40 of this chapter, if any;

(iii)* The nursing facility's policies regarding bed-hold periods, which must be consistent with paragraph *(e)(1)* of this section, permitting a resident to return; *and

(iv) The information specified in paragraph (e)(1) of this section.

Effective November 28, 2017

***§483.15*(d)(2) Bed-hold notice upon transfer. At the time of transfer of a resident for hospitalization or therapeutic leave, a nursing facility must provide to the resident and *the resident representative* written notice which specifies the duration of the bed-hold policy described in paragraph *(d)(1)* of this section.**

INTENT
To ensure that residents are made aware of a facility's bed-hold and reserve bed payment policy before and upon transfer to a hospital or when taking a therapeutic leave of absence from the facility.

DEFINITIONS
"Bed-hold": *Holding or reserving a resident's bed while the resident is absent from the facility for therapeutic leave or hospitalization.*

"Reserve Bed Payment": *Payments made by a State to the facility to hold a bed during a resident's temporary absence from a nursing facility.*

"Therapeutic Leave": *Absences for purposes other than required hospitalization.*

GUIDANCE
Notice of Bed-Hold Policy
All facilities must have policies that address holding a resident's bed during periods of absence, such as during hospitalization or therapeutic leave. Additionally, facilities must provide written information about these policies to residents prior to and upon transfer for such absences. This information must be provided to all facility residents, regardless of their payment source.

These *provisions* require *facilities to issue* two notices related to bed-hold policies. The first notice could be given well in advance of any transfer, *i.e., information provided in the admission packet.* Reissuance of the first notice would be required if the bed-hold policy under the State plan or the facility's policy were to change.

The second notice must be provided to the resident, and if applicable the resident's representative, at the time of transfer, or in cases of emergency transfer, within 24 hours. It is expected that facilities will document multiple attempts to reach the resident's representative in cases where the facility was unable to notify the representative.
The notice must provide information to the resident that explains the duration of bed-hold, if any, and the reserve bed payment policy. It should also address permitting the return of residents to the next available bed.

When a resident residing in a skilled nursing facility under Medicare is hospitalized or takes therapeutic leave, Medicare will not pay to hold the bed. Facility policies may allow the resident to pay privately to hold his or her bed. While the provisions of this requirement specifically address bed-hold under Medicaid law, facilities must make all residents aware in writing of their policies related to holding beds during absences from the facility.

Effective November 28, 2017

***NOTE**: Residents not covered by Medicare or Medicaid, may be permitted to privately provide reserve bed payments.*

Medicaid law requires each state Medicaid plan to address bed-hold policies for hospitalization and periods of therapeutic leave. State plans vary in payment for and duration of bed-holds. However, federal regulations do not require states to pay nursing facilities for holding beds while the resident is away from the facility. In general, the State plan sets the length of time, if any, that the state will pay the facility for holding a bed for a Medicaid-eligible resident. It is the responsibility of the survey team to know the bed-hold policies of their State Medicaid plan.

Additionally, §483.15 (e)(1) and F626 require facilities to permit residents to return to the facility immediately to the first available bed in a semi-private room.

As stated above, a participating facility *must* provide notice to its residents *and if applicable, their representatives,* of the facility's bed-hold policies*, as stipulated in each State's plan. This notice must be provided* prior to *and upon* transfer *and must include information on how long a facility will hold the bed, how reserve bed payments will be made (if applicable), and the conditions upon which the resident would return to the facility. These conditions are:*

- *The resident requires the services which the facility provides; and*
- *The resident is eligible for Medicare skilled nursing facility services or Medicaid nursing facility services.*

Bed-hold for days of absence in excess of the State's bed-hold limit *is* considered *a* non-covered service which means that the resident could use his/her own income to pay for the bed-hold. However, if a resident does not elect to pay to hold *his or her* bed, *the resident will be permitted to return* to the next available bed, *consistent with the requirements at §483.15(e)*.

The provision at §483.15(d)(1)(ii) references regulations for Medicaid Payments for Reserving Beds in Institutions (§447.40), which state "Absences for purposes other than required hospitalization (which cannot be anticipated and planned) are included in the patient's plan of care." This means that therapeutic leave of absence must be consistent with the resident's goals for care, be assessed by the comprehensive assessment, and incorporated into the comprehensive care plan, and cannot be a means of involuntarily discharging the resident.

INVESTIGATIVE PROTOCOL

Use the Critical Element (CE) Pathways for Community Discharge, or Hospitalization, as appropriate, along with the above interpretive guidelines when determining if the facility meets the requirements for, or investigating concerns related to the facility requirements for bed-hold.

Summary of Investigative Procedure

If concerns arise regarding notice of bed-hold, review the medical record for evidence of whether a notice of bed-hold was provided both (1) prior to and (2) upon transfer. Look for documentation such as a copy of the dated notice(s), progress notes, transfer checklist(s), or other evidence that the notice was given. Additionally, ask to review facility policies on bed-hold. Review the facility's admission packet to determine if notice of bed-hold is given at admission. If not, determine how the facility notifies residents prior to transfer.

Ask the resident, or if applicable, the resident's representative(s), whether they received the bed-hold notice and understand the facility's bed-hold policy. If not, determine how the facility notifies residents of this information prior to transfer.

F626
***§483.15*(e)(1) Permitting residents to return to facility.**
A facility must establish and follow a written policy *on permitting residents to return to the facility after they are hospitalized or placed on therapeutic leave. The policy must provide for the following.*

- ***(i) A* resident, whose hospitalization or therapeutic leave exceeds the bed-hold period under the State plan, *returns to the facility to their previous room if available or* immediately upon the first availability of a bed in a semi-private room if the resident—**
  - **(A) Requires the services provided by the facility; and**
  - **(B) Is eligible for *Medicare skilled nursing facility services or* Medicaid nursing facility services.**
- ***(ii) If the facility that determines that a resident who was transferred with an expectation of returning to the facility, cannot return to the facility, the facility must comply with the requirements of paragraph (c) as they apply to discharges.***

§483.15(e)(2) Readmission to a composite distinct part. When the facility to which a resident returns is a composite distinct part (as defined in § 483.5), the resident must be permitted to return to an available bed in the particular location of the composite distinct part in which he or she resided previously. If a bed is not available in that location at the time of return, the resident must be given the option to return to that location upon the first availability of a bed there.

INTENT
*To ensure that facilities develop and implement policies that address bed-hold and return to the facility for all residents. Specifically, residents who are hospitalized or on therapeutic leave are allowed to return for skilled nursing or nursing facility care or services. In situations where the facility intends to discharge the resident, the facility must comply with Transfer and Discharge Requirements at §483.15(c), **and** the resident must be permitted to return and resume residence in the facility while an appeal is pending.*

DEFINITIONS
"Bed-hold": *Holding or reserving a resident's bed while the resident is absent from the facility for therapeutic leave or hospitalization.*

"Composite Distinct Part": *A composite distinct part is a distinct part consisting of two or more noncontiguous components that are not located within the same campus, as that term is defined in §413.65(a)(2). Additional requirements specific to SNF/NF composite distinct parts are found at §483.5.*

"Campus": *Campus is defined in §413.65(a)(2) and means the physical area immediately adjacent to the provider's main buildings, other areas and structures that are not strictly*

contiguous to the main buildings but are located within 250 yards of the main buildings, and any other areas determined on an individual case basis, by the CMS regional office, to be part of the provider's campus.

"Distinct Part": *A distinct part SNF or NF is physically distinguishable from the larger institution or institutional complex that houses it, meets the requirements of this paragraph and of paragraph (b)(2) of this section, and meets the applicable statutory requirements for SNFs or NFs in sections 1819 or 1919 of the Act, respectively. A distinct part SNF or NF may be comprised of one or more buildings or designated parts of buildings (that is, wings, wards, or floors) that are: In the same physical area immediately adjacent to the institution's main buildings; other areas and structures that are not strictly contiguous to the main buildings but are located within close proximity of the main buildings; and any other areas that CMS determines on an individual basis, to be part of the institution's campus. A distinct part must include all of the beds within the designated area, and cannot consist of a random collection of individual rooms or beds that are scattered throughout the physical plant. The term "distinct part" also includes a composite distinct part that meets the additional requirements of paragraph (c) of this section. Additional requirements specific to SNF/NF distinct parts are found at 483.5.*

"Therapeutic Leave": *Absences for purposes other than required hospitalization.*

GUIDANCE §483.15 (e)

Facilities must develop *and implement* policies *for bed-hold and* permit*ting residents to return following* hospitalization or therapeutic leave. *These policies must address how the facility will allow residents to return when their hospitalization or therapeutic leave has exceeded the bed-hold period allowed by the State Medicaid plan. Duration of and payment for bed-hold for residents eligible for Medicaid vary by State. The policy must also address how residents who pay privately, or receive Medicare, may pay to reserve their bed.*

NOTE*: These requirements also apply to a resident who was receiving Medicaid at the time of his or her hospitalization, and returns needing skilled nursing (Medicare) care or services.*

Residents must be permitted to return to their previous room, if available, or to the next available bed in a semi-private room, providing the resident:

- *Still requires the services provided by the facility; and*
- *Is eligible for Medicare skilled nursing facility or Medicaid nursing facility services.*

Medicaid-eligible residents must be *permitted to return* to the first available bed even if the residents have outstanding Medicaid balances.

Composite Distinct Part

If a facility does not have a composite distinct part this provision does not apply. If there are concerns as to whether or not a facility is appropriately certified as a distinct or composite distinct part, consult with the CMS Regional Office for clarification.

Effective November 28, 2017

When a resident is returning to a composite distinct part, he/she must be allowed to return to an available bed in the particular location of the composite distinct part in which he/she resided previously, or the next available bed in that location.

Not Permitting Residents to Return

Not permitting a resident to return following hospitalization or therapeutic leave requires a facility to meet the requirements for a facility-initiated discharge as outlined in §483.15(c)(1)(ii). A facility must not discharge a resident unless:

1. *The discharge or transfer is necessary for the resident's welfare and the facility cannot meet the resident's needs.*
2. *The resident's health has improved sufficiently so that the resident no longer needs the services of the facility.*
3. *The resident's clinical or behavioral status endangers the safety of individuals in the facility.*
4. *The resident's clinical or behavioral status endangers the health of individuals in the facility.*
5. *The resident has failed to pay for (or to have paid under Medicare or Medicaid) his or her stay at the facility.*
6. *The facility ceases to operate.*

For concerns related to a facility not permitting a resident to return, the surveyor should investigate to determine if the basis for discharge meets one of the requirements above (See F622, §483.15(c)(1)(ii)).

As noted at 483.15(c)(2)(i)(B), when the facility transfers or discharges a resident for the resident's welfare, or because the resident's needs cannot be met in the facility, the medical record must contain documentation of the specific resident needs that cannot be met, facility attempts to meet those needs, and the service available at the receiving facility to meet the needs. Resident decisions to refuse care should not be considered a basis for transfer or discharge unless the refusal poses a risk to the resident's or other individuals' health and/or safety. In situations where a resident's choice to refuse care or treatment poses a risk to the resident's or others' health or safety, the comprehensive care plan must identify the care or service being declined, the risk the declination poses to the resident, and efforts by the interdisciplinary team to educate the resident and the representative, as appropriate (See F656, 483.21(b)(1)(ii), Comprehensive Care Plans.)

If unable to resolve situations where a resident's refusal for care poses a risk to the resident's or others' health or safety, the facility administration, nursing and medical director may wish to convene an ethics meeting, which includes legal consultation, in order to determine if the facility can meet the resident's needs, or if the resident should be transferred or discharged.

If a facility does not permit a resident who went on therapeutic leave to return, the facility must meet the requirements for a facility-initiated discharge at F622. Because the facility was able to care for the resident prior to therapeutic leave, documentation related to the basis for discharge must clearly show why the facility can no longer care for the resident.

Effective November 28, 2017

Additionally, facilities must not treat situations where a resident goes on therapeutic leave and returns later than agreed upon, as a resident-initiated discharge. The resident must be permitted to return and be appropriately assessed for any ill-effects from being away from the facility longer than expected, and provide any needed medications or treatments which were not administered because they were out of the building. If a resident has not returned from therapeutic leave as expected, the medical record should show evidence that the facility attempted to contact the resident and resident representative. The facility must not initiate a discharge unless it has ascertained from the resident or resident representative that the resident does not wish to return.

A facility may have concerns about permitting a resident to return to the facility after a hospital stay due to the resident's clinical or behavioral condition at the time of transfer. The facility must not evaluate the resident based on his or condition when originally transferred to the hospital. If the facility determines it will not be permitting the resident to return, the medical record should show evidence that the facility made efforts to:

- *Determine if the resident still requires the services of the facility and is eligible for Medicare skilled nursing facility or Medicaid nursing facility services.*
- *Ascertain an accurate status of the resident's condition—this can be accomplished via communication between hospital and nursing home staff and/or through visits by nursing home staff to the hospital.*
- *Find out what treatments, medications and services the hospital provided to improve the resident's condition. If the facility is unable to provide the same treatments, medications, and services, the facility may not be able to meet the resident's needs and may consider initiating a discharge. For example, a resident who has required IV medication or frequent blood monitoring while in the hospital and the nursing home is unable to provide this same level of care.*
- *Work with the hospital to ensure the resident's condition and needs are within the nursing home's scope of care, based on its facility assessment, prior to hospital discharge. For example, the nursing home could ask the hospital to:*
    - *Attempt reducing a resident's psychotropic medication prior to discharge and monitor symptoms so that the nursing home can determine whether it will be able to meet the resident's needs upon return;*
    - *Convert IV medications to oral medications and ensure that the oral medications adequately address the resident's needs.*

If the facility determines the resident will not be returning to the facility, the facility must notify the resident, his or her representative, and the LTC ombudsman in writing of the discharge, including notification of appeal rights. If the resident chooses to appeal the discharge, the facility must allow the resident to return to his or her room or an available bed in the nursing home during the appeal process, unless there is evidence that the resident's return would endanger the health or safety of the resident or other individuals in the facility.

For concerns regarding notification of discharge, and the resident's right to appeal the discharge, refer to the regulation and guidance at §§483.15(c)(3)-(5)(F623).

Effective November 28, 2017

INVESTIGATIVE PROTOCOL

Use the Critical Element (CE) Pathways for Community Discharge, or Hospitalization, as appropriate, along with the above interpretive guidelines when determining if the facility meets the requirements for, or investigating concerns related to the facility requirements to permit residents to return following hospitalization or therapeutic leave.

Summary of Investigative Procedure

If concerns arise regarding facility failure to permit a resident to return, review the medical record for evidence of whether a notice of transfer and discharge and notice of bed-hold were provided. Determine the basis for discharge and how the facility evaluated the resident. The surveyor may have to obtain hospital records for further investigation. Review any other documentation necessary to ascertain the extent to which the facility made efforts to enable the resident to return.

In cases where a facility did not allow a resident to return due to lack of an available bed, the surveyor should review facility admissions beginning with when the resident was ready to return to determine if residents with similar care needs have been admitted. Additionally, if the facility does not readmit the resident due to risk to the health or safety of individuals in the facility, the surveyor should review documentation for how the facility made this determination.

KEY ELEMENTS OF NONCOMPLIANCE

To cite deficient practice at F626, the surveyor's investigation will generally show that the facility failed to:

- *Establish and/or implement a policy that is in accordance with the State Medicaid plan, and addresses returning to the facility following hospitalization or therapeutic leave; or*
- *Ensure that residents whose hospitalization or therapeutic leave exceeds the State's bed-hold period are returned to their previous room and/or the first available bed in a semi-private room; or*
- *Ensure (for a resident not permitted to return) the medical record and notification contain a valid basis for discharge; or*
- *Permit a resident to return to the same composite distinct part in which they previously resided.*

DEFICIENCY CATEGORIZATION

In addition to actual or potential physical harm, always consider whether psychosocial harm has occurred when determining severity level (See Appendix P, Section IV, E, Psychosocial Outcome Severity Guide).

Examples of Severity Level 4 Non-compliance: Immediate Jeopardy to Resident Health or Safety include, but are not limited to:

- *Facility failed to allow a resident to return following therapeutic leave to a family member's home, resulting in the resident being found living on the street, without food or shelter. The medical record did not contain evidence of a valid basis for discharge, and there was no evidence of discharge planning This was cross-referenced and also cited at F622, Transfer and Discharge Requirements, §483.15(c)(1), and F660, Discharge Planning Process, §483.21(c)(1).*

- *Facility failed to allow a resident to return following a hospitalization. The medical record did not accurately evaluate the resident, rather they used the resident's status prior to the transfer as the basis for discharge. This was cross-referenced and also cited at F622, Transfer and Discharge Requirements, §483.15(c)(1).*

Examples of Severity Level 3 Noncompliance: Actual Harm that is not Immediate Jeopardy include, but are not limited to:

- *Facility failed to allow a resident to return to a bed in the same composite distinct part in which they resided previously. The new location was far from the resident's family, resulting in the resident expressing sustained and persistent sadness and withdrawal.*
- *Facility failed to allow a resident to return to the nursing facility, following a hospitalization that exceeded the bed-hold policy (and state plan). The facility discharged the resident on the basis of being unable to meet his needs. The survey team was able to verify that the facility had accepted residents with similar conditions during the timeframe that the resident was ready to return. This resulted in the resident being sent to another facility which was in a location not easily accessible by the resident's family. The resident expressed feelings of depression and loneliness.*

An example of Severity Level 2 Noncompliance: No Actual Harm with Potential for More Than Minimal Harm that is Not Immediate Jeopardy includes, but is not limited to:

- *Facility failed to allow a resident to return to his/her previous room (even though it was available) upon return from the hospital, which resulted in no more than minimal harm as the resident adjusted to the new room. This noncompliance has the potential to cause more than minimal psychosocial harm.*

An example of Severity Level 1 noncompliance: No actual harm with potential for minimal harm includes, but is not limited to:

- *A facility which is a composite distinct part permitted a resident to return following hospitalization or therapeutic leave, however, the resident returned to a different location in the composite distinct part even though a bed was available in the same location where the resident had resided prior to transfer. The resident did not express displeasure with the situation.*

F635
§483.20(a) Admission orders
At the time each resident is admitted, the facility must have physician orders for the resident's immediate care.

INTENT §483.20(a)
To ensure *each* resident receives necessary care and services *upon admission*.

***GUIDANCE* §483.20(a)**
"Physician orders for immediate care" are those written *and/or verbal* orders facility staff need to provide essential care to the resident, consistent with the resident's mental and physical status upon admission *to the facility*. These orders should, at a minimum, include dietary, *medications*

(if necessary) and routine care to maintain or improve the resident's functional abilities until staff can conduct a comprehensive assessment and develop an interdisciplinary care plan.

F636
§483.20 Resident Assessment
The facility must conduct initially and periodically a comprehensive, accurate, standardized reproducible assessment of each resident's functional capacity.

§483.20(b) Comprehensive Assessments
§483.20(b)(1) Resident Assessment Instrument. A facility must make a comprehensive assessment of a resident's needs, *strengths, goals, life history and preferences,* using the resident assessment instrument (RAI) specified by *CMS*. The assessment must include at least the following:

(i) Identification and demographic information
(ii) Customary routine.
(iii) Cognitive patterns.
(iv) Communication.
(v) Vision.
(vi) Mood and behavior patterns.
(vii) Psychological well-being.
(viii) Physical functioning and structural problems.
(ix) Continence.
(x) Disease diagnosis and health conditions.
(xi) Dental and nutritional status.
(xii) Skin Conditions.
(xiii) Activity pursuit.
(xiv) Medications.
(xv) Special treatments and procedures.
(xvi) Discharge *planning.*
(xvii) Documentation of summary information regarding the additional assessment performed on the care areas triggered by the completion of the Minimum Data Set (MDS).
(xviii) Documentation of participation in assessment. The assessment process must include direct observation and communication with the resident, as well as communication with licensed and nonlicensed direct care staff members on all shifts.

§483.20(b)(2) When required. Subject to the timeframes prescribed in §413.343(b) of this chapter, a facility must conduct a comprehensive assessment of a resident in accordance with the timeframes specified in paragraphs (b)(2)(i) through (iii) of this section. The timeframes prescribed in §413.343(b) of this chapter do not apply to CAHs.

(i) Within 14 calendar days after admission, excluding readmissions in which there is no significant change in the resident's physical or mental condition. (For purposes of this section, "readmission" means a return to the facility following a temporary absence for hospitalization or therapeutic leave.)

***

(iii)Not less than once every 12 months.

Effective November 28, 2017

INTENT §483.20(b)(1)-(2)(i)&(iii)
To ensure that the *Resident Assessment Instrument* (RAI) is used*, in accordance with specified format and timeframes,* in conducting comprehensive assessments as part of an ongoing process through which the facility identifies each resident's *preferences and goals of care,* functional *and health status, strengths and needs, as well as offering guidance for further assessment once problems have been identified.*

DEFINITIONS §483.20(b)(1)-(2)(i)&(iii)
"Minimum Data Set": *The Minimum Data Set (MDS) is part of the U.S. federally mandated process for clinical assessment of all residents in Medicare or Medicaid-certified nursing homes. It is a core set of screening, clinical and functional status elements, including common definitions and coding categories, which forms the foundation of a comprehensive assessment.*

"Care Area Assessment (CAA) Process" *is a process outlined in Chapter 4 of the MDS manual designed to assist the assessor to systematically interpret the information recorded on the MDS. Once a care area has been triggered, nursing home providers use current, evidence-based clinical resources to conduct an assessment of the potential problem and determine whether or not to care plan for it. The CAA process helps the clinician to focus on key issues identified during the assessment process so that decisions as to whether and how to intervene can be explored with the resident. This process has three components:*

- ***Care Area Triggers (CATs)*** *are specific resident responses for one or a combination of MDS elements. The triggers identify residents who have or are at risk for developing specific functional problems and require further assessment.*
- ***Care Area Assessment (CAA)*** *is the further investigation of triggered areas, to determine if the care area triggers require interventions and care planning.*
- ***CAA Summary*** *(Section V of the MDS) provides a location for documentation of the care area(s) that have triggered from the MDS, the decisions made during the CAA process regarding whether or not to proceed to care planning, and the location and date of the CAA documentation.*

"Comprehensive Assessment" *includes the completion of the MDS as well as the CAA process, followed by the development and/or review of the comprehensive care plan. Comprehensive MDS assessments include Admission, Annual, Significant Change in Status Assessment and Significant Correction to Prior Comprehensive Assessment.*

"Resident Assessment Instrument (RAI)" *consists of three basic components: the Minimum Data Set (MDS) version 3.0, the Care Area Assessment (CAA) process and the RAI utilization guidelines. The utilization of these components of the RAI yields information about a resident's functional status, strengths, weaknesses, and preferences, as well as offering guidance on further assessment once problems have been identified.*

"Utilization Guidelines" *provide instructions for when and how to use the RAI. The Utilization Guidelines are also known as the Long-Term Care Facility Resident Assessment Instrument 3.0 User's Manual.*

Effective November 28, 2017

***GUIDANCE* §483.20(b)(1)-(2(i)&(iii)**
Each facility must use *the* RAI *specified by CMS* (which includes the MDS, utilization guidelines and the CAAs) to assess *each* resident. The facility is responsible for addressing all needs and strengths of residents regardless of whether the issue is included in the MDS or CAAs. The scope of the RAI does not limit the facility's responsibility to assess and address all care needed by the resident.

The information required in §483.20(b)*(1)*(i-xvi*ii*) is incorporated into the MDS, which forms the core *of the RAI process*. Additional assessment information is also gathered using triggered *Care Area Assessments* (CAAs) *after the completion of the comprehensive MDS*.

The facility is expected to use resident observation and communication as the primary source of information when completing the RAI. In addition to *record review,* direct observation and communication with the resident, the facility *must* use a variety of other sources, including communication with licensed and non-licensed staff members on all shifts and may include discussions with the resident's physician, *the resident's representative,* family members, or outside consultants.

At a minimum, facilities are required to complete a comprehensive assessment of each resident within 14 calendar days after admission to the facility, when there is a significant change in the resident's status and not less than once every 12 months while a resident. For the purpose of this guidance, not less than once every 12 months means within 366 days.

For additional requirements regarding a Significant Change in Status Assessment, see §483.20(b)(2)(ii).

If a comprehensive assessment was completed, any time prior to a temporary absence for hospitalization or a leave of absence, and upon return to the facility, the resident does not meet the criteria for a Significant Change in Status Assessment (SCSA), as defined in §483.20(b)(2)(ii), a comprehensive assessment is not required. For example, a resident had a comprehensive assessment completed within 14 days of admission, four months later was hospitalized, then returned to the facility. Upon return to the facility, the resident's status does not meet the criteria for a SCSA, therefore a comprehensive assessment is not required.

For additional information on assessment scheduling and completion requirements, see Chapter 2 of the Long-Term Care Facility Resident Assessment Instrument 3.0 User's Manual. Link to the LTCF RAI User's Manual: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursinghomeQualityInits/MDS30RAIManual.html.

The facility *must* use *the RAI process* to develop a *comprehensive* care plan, to provide the appropriate care and services for each resident, and to modify the care plan and care/services based on the resident's status.

PROBES §483.20(b)(1)-(2)(i)&(iii)

- *Did the facility complete a comprehensive assessment,* using the *CMS*-specified RAI process, within the regulatory timeframes (i.e. within 14 days after admission and at least

annually) *for each resident in the sample*?

- *Is there evidence in the clinical record that* the facility gathered *and analyzed* supplemental information based on the triggered CAAs *prior to developing the comprehensive* care plan? *For reference a list of CAAs is found in Section V of the MDS (Care Area Assessment Summary).*
- *Is there evidence of resident and/or resident representative participation in the assessment process? Examples include participating in the resident interviews, providing information about preferences or discharge goals.*
- *Ask licensed and non-licensed direct-care staff if they participate in the resident assessment process.*
- *Does the facility have a system in place to assure assessments are conducted in accordance with the specified timeframes for each resident?*

F637
§483.20(b)(2)(ii) Within 14 days after the facility determines, or should have determined, that there has been a significant change in the resident's physical or mental condition. (For purpose of this section, a "significant change" means a major decline or improvement in the resident's status that will not normally resolve itself without further intervention by staff or by implementing standard disease-related clinical interventions, that has an impact on more than one area of the resident's health status, and requires interdisciplinary review or revision of the care plan, or both.)

INTENT §483.20(b)(2)(ii)
To ensure that each resident who experiences a significant change in status is comprehensively assessed using the CMS-specified Resident Assessment Instrument (RAI) process.

DEFINITIONS §483.20(b)(2)(ii)
"Significant Change" *is a major decline or improvement in a resident's status that 1) will not normally resolve itself without intervention by staff or by implementing standard disease-related clinical interventions; the decline is not considered "self-limiting" (**NOTE**: Self-limiting is when the condition will normally resolve itself without further intervention or by staff implementing standard clinical interventions to resolve the condition.); 2) impacts more than one area of the resident's health status; and 3) requires interdisciplinary review and/or revision of the care plan. This does not change the facility's requirement to immediately consult with a resident's physician of changes as required under 42 CFR 483.10(i)(14), F580.*

"Significant Change in Status Assessment (SCSA)" *is a comprehensive assessment that must be completed when the Interdisciplinary Team (IDT) has determined that a resident meets the significant change guidelines for either major improvement or decline.*

"Assessment Reference Date (ARD)" *is the specific end point for the look-back periods in the Minimum Data Set (MDS) assessment process. This look-back period is also called the observation or assessment period.*

Effective November 28, 2017

GUIDANCE **§483.20(b)(2)(ii)**
A SCSA including Care Area Assessments (CAAs) must be completed within 14 days after a determination has been made that a significant change in the resident's status from baseline occurred. This may be determined by comparison of the resident's current status to the most recent comprehensive assessment and most recent Quarterly assessment, and the resident's condition is not expected to return to baseline within 2 weeks. A SCSA is appropriate if there are either two or more MDS areas of decline or two or more MDS areas of improvement or if the IDT determines that the resident would benefit from the SCSA assessment and subsequent care plan revision. The facility should document in the medical record when the determination is made that the resident meets the criteria for a Significant Change in Status Assessment.

A *Significant Change in Status MDS* is *required* when:

- *A* resident *enrolls in a hospice program; or*
- *A resident changes hospice providers and remains in the facility; or*
- *A resident receiving hospice services discontinues those services; or*
- *A resident experiences a consistent pattern of changes, with* either **two or *more*** *areas of decline or* ***two or more*** *areas of improvement, from baseline (as indicated by comparison of the resident's current status to the most recent CMS-required MDS).*

Examples of Decline include, but are not limited to:

- *Resident's decision-making ability has changed;*
- *Presence of a resident mood item not previously reported by the resident or staff and/or an increase in the symptom frequency, e.g., increase in the number of areas where behavioral symptoms are coded as being present and/or the frequency of a symptom increases for items in Section E Behavior;*
- *Changes in frequency or severity of behavioral symptoms of dementia that indicate progression of the disease process since last assessment;*
- *Any decline in an ADL physical functioning area (at least 1) where a resident is newly coded as Extensive assistance, Total dependence, or Activity did not occur since last assessment and does not reflect normal fluctuations in that individual's functioning;*
- *Resident's incontinence pattern changes or there was placement of an indwelling catheter;*
- *Emergence of unplanned weight loss problem (5% change in 30 days or 10% change in 180 days).*
- *Emergence of a new pressure ulcer at Stage 2 or higher, a new unstageable pressure ulcer/injury, a new deep tissue injury or worsening in pressure ulcer status;*
- *Resident begins to use a restraint of any type, when it was not used before;*
- *Emergence of a condition/disease in which a resident is judged to be unstable.*

Examples of Improvement include, but are not limited to:

- *Any improvement in ADL physical functioning area (at least 1) where a resident is newly coded as Independent, Supervision, or Limited assistance since last assessment and does not reflect normal fluctuations in that individual's functioning;*
- *Decrease in the number of areas where behavioral symptoms are coded as being present and/or the frequency of a symptom decreases;*

- *Resident's decision making ability improves;*
- *Resident's incontinence pattern improves;*

If there is only one change, *the* resident may still benefit from a SCSA as determined by the IDT or as initiated by the resident based on changes in the care plan. It is important to remember that each resident's situation is unique. The facility must document a rationale, in the resident's medical record, for completing a SCSA that does not meet the criteria for completion.

The facility may not complete a SCSA until after a Comprehensive Admission assessment has been completed.

A Significant Change in Status MDS is considered timely when:

- *The RN Assessment Coordinator signs the MDS as complete at section Z0500B & V0200B2 by the 14th calendar day* ***after the determination*** *that a significant change has occurred (determination date + 14 calendar days).*

If a *SCSA MDS is completed*, the next annual assessment is not due until 366 days after the *ARD* of the significant *change in status* assessment.

NOTE: For information on assessment scheduling for the MDS, see Chapter 2 of the Long-Term Care Facility Resident Assessment Instrument *3.0* User's Manual. *Link to the LTCF RAI User's Manual: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursinghomeQualityInits/MDS30RAIManual.html.*

Circumstances when a change in resident status is ***not*** *significant include, but are not limited to:*

- *Short-term acute illness, such as a mild fever secondary to a cold from which the IDT expects the resident to fully recover.*
- *Well-established, predictable cyclical patterns of clinical signs and symptoms associated with previously diagnosed conditions (e.g., depressive symptoms in a resident previously diagnosed with bipolar disease would not precipitate a Significant Change Assessment).*
- *Instances in which the resident continues to make steady progress under the current course of care. Reassessment is required only when the condition has stabilized.*
- *Instances in which the resident has stabilized but is expected to be discharged in the immediate future. The facility has engaged in discharge planning with the resident and family, and a comprehensive reassessment is not necessary to facilitate discharge planning.*

PROBES §483.20(b)(2)(ii)

- *Did* the facility identif*y*, in a timely manner, those residents who experienced a *significant* change *in status*?
- *Is there documentation in the medical record when the determination was made that the resident met the criteria for a Significant Change in Status Assessment?*
- *Did* the facility reassess residents who had a significant change in status, using the *CMS*-specified RAI, within 14 days after determining the change was significant?

Effective November 28, 2017

F638
§483.20(c) Quarterly Review Assessment
A facility must assess a resident using the quarterly review instrument specified by the State and approved by CMS not less frequently than once every 3 months.

INTENT §483.20(c)
To assure *each* resident *is assessed using the standardized Quarterly Review assessment tool no less than once every 3 months between comprehensive assessments*.

DEFINITIONS §483.20(c)
"Quarterly Review Assessment" *is an OBRA '87-required, non-comprehensive assessment that must be completed at least every 92 days following the previous OBRA assessment of any type. It is used to track a resident's status between comprehensive assessments to ensure critical indicators of gradual change in a resident's status are monitored. As such, not all Minimum Data Set (MDS) items appear on the Quarterly assessment.*

GUIDANCE **§483.20(c)**
At least *every 92 day*s, the facility shall review each resident with respect to those MDS items specified *in the CMS* quarterly assessment *(MDS)*.

A Quarterly assessment is considered timely if:

- *The Assessment Reference Date (ARD) of the Quarterly MDS is* ***within 92 days*** *(ARD of most recent OBRA assessment +92 days) after the ARD of the previous OBRA assessment (Quarterly, Admission, Annual, Significant Change in Status, Significant Correction to Prior Comprehensive or Quarterly assessment)* ***AND***
- *The MDS completion date (Item Z0500B) must be* ***no later than*** *14 days after the ARD (ARD + 14 calendar days).*

If the resident has experienced a significant change in status, the next quarterly review is due no later than 3 months after the ARD of the *S*ignificant Change *in Status* Assessment.

For information on assessment scheduling for the MDS, see Chapter 2 of the Long-Term Care Facility Resident Assessment Instrument *3.0* User's Manual.

Link to the LTCF RAI User's Manual: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursinghomeQualityInits/MDS30RAIManual.html.

NOTE*: The Quarterly MDS does not require the completion of Care Area Assessments (CAAs). However, the resident's care plan must be reviewed and revised by the interdisciplinary team after each assessment as required at §483.21(b)(2)(iii).*

PROBES §483.20(c)

- *Does* the facility assess *residents, using the CMS-specified quarterly review assessment,* no less than once every 3 months, *between comprehensive assessments*?

Effective November 28, 2017

- *Is there evidence of resident and/or resident representative participation in the assessment process? Examples include participating in the resident interviews and providing information about preferences or discharge goals.*

F639
§483.20(d) Use
A facility must maintain all resident assessments completed within the previous 15 months in the resident's active record *and use the results of the assessments to develop, review and revise the resident's comprehensive care plan.*

INTENT §483.20(d)
Facilities are required to maintain 15 months of assessment data in *each* resident's active clinical record.

***GUIDANCE* §483.20(d)**
The requirement to maintain 15 months of data in the resident's active clinical record applies regardless of form of storage to all *Minimum Data Set* (MDS) records, including the *Care Area Assessment* (CAA) Summary, Quarterly Assessment records, Identification Information and Entry, Discharge and Reentry Tracking Records and MDS Correction Requests (including signed attestation). MDS assessments must be kept in the resident's active clinical record for 15 months following the final completion date for all assessments and correction requests. Other assessment types require maintaining them in the resident's active clinical record for 15 months following:

- The entry date for tracking records including re-entry; and
- The date of discharge or death for discharge and death in facility records.

Facilities may maintain MDS data electronically regardless of whether the entire clinical record is maintained electronically and regardless of whether the facility has an electronic signature process in place. This is in accordance with state and local law, and when this is authorized by the long- term care facility's policy.

Facilities that maintain their MDS data electronically and do not utilize an electronic signature process must ensure that hard copies of the MDS assessment signature pages are maintained for every MDS assessment conducted in the resident's active clinical record for 15 months. (This includes enough information to identify the resident and type and date of assessment linked with the particular assessment's signature pages),

The information, regardless of form of storage (i.e., hard copy or electronic), must be kept in a centralized location and must be readily and easily accessible. This information must be available to all professional staff members (including consultants) who need to review the information in order to provide care to the resident. (This information must also be made readily and easily accessible for review by the State Survey agency and CMS.) *Resident specific information must also be available to the individual resident; if there are concerns, please refer to F573.*

Effective November 28, 2017

After the 15-month period, RAI information may be thinned from the clinical record and stored in the medical records department, provided that it is easily retrievable if requested by clinical staff, the State agency, or CMS. ***NOTE**: States may have more stringent requirements for this process.*

If there are concerns about how the results of the resident assessment are used to develop, review and revise the resident's comprehensive care plan - See §483.21(b)(2)(iii), F657.

F640
§483.20(f) Automated data processing requirement-
§483.20(f)(1) Encoding data. Within 7 days after a facility completes a resident's assessment, a facility must encode the following information for each resident in the facility:

- **(i) Admission assessment.**
- **(ii) Annual assessment updates.**
- **(iii) Significant change in status assessments.**
- **(iv) Quarterly review assessments.**
- **(v) A subset of items upon a resident's transfer, reentry, discharge, and death.**
- **(vi) Background (face-sheet) information, if there is no admission assessment.**

§483.20(f)(2) Transmitting data. Within 7 days after a facility completes a resident's assessment, a facility must be capable of transmitting to the CMS System information for each resident contained in the MDS in a format that conforms to standard record layouts and data dictionaries, and that passes standardized edits defined by CMS and the State.

§483.20(f)(3) Transmittal requirements. Within 14 days after a facility completes a resident's assessment, a facility must electronically transmit encoded, accurate, and complete MDS data to the CMS System, including the following:

- **(i)Admission assessment.**
- **(ii) Annual assessment.**
- **(iii) Significant change in status assessment.**
- **(iv) Significant correction of prior full assessment.**
- **(v) Significant correction of prior quarterly assessment.**
- **(vi) Quarterly review.**
- **(vii) A subset of items upon a resident's transfer, reentry, discharge, and death.**
- **(viii) Background (face-sheet) information, for an initial transmission of MDS data on resident that does not have an admission assessment.**

§483.20(f)(4) Data format. The facility must transmit data in the format specified by CMS or, for a State which has an alternate RAI approved by CMS, in the format specified by the State and approved by CMS.

INTENT §483.20(f)(1-*4*)
To ensure that facilities have provided resident specific information for payment and quality measure purposes.

Effective November 28, 2017

To enable a facility to better monitor *each* resident's decline and progress over time. Computer-aided data analysis facilitates a more efficient, comprehensive and sophisticated review of health data.

DEFINITIONS §483.20(f)(1-4)

"Accurate" means that the encoded MDS data matches the MDS form in the clinical record. Also refer to guidance regarding accuracy at §483.20(g), and the information accurately reflects the resident's status as of the Assessment Reference Date (ARD).

"Background (face-sheet) information" refers to the MDS Entry tracking record

"Capable of transmitting" means that the facility has encoded and edited according to CMS specifications, the record accurately reflects the resident's overall clinical status as of the assessment reference date, and the record is ready for transmission.

"Complete" means that all items required according to the record type, and in accordance with CMS' record specifications and State required edits are in effect at the time the record is completed.

"Discharge subset of items" refers to the MDS Discharge assessment.

"Encoding" means entering information into *the facility MDS software in the* computer.

"Passing standard edits" means that the encoded responses to MDS items are consistent and within range, in accordance with CMS-specified standards. In general, inconsistent responses are either not plausible or ignore a skip pattern on the MDS. An example of inconsistency would be if one or more MDS items on a list were checked as present, and the "None of the Above" response was also checked for the same list. Out of range responses are invalid responses, such as using a response code of 2 for an MDS item for which the valid responses are zero or 1.

"Transmitted" means electronically transmitting to the *Quality Improvement Evaluation System (*QIES*) Assessment Submission and Processing (*ASAP*)* System, an MDS record that passes CMS' standard edits and is accepted into the system, within 14 days of the final completion date, or event date in the case of Entry and Death in Facility situations, of the record.

"Transmitting data" refers to electronically sending encoded MDS information, from the facility to the QIES ASAP System.

***GUIDANCE* §483.20(f)(1-*4*)**

Facilities are required to encode MDS data for each resident in the facility.

Facilities are required to electronically transmit MDS data to the CMS System for each resident in the facility. The CMS System for MDS data is named the QIES ASAP System.

Effective November 28, 2017

Facilities are responsible to edit the encoded MDS data to ensure that it meets the standard edit specifications.

For §483.20(f)(1)(v), the subset of items required upon a resident's entry, transfer, discharge and death are contained in the Entry and Death in Facility Tracking records and Discharge assessments. Refer to Chapter 2 of *the Long-Term Care Resident Assessment Instrument User's Manual* for further information about these records.

All nursing homes must computerize MDS information. The facility must edit MDS information using standard CMS-specified edits, revise the information to conform to the edits and to be accurate, and be capable of transmitting that data to the QIES ASAP system within 7 days:

- *For a comprehensive assessment (Admission, Annual, Significant Change in Status, and Significant Correction to Prior Comprehensive), encoding must occur within 7 days after the Care Plan Completion Date (V0200C2 + 7 days).*
- *For a Quarterly, Significant Correction to Prior Quarterly, Discharge, or PPS assessment, encoding must occur within 7 days after the MDS Completion Date (Z0500B + 7 days).*
- *For a tracking record, encoding should occur within 7 days of the Event Date (A1600 + 7 days for Entry records and A2000 + 7 days for Death in Facility records).*

Submission must be according to State and Federal time frames. Therefore the facility must:

- Encode the MDS and CAAs Summary (where applicable) in machine readable format; and
  - Edit the MDS and CAA Summary (where applicable) according to edits specified by CMS. Within the 7 day time period specified above for editing, the facility must revise any information on the encoded MDS and CAA Summary (if applicable) that does not pass CMS-specified edits, revise any otherwise inaccurate information, and make the information ready for submission. The MDS Vendor software used at the facility should have an automated editing process that alerts the user to entries in an MDS record that do not conform to the CMS-specified edits and that prompts the facility to complete revisions within the 7-day editing and revision period. After editing and revision, MDS information and CAA summary information (if applicable) must always accurately reflect the resident's overall clinical status as of the original ARD for an assessment or the original event date for a discharge or entry.

Electronically submit MDS information to the QIES ASAP system within 14 days:

- ***Assessment Transmission:*** *Comprehensive assessments must be transmitted electronically within 14 days of the Care Plan Completion Date (V0200C2 + 14 days). All other assessments must be submitted within 14 days of the MDS Completion Date (Z0500B + 14 days).*
- ***Tracking Information Transmission:*** *For Entry and Death in Facility tracking records, information must be transmitted within 14 days of the Event Date (A1600 + 14 days for Entry records and A2000 + 14 days for Death in Facility records).*

Effective November 28, 2017

Only CMS-required MDS assessments (e.g., OBRA and Medicare Part A PPS) are permitted to be transmitted into the QIES ASAP System. Assessments completed to meet third party payer (i.e. private insurance or managed care) requirements ***cannot*** *be transmitted to CMS. OBRA MDS assessments completed anytime a facility is NOT certified to participate in Medicare/Medicaid cannot be transmitted.*

PROCEDURES **§483.20(f)(1-*4*)**
If the surveyor suspects the facility is not encoding and submitting assessments as required, the surveyor should review the facility's MDS 3.0 NH Final Validation Report to verify assessment submission into the QIES ASAP System.

F641
§483.20(g) Accuracy of Assessments.
The assessment must accurately reflect the resident's status.

INTENT §483.20(g)
To assure that each resident receives an accurate assessment*, reflective of the resident's status at the time of the assessment,* by staff qualified to assess relevant care areas and are knowledgeable about the resident's status, needs, strengths, and areas of decline.

GUIDANCE **§483.20(g)**
"Accuracy of Assessment" means that the appropriate, qualified health professionals correctly document the resident's medical, functional, and psychosocial problems and identify resident strengths to maintain or improve medical status, functional abilities, and psychosocial status *using the appropriate Resident Assessment Instrument (RAI) (i.e. comprehensive, quarterly, significant change in status).*

Facilities are responsible for ensuring that all participants in the assessment process have the requisite knowledge to complete an accurate assessment.

The determination of appropriate participation of health professionals must be based on the physical, mental and psychosocial condition of *each* resident*. This includes an* appropriate level of involvement of physicians, nurses, rehabilitation therapists, activities professionals, medical social workers, dietitians, and other professionals, such as developmental disabilities specialists, in assessing the resident, and in correcting resident assessments. Involvement of other disciplines is dependent upon resident status and needs.

The assessment must represent an accurate picture of the resident's status during the observation period of the MDS. The Observation Period (also known as the Look-back period) is the time period over which the resident's condition or status is captured by the MDS assessment and ends at 11:59 p.m. on the day of the Assessment Reference Date (ARD). Be aware that different items on the MDS have different Observation Periods.

When the MDS is completed, only those occurrences during the observation period will be captured on the assessment. In other words, if it did not occur during the observation period, it is not coded on the MDS.

Effective November 28, 2017

The initial comprehensive assessment provides starting point data for ongoing assessment of resident progress.

PROBES §483.20(g)

- Based on your total review of the resident, *observations, interviews and record reviews*, *does* each portion of the *MDS* assessment accurate*ly reflect the resident's status as of the Assessment Reference Date?*
- *Is there evidence that the health professionals who assessed the resident had the skills and qualifications to conduct the assessment?* For example, has the resident's nutritional status been assessed by someone who is knowledgeable in nutrition and capable of correctly assessing a resident?

F642
§483.20(h) Coordination.
A registered nurse must conduct or coordinate each assessment with the appropriate participation of health professionals.

§483.20(i) Certification.
§483.20(i)(1) A registered nurse must sign and certify that the assessment is completed.

§483.20(i)(2) Each individual who completes a portion of the assessment must sign and certify the accuracy of that portion of the assessment.

§483.20(j) Penalty for Falsification.
§483.20(j)(1)Under Medicare and Medicaid, an individual who willfully and knowingly—

(i) Certifies a material and false statement in a resident assessment is subject to a civil money penalty of not more than $1,000 for each assessment; or
(ii) Causes another individual to certify a material and false statement in a resident assessment is subject to a civil money penalty or not more than $5,000 for each assessment.

§483.20(j)(2) Clinical disagreement does not constitute a material and false statement.

INTENT §483.20(h)-*(i)*
Each resident's assessment will be coordinated by and certified as complete by a registered nurse, and all individuals who complete a portion of the assessment will sign and certify to the accuracy of the portion of the assessment he or she completed.

GUIDANCE* §483.20(h)-*(j)
Whether *Minimum Data Set* (MDS) assessments are manually completed, or computer-generated following data entry, each individual assessor is responsible for certifying the accuracy of responses relative to the resident's condition and discharge or entry status. Manually completed forms are signed and dated by each individual assessor the day they complete their portion(s) of the *assessment.*

Effective November 28, 2017

Electronic Signatures
When MDS forms are completed directly on the facility's computer (i.e., no paper form has been manually completed), then each individual assessor signs and dates a computer-generated hard copy, or provides an electronic signature, after they review it for accuracy of the portion(s) they completed.

Facilities may use electronic signatures on the MDS when permitted to do so by state and local law and when this is authorized by the facility's policy. Additionally, *the facility* must have written policies in place to ensure proper security measures *are in place* to protect use of an electronic signature by anyone other than *the person* to which the electronic signature belongs. The policy must also ensure access to a hard copy of clinical records is made available to surveyors and others who are authorized access to clinical records by law*, including the resident and/or resident representative.*

Facilities that are not capable of maintaining the MDS signatures electronically must adhere to the current federal requirements *at §483.20(d)* addressing the need for either a hand-written copy or a computer-generated form. All state licensure and state practice regulations continue to apply to certified facilities.

NOTE: Where state law or regulations are more restrictive than federal requirements, the provider needs to apply the state law standard.

Backdating Completion Dates - Backdating completion dates is not acceptable – note that recording the actual date of completion is not considered backdating. For example, if an MDS was completed electronically and a hard copy was printed two days later, writing the date the MDS was completed on the hard copy is not considered backdating.

Patterns of MDS Assessment and Submissions
MDS information serves as the clinical basis for care planning and care delivery *and provides information for Medicare and Medicaid payment systems, quality monitoring and public reporting*. MDS information as it is reported impacts a nursing home's payment rate and standing in terms of the quality monitoring process. A *willfully and knowingly-provided* false assessment may be indicative of payment fraud or attempts to avoid reporting negative quality measures.

All information recorded within the MDS Assessment must reflect the resident's status at the time of the Assessment Reference Date (ARD).

A pattern within a nursing home of clinical documentation or of MDS assessment or reporting practices that result in higher *Resource Utilization Group* (RUG) scores, untriggering *Care Area Assessments* (CAAs) or unflagging Quality *Measures* (Q*M*s), where the information does not accurately reflect the resident's status, may be indicative of payment fraud or attempts to avoid reporting negative quality measures. Such practices may include, but are not limited to, a pattern or high prevalence of the following:

- Submitting MDS Assessments (including any reason(s) for assessment, routine or non routine) or tracking records, where the information does not accurately reflect the

resident's status as of ARD, or the Discharge or Entry date, as applicable;

- Submitting correction(s) to information in the *Quality Improvement Evaluation System Assessment Submission and Processing (*QIES ASAP*)* where the corrected information does not accurately reflect the resident's status as of the original ARD, or the original Discharge or Entry date, as applicable, or where the record it claims to correct does not appear to have been in error;
- Submitting Significant Correction Assessments where the assessment it claims to correct does not appear to have been in error;
- Submitting Significant Change in Status Assessments where the criteria for significant change in the resident's status do not appear to be met;
- Delaying or withholding MDS Assessments (including any reason(s) for assessment, routine or non-routine), Discharge or Entry Tracking information, or correction(s) to information in the QIES ASAP system.

PROCEDURES AND PROBES §483.20(h)-(j)

- *When such patterns or practices are noticed, they should be reported by the State Agency to the Regional Office and Medicaid Fraud Control Unit.*
- Are the appropriate certifications in place, including the RN Coordinator's certification of completion of an MDS assessment or Correction Request, and the certification of individual assessors of the accuracy and completion of the portion(s) of the assessment or tracking record completed?

F644
§483.20(e) Coordination.
A facility must coordinate assessments with the pre-admission screening and resident review *(PASARR)* program under Medicaid in subpart C *of this part* to the maximum extent practicable to avoid duplicative testing and effort. *Coordination includes:*

§483.20(e)*(1)Incorporating the recommendations from the PASARR level II determination and the PASARR evaluation report into a resident's assessment, care planning, and transitions of care.*

§483.20(e)*(2) Referring all level II residents and all residents with newly evident or possible serious mental disorder, intellectual disability, or a related condition for level II resident review upon a significant change in status assessment.*

INTENT §483.20(e)
To ensure that the facility coordinates with the appropriate, State-designated authority, to ensure that individuals with a mental disorder, intellectual disability or a related condition receives care and services in the most integrated setting appropriate to their needs.

DEFINITIONS §483.20(e)
***"Intellectual Disability (ID)"** is defined in 42 CFR 483.102(b)(3), as follows:*
An individual is considered to have intellectual disability (ID) if he or she has—

(i) A level of retardation (mild, moderate, severe or profound) described in the American Association on Intellectual's Disability Manual on Classification in Intellectual

Disability (1983);or

(ii) A related condition as defined by §435.1010 of this chapter.

"Mental Disorder (MD)" *For purposes of this section, the term "mental disorder" is the equivalent of "mental illness" used in the definition of serious mental illness in 42 CFR 483.102(b)(1), which states:*

An individual is considered to have a serious mental illness (MI) if the individual meets the following requirements on diagnosis, level of impairment and duration of illness:

(i) Diagnosis. The individual has a major mental disorder diagnosable under the Diagnostic and Statistical Manual of Mental Disorders, 3rd edition, revised in 1987.

This mental disorder is—

(A) A schizophrenic, mood, paranoid, panic or other severe anxiety disorder; somatoform disorder; personality disorder; other psychotic disorder; or another mental disorder that may lead to a chronic disability; but

(B) Not a primary diagnosis of dementia, including Alzheimer's disease or a related disorder, or a non-primary diagnosis of dementia unless the primary diagnosis is a major mental disorder as defined in paragraph (b)(1)(i)(A) of this section.

(ii) Level of impairment. The disorder results in functional limitations in major life activities within the past 3 to 6 months that would be appropriate for the individual's developmental stage. An individual typically has at least one of the following characteristics on a continuing or intermittent basis:

(A) Interpersonal functioning. The individual has serious difficulty interacting appropriately and communicating effectively with other persons, has a possible history of altercations, evictions, firing, fear of strangers, avoidance of interpersonal relationships and social isolation;

(B) Concentration, persistence, and pace. The individual has serious difficulty in sustaining focused attention for a long enough period to permit the completion of tasks commonly found in work settings or in work-like structured activities occurring in school or home settings, manifests difficulties in concentration, inability to complete simple tasks within an established time period, makes frequent errors, or requires assistance in the completion of these tasks; and

(C) Adaptation to change. The individual has serious difficulty in adapting to typical changes in circumstances associated with work, school, family, or social interaction, manifests agitation, exacerbated signs and symptoms associated with the illness, or withdrawal from the situation, or requires intervention by the mental health or judicial system.

(iii) Recent treatment. The treatment history indicates that the individual has experienced at least one of the following:

(A) Psychiatric treatment more intensive than outpatient care more than once in the past 2 years (e.g., partial hospitalization or inpatient hospitalization); or

(B) Within the last 2 years, due to the mental disorder, experienced an episode of significant disruption to the normal living situation, for which supportive services were required to maintain functioning at home, or in a residential treatment environment, or which resulted in intervention by housing or law enforcement officials.

Effective November 28, 2017

"Persons with Related Conditions" *is defined in 42 CFR 435.1010 as follows:*
Persons with related conditions means individuals who have a severe, chronic disability that meets all of the following conditions:

(a) It is attributable to—
- *(1) Cerebral palsy or epilepsy; or*
- *(2) Any other condition, other than a mental illness, found to be closely related to Intellectual Disability because this condition results in impairment of general intellectual functioning or adaptive behavior similar to that of mentally retarded persons, and requires treatment or services similar to those required for these persons.*

(b) It is manifested before the person reaches age 22.

(c) It is likely to continue indefinitely.

(d) It results in substantial functional limitations in three or more of the following areas of major life activity:
- *(1) Self-care.*
- *(2) Understanding and use of language.*
- *(3) Learning.*
- *(4) Mobility.*
- *(5) Self-direction.*
- *(6) Capacity for independent living.*

"Preadmission Screening and Resident Review (PASARR)" *is a federal requirement to help ensure that individuals who have a mental disorder or intellectual disabilities are not inappropriately placed in nursing homes for long term care. PASARR requires that 1) all applicants to a Medicaid-certified nursing facility be evaluated for a serious mental disorder and/or intellectual disability; 2) be offered the most appropriate setting for their needs (in the community, a nursing facility, or acute care setting); and 3) receive the services they need in those settings. Regulations governing PASARR are found at 42 CFR §§483.100-483.138.*

"Specialized Services for MD or ID" *means the services specified by the State that exceed the services ordinarily provided by the nursing facility (NF) under its per diem rate. These services must be provided or arranged by the state and could include hiring additional staff or contractors such as qualified mental health/intellectual disability professionals. When specialized services are combined with services provided by the nursing facility, the result is a continuous and aggressive implementation of an individualized plan of care for individuals with MD or ID. The resident's Level II PASARR identifies the specialized services required by the resident.*

GUIDANCE **§483.20(e)**

With respect to the responsibilities under the Pre-Admission Screening and Resident Review (PASARR) program, the State is responsible for conducting the screens, preparing the PASARR report, and providing or arranging the specialized services that are needed as a result of conducting the screens. The State is required to provide a copy of the PASARR report to the facility. This report must list the specialized services that the individual requires and that are the responsibility of the State to provide. All other needed services are the responsibility of the facility to provide.

Effective November 28, 2017

The PASARR process requires that all applicants to Medicaid-certified nursing facilities be screened for possible serious mental disorders or intellectual disabilities and related conditions. This initial pre-screening is referred to as PASARR Level I, and is completed prior to admission to a nursing facility. A negative Level I screen permits admission to proceed and ends the PASARR process unless a possible serious mental disorder or intellectual disability arises later. A positive Level 1 screen necessitates an in-depth evaluation of the individual by the state-designated authority, known as PASARR Level II, which must be conducted prior to admission to a nursing facility.

PASARR Level II is a comprehensive evaluation by the appropriate state-designated authority and determines whether the individual has MD, ID or a related condition, determines the appropriate setting for the individual and recommends what, if any, specialized services and/or rehabilitative services the individual needs.

The Level II evaluation report must be used by the facility when conducting assessments of the resident, developing the care plan, and when transitions of care occur. Incorporating the Level II information in these processes promotes comprehensive assessment and provision of care for residents with MD or ID.

The State must provide or arrange for the provision of specialized services to all NF residents with MD or ID in accordance with §483.120, whose needs are such that continuous supervision, treatment and training by qualified mental health or intellectual disability personnel is necessary, as identified in the resident's PASARR Level II. Specialized services provided or arranged by the State may be provided in the NF or through off-site visits arranged by the NF, while the resident lives in the facility.

The facility must notify the state-designated mental health or intellectual disability authority promptly when a resident with MD or ID experiences a significant change in mental or physical status. For additional information regarding resident referral after a significant change in status, see requirements at §483.20(k)(4), F646, MD/ID significant change notification.

Any resident with newly evident or possible serious mental disorder, ID or a related condition must be referred, by the facility to the appropriate state-designated mental health or intellectual disability authority for review.

*Examples of individuals who may not have previously been identified by PASARR to have MD, ID or a related condition include: **NOTE**: this is not an exhaustive list. (RAI Manual 2-29)*

- *A resident who exhibits behavioral, psychiatric, or mood related symptoms suggesting the presence of a mental disorder (where dementia is not the primary diagnosis).*
- *A resident whose intellectual disability or related condition was not previously identified and evaluated through PASARR.*
- *A resident transferred, admitted, or readmitted to a NF following an inpatient psychiatric stay or equally intensive treatment.*

Effective November 28, 2017

PROBES §483.20(e)

- *For residents with a Level II determination and recommendations, has the facility incorporated the determination and recommendations into the resident's assessment and care plan?*
- *How does the facility identify residents with newly evident or possible serious mental disorder, ID or a related condition?*
- *If a resident was identified with newly evident or possible serious MD, ID or a related condition, did the facility refer the resident to the appropriate state-designated authority for review?*
- *Is there evidence that the facility provides the next care setting with the resident's PASARR Level II recommendations when a resident with MD or ID transitions to another care setting?*
- *Has the facility arranged for the resident to receive specialized services through off-site visits, if appropriate, to meet the resident's needs as identified in the resident's PASARR Level II recommendations?*

F645

§483.20(*k*) Preadmission Screening for individuals *with a mental disorder* and individuals with *intellectual disability*.

§483.20(*k*)(1) A nursing facility must not admit, on or after January 1, 1989, any new residents with:

(i) Mental *disorder* as defined in paragraph *(k)(3)(i)* of this section, unless the State mental health authority has determined, based on an independent physical and mental evaluation performed by a person or entity other than the State mental health authority, prior to admission,

(A) That, because of the physical and mental condition of the individual, the individual requires the level of services provided by a nursing facility; and

(B) If the individual requires such level of services, whether the individual requires specialized services; or

(ii) *Intellectual disability*, as defined in paragraph *(k)(3)(ii)* of this section, unless the State *intellectual disability* or developmental disability authority has determined prior to admission—

(A) That, because of the physical and mental condition of the individual, the individual requires the level of services provided by a nursing facility; and

(B) If the individual requires such level of services, whether the individual requires specialized services for intellectual disability.

§483.20(*k*)*(2) Exceptions. For purposes of this section-*

(i)The preadmission screening program under paragraph(k)(1) of this section need not provide for determinations in the case of the readmission to a nursing facility of an individual who, after being admitted to the nursing facility, was transferred for care in a hospital.

(ii) The State may choose not to apply the preadmission screening program under paragraph (k)(1) of this section to the admission to a nursing facility of an individual-

(A) Who is admitted to the facility directly from a hospital after receiving acute inpatient care at the hospital,
(B) Who requires nursing facility services for the condition for which the individual received care in the hospital, and
(C) Whose attending physician has certified, before admission to the facility that the individual is likely to require less than 30 days of nursing facility services.

§483.20(*k*)(*3*) Definition. For purposes of this section-
(i) An individual is considered to have *a* mental *disorder* if the individual has a serious mental *disorder* defined in 483.102(b)(1).
(ii) An individual is considered to *have an intellectual disability* if the individual *has an intellectual disability* as defined in §483.102(b)(3) or is a person with a related condition as described in 435.1010 of this chapter.

INTENT §483.20(*k*)(1)-(3)
To ensure each resident in a nursing facility is screened for a mental disorder (MD) or intellectual disability (ID) prior to admission and that individuals identified with MD or ID are evaluated and receive *care and services in the most integrated setting appropriate to their needs*.

DEFINITIONS §483.20(*k*)(1)-(3)
"Intellectual Disability (ID)" *is defined in 42 CFR 483.102(b)(3) as follows:*
An individual is considered to have intellectual disability (ID) if he or she has—
(i) A level of retardation (mild, moderate, severe or profound) described in the American Association on Intellectual's Disability Manual on Classification in Intellectual Disability (1983);or
(ii) A related condition as defined by §435.1010 of this chapter.

"Mental Disorder (MD)" *For purposes of this section, the term "mental disorder" is the equivalent of "mental illness" used in the definition of serious mental illness in 42 CFR 483.102(b)(1), which states:*
An individual is considered to have a serious mental illness (MI) if the individual meets the following requirements on diagnosis, level of impairment and duration of illness:
(i) Diagnosis. The individual has a major mental disorder diagnosable under the Diagnostic and Statistical Manual of Mental Disorders, 3rd edition, revised in 1987.
This mental disorder is—
(A) A schizophrenic, mood, paranoid, panic or other severe anxiety disorder; somatoform disorder; personality disorder; other psychotic disorder; or another mental disorder that may lead to a chronic disability; but
(B) Not a primary diagnosis of dementia, including Alzheimer's disease or a related disorder, or a non-primary diagnosis of dementia unless the primary diagnosis is a major mental disorder as defined in paragraph (b)(1)(i)(A) of this section.
(ii) Level of impairment. The disorder results in functional limitations in major life activities within the past 3 to 6 months that would be appropriate for the individual's developmental stage. An individual typically has at least one of the following characteristics on a continuing or intermittent basis:
(A) Interpersonal functioning. The individual has serious difficulty interacting

appropriately and communicating effectively with other persons, has a possible history of altercations, evictions, firing, fear of strangers, avoidance of interpersonal relationships and social isolation;

(B) Concentration, persistence, and pace. The individual has serious difficulty in sustaining focused attention for a long enough period to permit the completion of tasks commonly found in work settings or in work-like structured activities occurring in school or home settings, manifests difficulties in concentration, inability to complete simple tasks within an established time period, makes frequent errors, or requires assistance in the completion of these tasks; and

(C) Adaptation to change. The individual has serious difficulty in adapting to typical changes in circumstances associated with work, school, family, or social interaction, manifests agitation, exacerbated signs and symptoms associated with the illness, or withdrawal from the situation, or requires intervention by the mental health or judicial system.

(iii) Recent treatment. The treatment history indicates that the individual has experienced at least one of the following:

(A) Psychiatric treatment more intensive than outpatient care more than once in the past 2 years (e.g., partial hospitalization or inpatient hospitalization); or

(B) Within the last 2 years, due to the mental disorder, experienced an episode of significant disruption to the normal living situation, for which supportive services were required to maintain functioning at home, or in a residential treatment environment, or which resulted in intervention by housing or law enforcement officials.

***"Persons with Related Conditions"** is defined in 42 CFR 435.1010 as follows:*
Persons with related conditions means individuals who have a severe, chronic disability that meets all of the following conditions:

(a) It is attributable to—

(1) Cerebral palsy or epilepsy; or

(2) Any other condition, other than a mental illness, found to be closely related to Intellectual Disability because this condition results in impairment of general intellectual functioning or adaptive behavior similar to that of mentally retarded persons, and requires treatment or services similar to those required for these persons.

(b) It is manifested before the person reaches age 22.

(c) It is likely to continue indefinitely.

(d) It results in substantial functional limitations in three or more of the following areas of major life activity:

(1) Self-care.

(2) Understanding and use of language.

(3) Learning.

(4) Mobility.

(5) Self-direction.

(6) Capacity for independent living.

Effective November 28, 2017

"Preadmission Screening and Resident Review (PASARR)" *is a federal requirement to help ensure that individuals are not inappropriately placed in nursing homes for long term care. PASARR requires that 1) all applicants to a Medicaid-certified nursing facility be evaluated for serious mental disorder and/or intellectual disability; 2) be offered the most appropriate setting for their needs (in the community, a nursing facility, or acute care setting); and 3) receive the services they need in those settings. Regulations governing PASARR are found at 42 CFR §483.100-483.138.*

"Specialized Services for MD or ID" *means the services specified by the State that exceed the services ordinarily provided by the nursing facility (NF) under its per diem rate. These services must be provided or arranged by the state and could include hiring additional staff or contractors such as qualified mental health/intellectual disability professionals. When specialized services are combined with services provided by the nursing facility, the result is a continuous and aggressive implementation of an individualized plan of care for individuals with MD or ID. The resident's Level II PASARR identifies the specialized services required by the resident.*

"Rehabilitative services for MD or ID" *refers to those services of lesser frequency or intensity to be implemented by all levels of nursing facility staff that come into contact with any resident who has as mental disorder or who has intellectual disability. These services are necessary regardless of whether or not they are specified in the PASARR Level II documents and whether or not the resident requires additional services to be provided or arranged for by the State.*

GUIDANCE §483.20(k)(1)-(3)
The PASARR process requires that all applicants to Medicaid-certified nursing facilities be screened for possible serious mental disorders, intellectual disabilities and related conditions. This initial screening is referred to as Level I Identification of individuals with MD or ID (§483.128) and is completed prior to admission to a nursing facility. The purpose of the Level I pre-admission screening is to identity individuals who have or may have MD/ID or a related condition, who would then require PASARR Level II evaluation and determination prior to admission to the facility.

A negative Level I screen permits admission to proceed and ends the pre-screening process unless possible serious mental disorder or intellectual disability arises later. A positive Level 1 screen necessitates an in-depth evaluation of the individual, by the state-designated authority, known as Level II PASARR, which must be conducted prior to admission to the facility.

Failure to pre-screen residents prior to admission to the facility may result in the failure to identify residents who have or may have MD, ID or a related condition. A record of the pre-screening should be retained in the resident's medical record.

Individuals who have or are suspected to have MD, ID or a related condition (as indicated by a positive Level 1 screen) may not be admitted to a Medicaid-certified nursing facility unless approved based on Level II PASARR evaluation and determination. Exceptions to this requirement are specified in §483.20(k)(2) and may be exercised at the discretion of the State, as specified in the State's PASARR process.

Effective November 28, 2017

Level II PASARR is a comprehensive evaluation conducted by the appropriate state-designated authority that determines whether an individual has MD, ID or a related condition as defined above, determines the appropriate setting for the individual, and recommends what, if any, specialized services and/or rehabilitative services the individual needs. The Level II PASARR cannot be conducted by the nursing facility.

Each State Medicaid Agency has specific processes for conducting Level I screens and Level II PASARR evaluations and determinations. Exceptions to the pre-screening requirements are specified in §483.20(k)(2) and may be exercised at the discretion of the State, as specified in the State's PASARR process. Facility staff and surveyors should be acquainted with their States' requirements.

If the State program permits the use of the exceptions specified in §483.20(k)(2), and the resident remains in the facility longer than 30 days, the facility must screen the individual using the State's Level I screening process and refer any resident who has or may have MD, ID or a related condition to the appropriate state-designated authority for Level II PASARR evaluation and determination. ***NOTE****: under 42 CFR 483.106(b)(2)(ii), If an individual who enters a NF as an exception (an exempted hospital discharge) is later found to require more than 30 days of NF care, the State mental health or intellectual disability authority must conduct a Level II resident review within 40 calendar days of admission.*

The State is responsible for providing *or arranging for* specialized services *for* residents with M*D or* ID residing in Medicaid-certified facilities. The facility is required to provide all other care and services appropriate to the resident's condition. Therefore, if a facility has residents with M*D or* ID, do not survey for specialized services, but survey for all other requirements, including resident rights, quality of life, and quality of care.

PROCEDURES AND PROBES §483.20(k)(1)-(3)

- *If the resident's Level II PASSR report indicates that he or she needs specialized services but the resident is not receiving them, the State Survey Agency would notify the State-designated mental health or intellectual disability authority that evaluated the resident prior to admission. NF services alone are not ordinarily of the intensity to meet the needs of residents with MD or ID.*
- *Is there evidence of Level I pre-screening of residents prior to admission to the nursing facility to identify residents who have or may have MD, ID or a related condition, who requires Level II PASARR evaluation?*
- *Are residents with a positive Level I PASARR screen evaluated by the designated state-authority, through the Level II PASARR process, and approved for admission* ***prior*** *to admission to the nursing facility?*
- *If pre-admission screening of residents expected to be in the facility 30 days or less is not performed, in accordance with the State PASARR process, does the facility screen residents who have or may have MD, ID or a related condition, if the resident remains in the facility longer than 30 days? Are residents who have a positive screen then referred to the appropriate state-authority for Level II evaluation and determination?*

Effective November 28, 2017

If *the resident has a* M*D* or ID, did the State Mental Health or Intellectual Disabilities Authority determine:

- Whether the residents needed the services of a nursing facility
- Whether the residents need specialized services for their M*D* or ID?

DEFICIENCY CATEGORIZATIONS

Severity Level 4 Considerations: Immediate Jeopardy to Resident Health or Safety

An example of Level 4, immediate jeopardy to resident health and safety, include, but is not limited to:

- *A resident with bipolar disorder was newly admitted to the facility prior to Level II PASARR evaluation and determination. The facility's failure to ensure the Level II PASARR process was completed prior to admission resulted in the resident no longer receiving needed psychotherapy 4 times per week. The interruption in receiving needed psychotherapy services caused the resident to relapse into a depressive state, during which the resident engaged in social withdrawal and self-cutting behaviors resulting in hospitalization of the resident.*

Severity Level 3 Considerations: Actual Harm that is not Immediate Jeopardy

An example of Level 3, actual harm that is not immediate jeopardy includes but is not limited to:

- *The facility failed to ensure Level 1 pre-screening of a new resident for MD/ID or a related condition prior to admission to the facility. The resident had cerebral palsy, which is a related condition. The lack of pre-screening resulted in the resident's condition not being identified prior to admission and the resident not being evaluated through the Level II PASARR process. The resident did not receive the specialized rehabilitation services she needed which resulted in a decline in her function.*

Severity Level 2 Considerations: No Actual Harm with Potential for More Than Minimal Harm that is Not Immediate Jeopardy

An example of Level 2, no actual harm, with potential for more than minimal harm, that is not immediate jeopardy, includes, but is not limited to:

- *The facility failed to ensure Level 1 pre-screening of new residents for MD/ID or a related condition, prior to admission to the facility. While the residents did not have MD/ID or a related condition, the facility admitted the residents without knowing if the residents had one of these conditions. The failure to determine whether the residents had MD/ID or a related condition had the potential to cause more than minimal harm to new and/or current residents.*

Severity Level 1: No Actual Harm with Potential for Minimal Harm

Failure to ensure residents are pre-screened for MD/ID or a related condition, prior to admission to the facility, could prevent the resident from attaining or maintaining his/her highest practicable level or result in a decline in the resident's physical, mental or psychosocial well-being. Therefore, Severity Level 1 does not apply for this regulatory requirement.

F646

§483.20(*k*)*(4)* *A nursing facility must notify the state mental health authority or state intellectual disability authority, as applicable, promptly after a significant change in the*

mental or physical condition of a resident who has mental illness or intellectual disability for resident review.

INTENT §483.20(k)(4)
To ensure that individuals with a mental disorder or intellectual disabilities continue to receive the care and services they need in the most appropriate setting, when a significant change in their status occurs.

DEFINITIONS §483.20(k)(4)
"Preadmission Screening and Resident Review (PASARR)" *is a federal requirement to help ensure that individuals who have a mental disorder or intellectual disabilities are not inappropriately placed in nursing homes for long term care. PASARR requires that 1) all applicants to a Medicaid-certified nursing facility be evaluated for a serious mental disorder and/or intellectual disability; 2) be offered the most appropriate setting for their needs (in the community, a nursing facility, or acute care setting); and 3) receive the services they need in those settings. Regulations governing PASARR are found at 42 CFR §483.100-138.*

"Significant Change" *is a major decline or improvement in a resident's status that 1) will not normally resolve itself without intervention by staff or by implementing standard disease-related clinical interventions; the decline is not considered "self-limiting" (**NOTE**: Self-limiting is when the condition will normally resolve itself without further intervention or by staff implementing standard clinical interventions to resolve the condition.); 2) impacts more than one area of the resident's health status; and 3) requires interdisciplinary review and/or revision of the care plan. This does not change the facility's requirement to immediately consult with a resident's physician of changes as required under 42 CFR 483.10(i)(14), F580.*

"Significant Change in Status Assessment (SCSA)" *is a comprehensive assessment for a resident that must be completed when the Interdisciplinary Team (IDT) has determined that a resident meets the significant change guidelines for either improvement or decline.*

GUIDANCE §483.20(k)(4)
As part of the Pre-Admission Screening and Resident Review (PASARR) process, the facility is required to notify the appropriate state mental health authority or state intellectual disability authority when a resident with a mental disorder (MD) or intellectual disability (ID) has a significant change in their physical or mental condition.

The nursing facility must notify the state mental health (SMH)/ID authority of significant changes in residents with MD or ID independent of the findings of the SCSA. PASARR Level II is to function as an independent assessment process for this population with special needs, in parallel with the facility's assessment process. Nursing facilities should know their State's PASARR policy on referral to the SMH/ID authority, so that these authorities may exercise their expert judgment about when a Level II evaluation is needed.

Referral to the SMH/ID authority should be made as soon as the criteria indicative of a significant change are evident — the facility should not wait until the SCSA is complete.

Effective November 28, 2017

Facilities should look to their state PASARR program requirements for specific procedures. PASARR contact information for the SMH/ID authorities and the State Medicaid Agency is available at http://www.pasrrassist.org/resources/personnel/pasrr-state-lead-contact-information.

Referral for Level II resident review evaluation is required for individuals previously identified by PASARR to have a mental disorder, intellectual disability, or a related condition who experience a significant change. Examples of such changes include, but are not limited to:

- *A resident who demonstrates increased behavioral, psychiatric, or mood-related symptoms.*
- *A resident with behavioral, psychiatric, or mood-related symptoms that have not responded to ongoing treatment.*
- *A resident who experiences an improved medical condition—such that the residents' plan of care or placement recommendations may require modifications.*
- *A resident whose significant change is physical, but has behavioral, psychiatric, or mood-related symptoms, or cognitive abilities, that may influence adjustment to an altered pattern of daily living.*
- *A resident whose condition or treatment is or will be significantly different than described in the resident's most recent PASARR Level II evaluation and determination. (Note that a referral for a possible new Level II PASARR evaluation is required whenever such a disparity is discovered, whether or not associated with a SCSA.)*

Requirements for the completing a SCSA are found at §483.20(b)(2)(ii), F637, comprehensive assessment after significant change.

PROBES §483.20(k)(4)

- *When a significant change in status was identified in a resident with a mental disorder or intellectual disability, was the appropriate state mental health or intellectual disability authority promptly notified?*
- *Does the facility have a process in place to notify the appropriate state mental health or intellectual disability authority when a resident with a Level II PASARR has a significant change in his or her mental or physical status?*

F655

§483.21 Comprehensive Person-Centered Care Planning

§483.21(a) Baseline Care Plans

§483.21(a)(1) The facility must develop and implement a baseline care plan for each resident that includes the instructions needed to provide effective and person-centered care of the resident that meet professional standards of quality care. The baseline care plan must—

(i) Be developed within 48 hours of a resident's admission.

(ii) Include the minimum healthcare information necessary to properly care for a resident including, but not limited to—

(A) Initial goals based on admission orders.

(B) Physician orders.

(C) Dietary orders.

(D) Therapy services.

(E) Social services.
(F) PASARR recommendation, if applicable.

§483.21(a)(2) The facility may develop a comprehensive care plan in place of the baseline care plan if the comprehensive care plan—

(i) Is developed within 48 hours of the resident's admission.
(ii) Meets the requirements set forth in paragraph (b) of this section (excepting paragraph (b)(2)(i) of this section).

§483.21(a)(3) The facility must provide the resident and their representative with a summary of the baseline care plan that includes but is not limited to:

(i) The initial goals of the resident.
(ii) A summary of the resident's medications and dietary instructions.
(iii) Any services and treatments to be administered by the facility and personnel acting on behalf of the facility.
(iv) Any updated information based on the details of the comprehensive care plan, as necessary.

INTENT §483.21(a)
Completion and implementation of the baseline care plan within 48 hours of a resident's admission is intended to promote continuity of care and communication among nursing home staff, increase resident safety, and safeguard against adverse events that are most likely to occur right after admission; and to ensure the resident and representative, if applicable, are informed of the initial plan for delivery of care and services by receiving a written summary of the baseline care plan.

GUIDANCE §483.21(a)
Nursing homes are required to develop a baseline care plan within the first 48 hours of admission which provides instructions for the provision of effective and person-centered care to each resident. This means that the baseline care plan should strike a balance between conditions and risks affecting the resident's health and safety, and what is important to him or her, within the limitations of the baseline care plan timeframe.

Person-centered care means the facility focuses on the resident as the center of control, and supports each resident in making his or her own choices. Person-centered care includes making an effort to understand what each resident is communicating, verbally and nonverbally, identifying what is important to each resident with regard to daily routines and preferred activities, and having an understanding of the resident's life before coming to reside in the nursing home.

The baseline care plan must include the minimum healthcare information necessary to properly care for each resident immediately upon their admission, which would address resident-specific health and safety concerns to prevent decline or injury, such as elopement or fall risk, and would identify needs for supervision, behavioral interventions, and assistance with activities of daily living, as necessary. Baseline care plans are required to address, at a minimum, the following:

- *Initial goals based on admission orders.*
- *Physician orders.*
- *Dietary orders.*
- *Therapy services.*
- *Social services.*
- *PASARR recommendation, if applicable.*

The baseline care plan must reflect the resident's stated goals and objectives, and include interventions that address his or her current needs. It must be based on the admission orders, information about the resident available from the transferring provider, and discussion with the resident and resident representative, if applicable. Because the baseline care plan documents the interim approaches for meeting the resident's immediate needs, professional standards of quality care would dictate that it must also reflect changes to approaches, as necessary, resulting from significant changes in condition or needs, occurring prior to development of the comprehensive care plan. Facility staff must implement the interventions to assist the resident to achieve care plan goals and objectives.

Facilities may complete a comprehensive care plan instead of the baseline care plan. In this circumstance, the completion of the comprehensive care plan will not override the RAI process, and must be completed and implemented within 48 hours of admission and comply with the requirements for a comprehensive care plan at §483.21(b), with the exception of the requirement at (b)(2)(i) requiring the completion of the comprehensive care plan within 7 days of completion of the comprehensive assessment. If a comprehensive care plan is completed in lieu of the baseline care plan, a written summary of the comprehensive care plan must be provided to the resident and resident representative, if applicable, and in a language that the resident/representative can understand.

If the facility completes a comprehensive care plan instead of the baseline care plan, review the requirements of the comprehensive care plan at §483.21(b). If the care plan does not meet the requirements of §483.21(b), cite at the appropriate corresponding tag(s):

- *F656 Develop Comprehensive Care Plan*
- *F657 Care Plan Timing and Revision*
- *F658 Services Provided Meet Professional Standards*
- *F659 Qualified Persons*

Baseline Care Plan Summary

The facility must provide the resident and the representative, if applicable with a written summary of the baseline care plan by completion of the comprehensive care plan. The summary must be in a language and conveyed in a manner the resident and/or representative can understand. This summary must include:

- *Initial goals for the resident;*
- *A list of current medications and dietary instructions, and*
- *Services and treatments to be administered by the facility and personnel acting on behalf of the facility;*

The format and location of the summary is at the facility's discretion, however, the medical record must contain evidence that the summary was given to the resident and resident

representative, if applicable. The facility may choose to provide a copy of the baseline care plan itself as the summary, as long as it meets all of the requirements of the summary.

Given that the baseline care plan is developed before the comprehensive assessment, it is possible that the goals and interventions may change. In the event that the comprehensive assessment and comprehensive care plan identified a change in the resident's goals, or physical, mental, or psychosocial functioning, which was otherwise not identified in the baseline care plan, those changes must be incorporated into an updated summary provided to the resident and his or her representative, if applicable.

As the resident remains in the nursing home, additional changes will be made to the comprehensive care plan based on the assessed needs of the resident, however, these subsequent changes will not need to be reflected in the summary of the baseline care plan. Once the comprehensive care plan has been developed and implemented, and a summary of the updates given to the resident, the facility is no longer required to revise/update the written summary of the baseline care plan. Rather, each resident will remain actively engaged in his or her care planning process through the resident's rights to participate in the development of, and be informed in advance of changes to the care plan; see the care plan; and sign the care plan after significant changes. Refer to §483.10(c) for guidance related to Resident Rights and Facility Responsibilities regarding Planning and Implementing Care.

INVESTIGATIVE SUMMARY AND PROBES §483.21(a)

- *Use the Critical Element (CE) Pathway associated with the issue under investigation, or if there is no specific CE Pathway, use the General CE Pathway, along with the above interpretive guidelines when determining if the facility meets the requirements for, or investigating concerns related to the facility's requirement develop and implement a Baseline Care Plan. If systemic concerns are identified with Baseline Care Plans, use the probes below to assist in your investigation.*
- *Was the baseline care plan developed and implemented within 48 hours of admission to the facility?*
- *Does the resident's baseline care plan include:*
  - *The resident's initial goals for care;*
  - *The instructions needed to provide effective and person-centered care that meets professional standards of quality care;*
  - *The resident's immediate health and safety needs;*
  - *Physician and dietary orders;*
  - *PASARR recommendations, if applicable; and*
  - *Therapy and social services.*
- *Was the baseline care plan revised and updated as needed to meet the resident's needs until the comprehensive care plan was developed?*
- *If the resident experienced an injury or adverse event prior to the development of the comprehensive care plan, should the baseline care plan have identified the risk for the injury/event (i.e., if risk factors were known or obvious)?*
- *Did the facility provide the resident and his or her representative, if applicable, with a written summary of the baseline care plan that contained at least, without limitation:*
  - *Initial goals of the resident;*

- *A summary of current medications and dietary instructions;*
- *Services and treatments to be provided or arranged by the facility and personnel acting on behalf of the facility; and*
- *Any updated information based on details of the admission comprehensive assessment.*

F656
§483.21(b) Comprehensive Care Plans
§483.21(b)**(1) The facility must develop *and implement* a comprehensive *person-centered* care plan for each resident, *consistent with the resident rights set forth at §483.10(c)(2) and §483.10(c)(3),* that includes measurable objectives and time*frames* to meet a resident's medical, nursing, and mental and psychosocial needs that are identified in the comprehensive assessment. The comprehensive care plan must describe the following —**

(i) The services that are to be furnished to attain or maintain the resident's highest practicable physical, mental, and psychosocial well-being as required under *§483.24*, §483.25 *or §483.40;* and

(ii) Any services that would otherwise be required under *§483.24,* §483.25 *or §483.40* but are not provided due to the resident's exercise of rights under §483.10, including the right to refuse treatment under §483.10(*c*)(*6*).

(iii) Any specialized services or specialized rehabilitative services the nursing facility will provide as a result of PASARR recommendations. If a facility disagrees with the findings of the PASARR, it must indicate its rationale in the resident's medical record.

(iv)In consultation with the resident and the resident's representative(s)—

(A) The resident's goals for admission and desired outcomes.

(B) The resident's preference and potential for future discharge. Facilities must document whether the resident's desire to return to the community was assessed and any referrals to local contact agencies and/or other appropriate entities, for this purpose.

(C) Discharge plans in the comprehensive care plan, as appropriate, in accordance with the requirements set forth in paragraph (c) of this section.

INTENT §483.21(b)
Each resident will have a person-centered comprehensive care plan developed and implemented to meet his other preferences and goals, and address the resident's medical, physical, mental and psychosocial needs.

DEFINITIONS §483.21(b)
"Resident's Goal": *The resident's desired outcomes and preferences for admission, which guide decision making during care planning.*

"Interventions"*: Actions, treatments, procedures, or activities designed to meet an objective.*

"Measurable": *The ability to be evaluated or quantified.*

"Objective": *A statement describing the results to be achieved to meet the resident's goals.*

Effective November 28, 2017

"Person-centered care": *means to focus on the resident as the locus of control and support the resident in making their own choices and having control over their daily lives.*

GUIDANCE* §483.*21(b)

Through the care planning process, facility staff must work with the resident and his/her representative, if applicable, to understand and meet the resident's preferences, choices and goals during their stay at the facility. The facility must establish, document and implement the care and services to be provided to each resident to assist in attaining or maintaining his or her highest practicable quality of life. Care planning drives the type of care and services that a resident receives. If care planning is not complete, or is inadequate, the consequences may negatively impact the resident's quality of life, as well as the quality of care and services received.

Facilities are required to develop care plans that describe the resident's medical, nursing, physical, mental and psychosocial needs and preferences and how the facility will assist in meeting these needs and preferences. Care plans must include person-specific, measurable objectives and timeframes in order to evaluate the resident's progress toward his/her goal(s).

Care plans must be person-centered and reflect the resident's goals for admission and desired outcomes. Person-centered care means the facility focuses on the resident as the center of control, and supports each resident in making his or her own choices. Person-centered care includes making an effort to understand what each resident is communicating, verbally and nonverbally, identifying what is important to each resident with regard to daily routines and preferred activities, and having an understanding of the resident's life before coming to reside in the nursing home.

Residents' goals set the expectations for the care and services he or she wishes to receive. For example, a resident admitted for rehabilitation may have the following goal – "Receive the necessary care and services so that I may return to independent living." Another resident may have a goal of receiving the necessary care and services to meet needs they cannot independently achieve, while maintaining as much independence as possible. And yet another resident or his or her representative, if applicable, may have a goal of receiving the necessary care and services to keep the resident comfortable and pain-free at the end of their life. Each of these examples would be supported by measurable objectives, interventions and timeframes designed to meet each specific resident goal.

Measurable objectives describe the steps toward achieving the resident's goals, and can be measured, quantified, and/or verified. For example, "Mrs. Jones, who underwent hip replacement, will report adequate pain control (as evidenced by pain at 1-3, on a scale of 1-10) throughout her SNF stay." Facility staff will use this objective to monitor the resident's progress.

The comprehensive care plan must reflect interventions to enable each resident to meet his/her objectives. Interventions are the specific care and services that will be implemented. Interventions for the example above, related to pain, may include, but are not limited to:

- *Evaluate pain level using pain scale (0-10) 45 minutes after administering pain medication;*
- *Administer pain medication 45-60 minutes prior to physical therapy.*

When developing the comprehensive care plan, facility staff must, at a minimum, use the Minimum Data Set (MDS) to assess the resident's clinical condition, cognitive and functional status, and use of services.

If a Care Area Assessment (CAA) is triggered, the facility must further assess the resident to determine whether the resident is at risk of developing, or currently has a weakness or need associated with that CAA, and how the risk, weakness or need affects the resident. Documentation regarding these assessments and the facility's rationale for deciding whether or not to proceed with care planning for each area triggered must be recorded in the medical record.

There may be times when a resident risk, weakness or need is identified within the context of the MDS assessment, but may not cause a CAA to trigger. The facility is responsible for addressing these areas and must document the assessment of these risks, weaknesses or needs in the medical record and determine whether or not to develop a care plan and interventions to address the area. If the decision to proceed to care planning is made, the interdisciplinary team (IDT), in conjunction with the resident and/or resident's representative, if applicable,, must develop and implement the comprehensive care plan and describe how the facility will address the resident's goals, preferences, strengths, weaknesses, and needs.

NOTE: *Although Federal requirements dictate the completion of RAI assessments according to certain time frames, standards of good clinical practice dictate that the clinical assessment process is more fluid and should be ongoing. The lack of ongoing clinical assessment and identification of changes in condition, to meet the resident's needs between required RAI assessments should be addressed at 483.35 Nursing Services, F726 (competency and skills to identify and address a change in condition), and the relevant outcome tag, such as 483.12 Abuse, 483.24 Quality of Life, 483.25 Quality of Care, and/or 483.40 Behavioral Health.*

In some cases, a resident may wish to refuse certain services or treatments that professional staff believes may be indicated to assist the resident in reaching his or her highest practicable level of well-being or to keep the resident safe. *In situations where a resident's choice to decline care or treatment (e.g., due to preferences, maintain autonomy, etc.) poses a risk to the resident's health or safety, the comprehensive care plan must identify the care or service being declined, the risk the declination poses to the resident, and efforts by the interdisciplinary team to educate the resident and the representative, as appropriate. The facility's attempts to find alternative means to address the identified risk/need should be documented in the care plan.* See guidelines at §483.10(c)(6) *(F578)* for additional guidance concerning *the resident's decision to* refuse treatment. *Additionally, a resident's decision-making ability may decline over time. The facility must determine how the resident's decisions may increase risks to health and safety, evaluate the resident's decision making capacity, and involve the interdisciplinary team and the resident's representative, if applicable, in the care planning process.*

Effective November 28, 2017

In addition to addressing preferences and needs assessed by the MDS, the comprehensive care plan must coordinate with and address any specialized services or specialized rehabilitation services the facility will provide or arrange as a result of PASARR recommendations. If the IDT disagrees with the findings of the PASARR, it must indicate its rationale in the resident's medical record. The rationale should include an explanation of why the resident's current assessed needs are inconsistent with the PASARR recommendations and how the resident would benefit from alternative interventions. The facility should also document a resident's the resident's preference for a different approach to achieve goals or refusal of recommended services.

Residents' preferences and goals may change throughout their stay, so facilities should have ongoing discussions with the resident and resident representative, if applicable, so that changes can be reflected in the comprehensive care plan.

The comprehensive care plan must address a resident's preference for future discharge, as early as upon admission, to ensure that each resident is given every opportunity to attain his/her highest quality of life. This encourages facilities to operate in a person-centered fashion that addresses resident choice and preferences.

***INVESTIGATIVE SUMMARY AND* PROBES §483.21(b)**

Use the Critical Element (CE) Pathway associated with the issue under investigation, or if there is no specific CE Pathway, use the General Critical Element Pathway, along with the above interpretive guidelines when determining if the facility meets the requirements for, or investigating concerns related to the facility's requirement to develop and implement a Comprehensive Care Plan. If systemic concerns are identified with Comprehensive Care Plans, use the probes below to assist in your investigation.

- Does the care plan address the *goals, preferences,* needs *and* strengths *of the resident, including those* identified in the comprehensive resident assessment, *to assist the resident to attain or maintain his or her highest practicable well-being and prevent avoidable decline*?
- *Are objectives and interventions person-centered, measurable, and do they include time frames to achieve the desired outcomes?*
- *Is there evidence of resident and, if applicable resident representative participation (or attempts made by the facility to encourage participation) in developing person-centered, measurable objectives and interventions?*
- *Does the care plan describe specialized services and interventions to address PASARR recommendations, as appropriate?*
- *Is there evidence that the care plan interventions were implemented consistently across all shifts?*
- *Is there a process in place to ensure direct care staff are aware of and educated about the care plan interventions?*
- Determine whether the facility has provided adequate information to the resident and*, if applicable* resident representative so that he/she was able to make informed choices regarding treatment and services.
- *Evaluate whether* the care plan reflects the facility's efforts to find alternative means to address *care of the resident if he or she has refused treatment.*

Effective November 28, 2017

POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION

For *concerns regarding the delivery of care within professional standards of practice*, see §483.21(b)(3) *in F-tag F658.*

If the surveyor identifies concerns about the resident's care plan being individualized and person-centered, the surveyor should also review requirements at:

- *Resident assessment, §483.20*
- *Activities, §483.24(c)*
- *Nursing services, §483.35*
- *Food and nutrition services, §483.60*
- *Facility assessment, §483.70(e)*

Key Elements of Noncompliance §483.21(b): To cite deficient practice at F656, the surveyor's investigation will generally show that the facility failed to do one or more of the following:

Develop and implement a care plan that:

- *Is comprehensive and individualized;*
- *Is consistent with the resident's goals and right to be informed and participate in his/her treatment;*
- *Meets each of the medical, nursing, mental and psychosocial needs identified on the resident's comprehensive assessment;*
- *Includes measurable objectives, interventions and timeframes for how staff will meet the resident's needs.*

Develop and implement a care plan that describes all of the following:

- *Resident goals and desired outcomes;*
- *The care/services that will be furnished so that the resident can attain or maintain his/her highest practicable physical, mental and psychosocial well-being;*
- *The specialized services to be provided as a result of the PASARR evaluation and/or the comprehensive assessment;*
- *The resident's discharge plan and any referrals to the local contact agency;*
- *Refusals of care and action taken by facility staff to educate the resident and resident representative, if applicable, regarding alternatives and consequences.*

DEFICIENCY CATEGORIZATION

Examples of Level 4, immediate jeopardy to resident health and safety, include, but are not limited to:

- *A resident has a known history of inappropriate sexual behaviors and aggression, but the comprehensive care plan did not address the resident's inappropriate sexual behaviors or aggression which placed the resident and other residents in the facility at risk for serious physical and/or psychosocial injury, harm, impairment, or death.*
- *The facility failed to implement care plan interventions to monitor a resident with a known history of elopement attempts, which resulted in the resident leaving the building unsupervised, putting the resident at risk for serious injury or death.*

Effective November 28, 2017

Examples of Level 3, actual harm that is not immediate jeopardy include, but are not limited to:

- *The CAA Summary for a resident indicates the need for a care plan to be developed to address nutritional risks in a resident who had poor nutritional intake. A care plan was not developed, or the care plan interventions did not address the problems/risks identified. The lack of interventions caused the resident to experience weight loss.*
- *Lack of care plan interventions to address a resident's anxiety, depression, and hallucinations resulted in psychosocial harm to the resident*

Examples of Level 2, no actual harm, with potential for than more than minimal harm, that is not immediate jeopardy, include, but are not limited to:

- *During the comprehensive assessment, a resident indicated a desire to participate in particular activities, but the comprehensive care plan did not address the resident's preferences for activities, which resulted in the resident complaining of being bored, and sometimes feeling sad about not participating in activities he/she expressed interest in attending.*
- *An inaccurate or incomplete care plan resulted in facility staff providing one staff to assist the resident, when the resident required the assistance of two staff, which had the potential to cause more than minimal harm.*

An example of Level 1, no actual harm with potential for no more than a minor negative impact on the resident, includes, but is not limited to:

- *For one or more care plans, the staff did not include a measurable objective, which resulted in no more than a minor negative impact on the involved residents.*

F657

§483.21(b) Comprehensive Care Plans

§483.21(b)(2) **A comprehensive care plan must be—**

(i) Developed within 7 days after completion of the comprehensive assessment.

(ii) **Prepared by an interdisciplinary team, that includes** ***but is not limited to--***

(A) **The attending physician.**

(B) **A registered nurse with responsibility for the resident.**

(C) A nurse aide with responsibility for the resident.

(D) A member of food and nutrition services staff.

(E) **To the extent practicable, the participation of the resident** ***and the resident's representative(s). An explanation must be included in a resident's medical record if the participation of the resident and their resident representative is determined not practicable for the development of the resident's care plan.***

(F) **Other appropriate staff** ***or professionals*** **in disciplines as determined by the resident's needs** ***or as requested by the resident.***

(iii)Reviewed and revised by the interdisciplinary team after each assessment, including both the comprehensive and quarterly review assessments.

INTENT of §483.21(b)(2)

To ensure the timeliness of each resident's person-centered, comprehensive care plan, and to ensure that the comprehensive care plan is reviewed and revised by an interdisciplinary team

composed of individuals who have knowledge of the resident and his/her needs, and that each resident and resident representative, if applicable, is involved in developing the care plan and making decisions about his or her care.

DEFINITIONS
"Non-physician practitioner (NPP)" *is a nurse practitioner (NP), clinical nurse specialist (CNS), or physician assistant (PA).*

GUIDANCE §483.*21(b)(2)*
*Facility staff must develop the comprehensive care plan within seven days of the completion of the comprehensive assessment (Admission, Annual or Significant Change in Status) and review and revise the care plan after each assessment. "**After each assessment"** means after each assessment known as the Resident Assessment Instrument (RAI) or Minimum Data Set (MDS) as required by §483.20, except discharge assessments. For newly admitted residents, the comprehensive care plan must be completed within seven days of the completion of the comprehensive assessment and no more than 21 days after admission.*

As used in this requirement, "Interdisciplinary" means that professional disciplines, as appropriate, will work together to provide the greatest benefit to the resident. It does not mean that every goal must have an interdisciplinary approach. The mechanics of how the interdisciplinary team *(IDT)* meets its responsibilities in developing an interdisciplinary care plan (e.g., a face-to-face meeting, teleconference, written communication) is at the discretion of the facility. *In instances where an IDT member participates in care plan development, review or revision via written communication, the written communication in the medical record must reflect involvement of the resident and resident representative, if applicable, and other members of the IDT, as appropriate.*

The IDT must, at a minimum, consist of the resident's attending physician, a registered nurse and nurse aide with responsibility for the resident, a member of the food and nutrition services staff, and to the extent possible, the resident and resident representative, if applicable. If the *attending* physician *is unable to participate in the development of the care plan,, he/she* may *delegate participation to an NPP who is involved in the resident's care, to the extent permitted by state law, or* arrange *alternative methods of* providing input in the development and revision of the care plan, such as one-on-one discussions*, videoconferencing* and conference calls with the IDT.

The determination of other appropriate staff or professionals participation in the IDT should be based on the physical, mental and psychosocial condition of each resident. This includes an appropriate level of involvement of physicians, nurses, rehabilitation therapists, activities professionals, social workers, and other professionals, such as developmental disabilities specialists or spiritual advisor. Involvement of other individuals is dependent upon resident request and/or needs.

Each resident *has the* right to participate in choosing treatment options and must be *given* the opportunity to participate *in the development, review and revision of his/her care plan*. *Residents also have* the right to refuse treatment.

Effective November 28, 2017

Facility *staff have* a responsibility to assist residents to *engage in the care planning process*, e.g., helping residents and *resident* representatives, *if applicable* understand the assessment and care planning process; holding care planning meetings at the time of day when the resident is functioning best; planning enough time for information exchange and decision making; encouraging a resident's *representative to participate in care planning and* attend *care planning conferences*.

The facility must provide the resident and resident representative, if applicable with advance notice of care planning conferences to enable resident/resident representative participation. Resident and resident representative participation in care planning can be accomplished in many forms such as holding care planning conferences at a time the resident representative is available to participate, holding conference calls or video conferencing.

Facilities are expected to facilitate the residents' and if applicable, the resident representatives' participation in the care planning process. There are limited circumstances in which the inclusion of the resident and/or resident representative may not be practicable (or feasible). An example may be the case of a severely cognitively impaired resident who is unable to understand or participate in care plan development, and the resident's representative does not respond to facility attempts to make contact. If the facility determines that the inclusion of the resident and/or resident representative is not practicable, documentation of the reasons, including the steps the facility took to include the resident and/or resident representative, must be included in the medical record.

While Federal regulations at §483.10(c) affirm the resident's right to participate in care planning, request and/or refuse treatment, the regulations do not create the right for a resident or *resident* representative*, if applicable*, to demand that the facility use specific medical intervention*s* or treatment*s* that the facility deems *not medically necessary and/or reasonable.*

The resident's care plan must be reviewed after each assessment, as required by §483.20, except discharge assessments, and revised based on changing goals, preferences and needs of the resident and in response to current interventions.

NOTE: *Although Federal requirements dictate the completion of RAI assessments according to certain time frames, standards of good clinical practice dictate that the clinical assessment process is more fluid and should be ongoing. The lack of ongoing clinical assessment and identification of changes in condition, to meet the resident's needs between required RAI assessments should be addressed at 483.35 Nursing Services, F726 (competency and skills to identify and address a change in condition), and the relevant outcome tag, such as 483.12 Abuse, 483.24 Quality of Life, 483.25 Quality of Care, and/or 483.40 Behavioral Health.*

For concerns related to the resident's rights to participate in planning and implementing his or her care, see requirements at §483.10(c).

Effective November 28, 2017

INVESTIGATIVE SUMMARY AND PROBES §483.*21(b)(2)*

Use the Critical Element (CE) Pathway associated with the issue under investigation, or if there is no specific CE Pathway, use the General Critical Element Pathway, along with the above interpretive guidelines when determining if the facility meets the requirements for, or investigating concerns related to the facility's requirement for timely completion and IDT and resident involvement in the development of the Comprehensive Care Plan. If systemic concerns are identified with timeliness and IDT/resident involvement in the development of Comprehensive Care Plans, use the probes below to assist in your investigation.

- *Was a comprehensive plan of care developed within seven days of completion of the resident's comprehensive assessment?*
- Is *there evidence of participation in the care planning process by required IDT members?*
- *Ask required members of the IDT how they participate in the development, review and revision of care plans.*
- *Based on the resident's goals and needs, were other appropriate staff or professionals'* expertise utilized to develop a plan to improve the resident's functional abilities?

For example:

a. Did an occupational therapist *recommend* needed adaptive equipment or a speech therapist provide techniques to improve swallowing ability?

b. D*id* the dietitian and speech therapist determine the optimum textures and consistency for the resident's food that is nutritionally adequate and *compatible* with the resident's oropharyngeal capabilities *and food preferences*?

- Is there evidence of *attending* physician involvement in development of the care plan (e.g., presence at care plan meetings, conversations with team members concerning the care plan, conference calls, written communication)?
- How do staff make an effort to schedule care plan meetings at the best time of the day for residents and *if applicable, the resident representatives?*
- How do staff make the *care plan* process understandable to the resident *and resident representative, if applicable*?
- *Ask the resident and resident representative, if applicable if he or she actively participates in the care planning process? If not, what have been the barriers to participation?*
- *Ask the resident and if applicable, the resident representative if he or she has requested the participation of additional individuals care planning process. If so, was the request respected?*
- In what ways does staff involve the resident and *if applicable, the* resident representative in care planning? *If staff determine that the resident and/or resident representative involvement in care planning is not practicable, is the reason and the steps the facility took to include the resident and/or resident representative documented in the medical record?*
- *Is there evidence that the care plan is evaluated for effectiveness and revised following each required assessment, except discharge assessments, and as needed?*

Effective November 28, 2017

DEFICIENCY CATEGORIZATION

An example of Level 4, immediate jeopardy to resident health or safety, includes, but is not limited to:

- *The resident's care plan was not revised following a significant change assessment which identified an occurrence of resident-to resident sexual abuse, placing the abused resident and other residents at risk for serious injury, impairment or death.*

An example of Level 3, actual harm that is not immediate jeopardy includes, but is not limited to:

- *The facility failed to develop the comprehensive care plan within seven days of completion of the comprehensive assessment. This resulted in the resident sustaining a laceration requiring stitches due to a fall because appropriate fall prevention interventions were not implemented timely.*

Examples of Level 2, no actual harm with potential for than more than minimal harm that is not immediate jeopardy, include, but are not limited to:

- *Residents and their representatives, if applicable, are not routinely invited to participate in care planning. While the resident did not experience an actual decline in physical, mental, or psychosocial functioning and continued to meet goals established on the care plan, the care plan goals did not show evidence of resident and if applicable, the resident representative input, having the potential for more than minimal harm.*
- *Direct-care staff were not made aware of revisions to the resident's care plan by the IDT for three days to assist the resident in brushing his teeth. This resulted in staff not assisting the resident with brushing his teeth for three days, and the resident did not suffer actual harm.*

Examples of Level 1, no actual harm with potential for no more than a minor negative impact on the resident, include, but are not limited to:

- *Care plan was not reviewed by the IDT after the resident's quarterly assessment indicated a minor change in the resident's status..*
- *A required member of the IDT did not participate in development of the resident's care plan, which had no more than a minor negative impact to the resident.*

F658

§483.21(b)(3) Comprehensive Care Plans

The services provided or arranged by the facility, *as outlined by the comprehensive care plan,* must—

(i) Meet professional standards of quality.

INTENT §483.*21(b)(3)(i)*

The intent of this regulation is to assure that services being provided meet professional standards of quality.

GUIDANCE §483.*21(b)(3)(i)*

"Professional standards of quality" means *that care and* services are provided according to accepted standards of clinical practice. Standards may apply to care provided by a particular

clinical discipline or in a specific clinical situation or setting. Standards regarding quality care practices may be published by a professional organization, licensing board, accreditation body or other regulatory agency. Recommended practices to achieve desired resident outcomes may also be found in clinical literature. Possible reference sources for standards of practice include:

- Current manuals or textbooks on nursing, social work, physical therapy, etc.
- Standards published by professional organizations such as the American Dietetic Association, American Medical Association, American Medical Directors Association, American Nurses Association, National Association of Activity Professionals, National Association of Social Work, etc.
- Clinical practice guidelines published by the Agency for Healthcare Research and Quality.
- Current professional journal articles.

NOTE: *Although Federal requirements dictate the completion of RAI assessments according to certain time frames, standards of good clinical practice dictate that the clinical assessment process is more fluid and should be ongoing. The lack of ongoing clinical assessment and identification of changes in condition, to meet the resident's needs between required RAI assessments should be addressed at 483.35 Nursing Services, F726 (competency and skills to identify and address a change in condition), and the relevant outcome tag, such as 483.12 Abuse, 483.24 Quality of Life, 483.25 Quality of Care, and/or 483.40 Behavioral Health..*

PROCEDURES AND PROBES §483.*21(b)(3)(i)*

There is no requirement for the surveyor to cite a reference or source (e.g., current textbooks, professional organizations or clinical practice guidelines) for the standard of practice that has not been followed related to care and services provided within professional scopes of practice, such as failure of nursing staff to assess a change in the resident's condition. However, in cases where the facility provides a reference supporting a particular standard of practice for which the surveyor has concerns, the surveyor must provide evidence that the standard of practice the facility is using is not up-to-date, widely accepted, or supported by recent clinical literature. Such evidence should include a citation for the reference or source (e.g., current textbooks, professional organizations or clinical practice guidelines) for the current standard of practice from which facility deviated.

If a negative *or potentially negative* resident outcome is determined to be related to the facility's failure to meet professional standards and the team determines a deficiency has occurred, it should *also* be cited under the appropriate quality of care or other relevant requirement. *For example, if a resident develops a pressure injury because the facility's nursing staff failed to provide care in accordance with professional standards of quality, the team should cite the deficiency at both F658 and F686 (Skin Integrity).*

- *Do the services provided or arranged by the facility, as outlined in the comprehensive care plan, reflect accepted standards of practice?*
- *Are the references for standards of practice, used by the facility, up to date, and accurate for the service being delivered?*

Effective November 28, 2017

KEY ELEMENTS OF NONCOMPLIANCE:
To cite deficient practice at F658, the surveyor's investigation will generally show that the facility did one or more of the following:

- *Provided or arranged for services or care that did not adhere to accepted standards of quality;*
- *Provided a service or care when the accepted standards of quality dictate that the service or care should not have been provided;*
- *Failed to provide or arrange for services or care that accepted standards of quality dictate should have been provided.*

F659
§483.21(b)(3) Comprehensive Care Plans
The services provided or arranged by the facility, *as outlined by the comprehensive care plan,* must—

(ii) Be provided by qualified persons in accordance with each resident's written plan of care.
(iii) Be culturally-competent and trauma–informed.
[§483.21(b)(iii) will be implemented beginning November 28, 2019 (Phase 3)]

GUIDANCE §483.*21(b)(3)(ii)*
The facility must ensure that services provided or arranged are delivered by individuals who have the skills, experience and knowledge to do a particular task or activity. This includes proper licensure or certification, if required.

PROCEDURES AND* PROBES §483.*21(b)(3)(ii)
NOTE: *Provision of services by qualified individuals would be cited here, but implementation of the care plan would be cited in F656.*

- *Are the services identified in the comprehensive care plan being provided by qualified persons?*
- *Do staff assigned to the resident have the skills, experience and knowledge to provide care and services that meet the resident's needs?*

DEFICIENCY CATEGORIZATION
An example of Level 4, immediate jeopardy to resident health or safety includes, but is not limited to:

- *The facility had no qualified staff on duty knowledgeable or competent in how to care for a resident with a tracheostomy, posing a risk for serious injury, harm, impairment or death for the resident.*

An example of Level 3, actual harm that is not immediate jeopardy includes, but is not limited to:

- *The facility utilized a staff member who was not qualified to draw a resident's blood, according to the resident's care plan, resulting in the resident sustaining extensive bruising, swelling, pain and decreased ability to use the arm after the blood draw*

An example of Level 2, no actual harm with potential for than more than minimal harm that is not immediate jeopardy includes, but is not limited to:

- *The facility failed to ensure staff were qualified to perform blood pressure (BP) readings. During survey, staff were observed taking and reporting resident BPs that were abnormal. After further investigation, it was determined that staff were using the incorrect size BP cuff, yielding inaccurate BP readings, resulting in the potential for more than minimal harm.*

Non-compliance with this regulation places the resident at risk for more than minimal harm. Therefore, Severity Level 1 does not apply for this regulatory requirement.

F660

§483.21(c)(1) Discharge Planning Process

The facility must develop and implement an effective discharge planning process that focuses on the resident's discharge goals, the preparation of residents to be active partners and effectively transition them to post-discharge care, and the reduction of factors leading to preventable readmissions. The facility's discharge planning process must be consistent with the discharge rights set forth at 483.15(b) as applicable and—

(i) Ensure that the discharge needs of each resident are identified and result in the development of a discharge plan for each resident.

(ii) Include regular re-evaluation of residents to identify changes that require modification of the discharge plan. The discharge plan must be updated, as needed, to reflect these changes.

(iii) Involve the interdisciplinary team, as defined by §483.21(b)(2)(ii), in the ongoing process of developing the discharge plan.

(iv) Consider caregiver/support person availability and the resident's or caregiver's/support person(s) capacity and capability to perform required care, as part of the identification of discharge needs.

(v) Involve the resident and resident representative in the development of the discharge plan and inform the resident and resident representative of the final plan.

(vi) Address the resident's goals of care and treatment preferences.

(vii) Document that a resident has been asked about their interest in receiving information regarding returning to the community.

(A) If the resident indicates an interest in returning to the community, the facility must document any referrals to local contact agencies or other appropriate entities made for this purpose.

(B) Facilities must update a resident's comprehensive care plan and discharge plan, as appropriate, in response to information received from referrals to local contact agencies or other appropriate entities.

(C) If discharge to the community is determined to not be feasible, the facility must document who made the determination and why.

(viii) For residents who are transferred to another SNF or who are discharged to a HHA, IRF, or LTCH, assist residents and their resident representatives in selecting a post-acute care provider by using data that includes, but is not limited to SNF, HHA, IRF, or LTCH standardized patient assessment data, data on quality measures, and data on resource use to the extent the data is available. The facility must ensure that the post-

acute care standardized patient assessment data, data on quality measures, and data on resource use is relevant and applicable to the resident's goals of care and treatment preferences.

(ix) Document, complete on a timely basis based on the resident's needs, and include in the clinical record, the evaluation of the resident's discharge needs and discharge plan. The results of the evaluation must be discussed with the resident or resident's representative. All relevant resident information must be incorporated into the discharge plan to facilitate its implementation and to avoid unnecessary delays in the resident's discharge or transfer.

INTENT §483.21(c)(1)

This requirement intends to ensure that the facility has a discharge planning process in place which addresses each resident's discharge goals and needs, including caregiver support and referrals to local contact agencies, as appropriate, and involves the resident and if applicable, the resident representative and the interdisciplinary team in developing the discharge plan.

DEFINITIONS §483.21(c)(1)

"Discharge Planning": *A process that generally begins on admission and involves identifying each resident's discharge goals and needs, developing and implementing interventions to address them, and continuously evaluating them throughout the resident's stay to ensure a successful discharge.*

"Home Health Agency (HHA): *a public agency or private organization (or a subdivision of either) which is primarily engaged in providing skilled nursing services and other therapeutic services in the patient's home and meets the requirements of sections 1861(o) and 1891 of the Social Security Act.*

"Inpatient Rehabilitation Facility (IRF): *are freestanding rehabilitation hospitals or rehabilitation units in acute care hospitals that serve an inpatient population requiring intensive services for treatment.*

"Local Contact Agency": *refers to each State's designated community contact agencies that can provide individuals with information about community living options and available supports and services. These local contact agencies may be a single entry point agency, such as an Aging and Disability Resource Center (ADRC), an Area Agency on Aging (AAA), a Center for Independent Living (CIL), or other state designated entities.*

"Long Term Care Hospital (LTCH): *are certified as acute-care hospitals, but focus on patients who, on average, stay more than 25 days. Many of the patients in LTCHs are transferred there from an intensive or critical care unit. LTCHs specialize in treating patients who may have more than one serious condition, but who may improve with time and care, and return home.*

"Patient Assessment Data": *standardized, publicly available information derived from a post-acute care provider's patient/resident assessment instrument, e.g., Minimum Data Set (MDS), Outcome and Assessment Information Set (OASIS).*

Effective November 28, 2017

GUIDANCE §483.21(c)(1)
Discharge Planning
Discharge planning is the process of creating an individualized discharge care plan, which is part of the comprehensive care plan. It involves the interdisciplinary team (as defined in §483.21(b)(2)(ii) working with the resident and resident representative, if applicable, to develop interventions to meet the resident's discharge goals and needs to ensure a smooth and safe transition from the facility to the post-discharge setting. Discharge planning begins at admission and is based on the resident's assessment and goals for care, desire to be discharged, and the resident's capacity for discharge. It also includes identifying changes in the resident's condition, which may impact the discharge plan, warranting revisions to interventions. A well-executed discharge planning process, without avoidable complications, maximizes each resident's potential to improve, to the extent possible, based on his or her clinical condition. An inadequate discharge planning process may complicate the resident's recovery, lead to admission to a hospital, or even result in the resident's death.

The discharge care plan is part of the comprehensive care plan and must:

- *Be developed by the interdisciplinary team and involve direct communication with the resident and if applicable, the resident representative;*
- *Address the resident's goals for care and treatment preferences;*
- *Identify needs that must be addressed before the resident can be discharged, such as resident education, rehabilitation, and caregiver support and education;*
- *Be re-evaluated regularly and updated when the resident's needs or goals change;*
- *Document the resident's interest in, and any referrals made to the local contact agency;*
- *Identify post-discharge needs such as nursing and therapy services, medical equipment or modifications to the home, or ADL assistance*

Resident Discharge to the Community
Section Q of the Minimum Data Set (MDS) requires that individuals be periodically assessed for their interest in being transitioned to community living, unless the resident indicates otherwise. See: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/NHQIMDS30TrainingMaterials.html.
For residents who want to be discharged to the community, the nursing home must determine if appropriate and adequate supports are in place, including capacity and capability of the resident's caregivers at home. Family members, significant others or the resident's representative should be involved in this determination, with the resident's permission, unless the resident is unable to participate in the discharge planning process.
Each situation is unique to the resident, his/her family, and/or guardian/legally authorized representative. A referral to the Local Contact Agency (LCA) may be appropriate for many individuals, who could be transitioned to a community setting of their choice. The nursing home staff is responsible for making referrals to the LCA, if appropriate, under the process that the State has established. Nursing home staff should also make the resident and if applicable, the resident representative aware that the local ombudsman is available to provide information and assist with any transitions from the nursing home.
For residents who have been in the facility for a longer time, it is still important to inquire, as appropriate, whether the resident would like to talk with LCA experts about returning to the

community. New or improved community resources and supports may have become available since the resident was first admitted which may now enable the resident to return to a community setting.

If the resident is unable to communicate his or her preference or is unable to participate in discharge planning, the information should be obtained from the resident's representative.

Discharge planning must include procedures for:

- *Documentation of referrals to local contact agencies, the local ombudsman, or other appropriate entities made for this purpose;*
- *Documentation of the response to referrals; and*
- *For residents for whom discharge to the community has been determined to not be feasible, the medical record must contain information about who made that decision and the rationale for that decision.*

Discharge planning must identify the discharge destination, and ensure it meets the resident's health and safety needs, as well as preferences. If a resident wishes to be discharged to a setting that does not appear to meet his or her post-discharge needs, or appears unsafe, the facility must treat this situation similarly to refusal of care, and must:

- *Discuss with the resident, (and/or his or her representative, if applicable) and document the implications and/or risks of being discharged to a location that is not equipped to meet his/her needs and attempt to ascertain why the resident is choosing that location;*
- *Document that other, more suitable, options of locations that are equipped to meet the needs of the resident were presented and discussed;*
- *Document that despite being offered other options that could meet the resident's needs, the resident refused those other more appropriate settings;*
- *Determine if a referral to Adult Protective Services or other state entity charged with investigating abuse and neglect is necessary. The referral should be made at the time of discharge.*

As appropriate, facilities should follow their policies, or state law as related to discharges which are Against Medical Advice (AMA).

Residents who will be discharged to another SNF/NF, HHA, IRF, or LTCH

If a resident will be discharged to another SNF, an IRF, LTCH, or HHA, the facility must assist the resident in choosing an appropriate post-acute care provider that will meet the resident's needs, goals, and preferences. Assisting the resident means the facility must compile available data on other appropriate post-acute care options to present to the resident. Information the facility must gather about potential receiving providers includes, but is not limited to:

- *Publicly available standardized quality information, as reflected in specific quality measures, such as the CMS Nursing Home Compare, Home Health Compare, Inpatient Rehabilitation Facility (IRF) Compare, and Long-Term Care Hospital (LTCH) Compare websites, and*
- *Resource use data, which may include, number of residents/patients who are discharged to the community, and rates of potentially preventable hospital readmissions.*

The listing of potential providers and data compiled must be relevant to the resident's needs, and be aligned with the resident's goals of care and treatment preferences.
Facilities must also comply with Section 1128B of the Social Security Act (the Federal Anti-Kickback statute) when making referrals to other provider types. Section 1128B "prohibits the knowing and willful offer, payment, solicitation, or receipt of any remuneration, in cash or in kind, to induce or in return for referring an individual for the furnishing or arranging of any item or service for which payment may be made under a Federal health care program," https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/Downloads/fwa-laws-resourceguide.pdf.
In order to emphasize resident involvement, facilities are expected to present provider information to the resident and resident representative, if applicable, in an accessible and understandable format. For example, the facility should provide the aforementioned quality data on other post-acute care providers that meet the resident's needs, goals, and preferences, and are within the resident's desired geographic area. Facilities must then assist residents and/or resident representative as they seek to understand the data and use it to help them choose a post-acute care provider, or other setting for discharge, that is best suited to their goals, preferences, needs and circumstances. For residents who are discharged to another SNF/NF, a HHA, IRF, or LTCH the facility must provide evidence that the resident and if applicable, the resident representative was given provider information that includes standardized patient assessment data, and information on quality measures and resource use (where that data is available).

POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION
F624: *For concerns related to the immediate orientation and preparation necessary for a transfer which does not require discharge planning, such as transfers to a hospital emergency room or therapeutic leave.*

Summary of Investigative Procedures
Use the Community Discharge Critical Element (CE) Pathway, along with the above interpretive guidelines when determining if the facility meets the requirements for, or investigating concerns related to the facility's requirement to develop and implement an effective discharge planning process.

Briefly review the most recent comprehensive assessments, comprehensive care plan (specifically the discharge care plan), progress notes, and orders to identify whether the facility has identified and addressed the resident's goals and discharge needs. This information will guide observations and interviews to be made in order to corroborate concerns identified. If there are concerns related to systematic discharge planning, this may trigger a review of the nursing home's policies and procedures for discharge assessment and care planning.

NOTE*: Always observe for visual cues of psychosocial distress and harm (see Appendix P, Guidance on Severity and Scope Levels and Psychosocial Outcome Severity Guide).*

DEFICIENCY CATEGORIZATION
An example of Level 4, immediate jeopardy to resident health or safety, includes, but is not limited to:

- *The facility failed to ensure that the post-discharge destination and continuing care provider could meet the resident's needs prior to the discharge of a resident with a feeding tube to a residential group facility. The surveyor discovered that within 24 hours of discharge, the resident was transferred to the hospital for aspiration, was intubated for respiratory distress and diagnosed with brain death. Review of medical records showed no documentation of the resident's tube feeding needs in the discharge plan, or whether the nursing home informed the receiving facility of the presence of the feeding tube and the need for aspiration precautions. It was also unclear whether the nursing home had determined that the receiving facility had the ability to care for a resident with a feeding tube prior to placement of the individual.*

Examples of level 3, actual harm that is not immediate jeopardy include, but are not limited to:

- *The facility failed to develop and/or implement a discharge care plan for a resident who had expressed a desire to return home as soon as possible once she completed rehabilitation for a fractured hip. The medical record revealed the therapist had discontinued the active treatment one week ago. The resident stated and the medical record verified that the facility had not developed plans for her care after her discharge and had not contacted any community providers to assist in her discharge. She indicated that she has not slept well due to worrying about returning to her home and paying the rent while in the facility. The resident's home was over an hour away. She stated she was depressed over having to remain in the nursing home, and spent most of the day in her room as it was too far for her friends to visit.*
- *A facility failed to develop discharge plans to meet the needs and goals of each resident, resulting in significant psychosocial harm, when the facility determined it would be closing, necessitating the discharge of all residents. The facility notified residents and resident representatives it would assist with relocation. Interviews with residents and observations showed residents were agitated, fearful, and in tears over the impending move. Residents indicated they were not asked their preferences and many would be relocated far away from family. Residents also indicated they were not given opportunities to provide input into the discharge planning process, specifically regarding discharge location. Record review showed no evidence of interaction with residents or resident representatives related to discharge planning. This was cross-referenced and cited at F845, Facility Closure.*

An example of Level 2, no actual harm with potential for than more than minimal harm that is not immediate jeopardy, includes, but is not limited to:

- *Facility failed to develop a discharge care plan that addressed all of the needs for a resident being discharged home. Specifically, the care plan did not address the resident's need for an oxygen concentrator at home. After the resident was discharged to his home, a family member had to contact the physician to obtain the order and make arrangements for delivery of the equipment. Although there was a delay in obtaining the oxygen concentrator, the resident did not experience harm, however this four-hour delay had a potential for compromising the residents' ability to maintain his well-being.*

Severity Level 1 does not apply for this regulatory requirement. *The failure of the facility to provide appropriate discharge assessment and planning in order to meet the resident's needs*

and goals at the time of discharge from the nursing home and to ensure communication of necessary information for a safe transition of care places the resident at risk for more than minimal harm.

F661
§483.21(c)(2) Discharge Summary
When the facility anticipates discharge, a resident must have a discharge summary that includes, *but is not limited to, the following*:

- ***(i)*** **A recapitulation of the resident's stay *that includes, but is not limited to, diagnoses, course of illness/treatment or therapy, and pertinent lab, radiology, and consultation results.***
- ***(ii)*** **A final summary of the resident's status to include items in paragraph *(b)(1) of §483.20,* at the time of the discharge that is available for release to authorized persons and agencies, with the consent of the resident or resident's representative.**
- ***(iii) Reconciliation of all pre-discharge medications with the resident's post-discharge medications (both prescribed and over-the-counter).***
- ***(iv)*** **A post-discharge plan of care that is developed with the participation of the resident and, *with the resident's consent, the resident representative(s)*, which will assist the resident to adjust to his or her new living environment. *The post-discharge plan of care must indicate where the individual plans to reside, any arrangements that have been made for the resident's follow up care and any post-discharge medical and non-medical services.***

INTENT of §483.*21(c)(2)*
To ensure the facility communicates necessary information to the resident, continuing care provider and other authorized persons at the time of an anticipated discharge.

DEFINITIONS §483.21(c)(2)
"Anticipated Discharge"*: A discharge that is planned and not due to the resident's death or an emergency (e.g., hospitalization for an acute condition or emergency evacuation).*

"Continuing Care Provider"*: The entity or person who will assume responsibility for the resident's care after discharge. This includes licensed facilities, agencies, physicians, practitioners, and/or other licensed caregivers.*

"Recapitulation of Stay"*: A concise summary of the resident's stay and course of treatment in the facility.*

"Reconciliation of Medications": *A process of comparing pre-discharge medications to post-discharge medications by creating an accurate list of both prescription and over the counter medications that includes the drug name, dosage, frequency, route, and indication for use for the purpose of preventing unintended changes or omissions at transition points in care.*

Effective November 28, 2017

GUIDANCE §483.*21(c)(2)*

Overview

The discharge summary provides necessary information to continuing care providers pertaining to the course of treatment while the resident was in the facility and the resident's plans for care after discharge. A discharge summary must include an accurate and current description of the clinical status of the resident and sufficiently detailed, individualized care instructions, to ensure that care is coordinated and the resident transitions safely from one setting to another. The discharge summary may help reduce or eliminate confusion among the various facilities, agencies, practitioners, and caregivers involved with the resident's care.

In the case of discharge to a non-institutional setting such as the resident's home, provision of a discharge summary, with the resident's consent, to the resident's community-based physicians/practitioners allows the resident to receive continuous and coordinated, person-centered care.

For residents who are being discharged from the facility to another health care facility, the discharge summary enables the receiving facility to provide appropriate and timely care. The medical record must identify the receiving facilities for which or physicians/practitioners to whom the discharge summary is provided.

Content of the Discharge Summary

Recapitulation of Resident's Stay

Recapitulation of the resident's stay describes the resident's course of treatment while residing in the facility. The recapitulation includes, but is not limited to, diagnoses, course of illness, treatment, and/or therapy, and pertinent lab, radiology, and consultation results, including any pending lab results.

Final Summary of Resident Status

In addition to the recapitulation of the resident's stay, the discharge summary must include a final summary of the resident's status which includes the items from the resident's most recent comprehensive assessment identified at §483.20(b)(1)(i) – (xviii) Comprehensive Assessment. This is necessary to accurately describe the current clinical status of the resident. Items required to be in the final summary of the resident's status are:

- *Identification and demographic information;*
- *Customary routine;*
- *Cognitive patterns;*
- *Communication;*
- *Vision;*
- *Mood and Behavior patterns;*
- *Psychosocial well-being;*
- *Physical functioning and structural problems;*
- *Continence;*
- *Disease diagnoses and health conditions;*
- *Dental and nutritional status*
- *Skin condition;*
- *Activity pursuit;*

- *Medications;*
- *Special treatments and procedures;*
- *Discharge planning (as evidenced by most recent discharge care plan);,*
- *Documentation of summary information regarding the additional assessment performed on the care areas triggered by the completion of the MDS; and*
- *Documentation of participation in assessment. This refers to documentation of who participated in the assessment process. The assessment process must include direct observation and communication with the resident, as well as communication with licensed and non-licensed direct care/direct access staff members on all shifts.*

***NOTE**: In addition to the above, pursuant to §483.15(c)(2)(iii), the facility (transferring nursing home) must convey the following information to the receiving provider when a resident is discharged (or transferred) from that facility:*

- *Contact information of the practitioner (at the transferring nursing home) responsible for the care of the resident;*
- *Resident representative information, if applicable, including contact information;*
- *Advance directive information;*
- *All special instructions or precautions for ongoing care, as appropriate;*
- *Comprehensive care plan goals; and*
- *All other necessary information, including a copy of the resident's discharge summary, consistent with 483.21(c)(2) as applicable, and any other documentation, as applicable, to ensure a safe and effective transition of care.*

For concerns related to the above, see guidance at F622, §483.15(c)(2)(iii).

Timing of the Discharge Summary

*The discharge summary contains necessary medical information that the facility must furnish **at the time the resident leaves the facility**, to the receiving provider assuming responsibility for the resident's care after discharge. The discharge summary may be furnished in either hard copy or electronic format, if the provider assuming responsibility for the resident's care has the capacity to receive and use the discharge summary in electronic format. Delays in preparing and forwarding the discharge summary hinder the coordination required to provide optimal care to the resident. The medical record must contain the discharge summary information and identify the recipient of the summary.*

***NOTE:** In situations where there is no continuing care provider (e.g., resident has no primary care physician in the community), the facility is expected to document in the medical record efforts to assist the resident in locating a continuing care provider.*

Reconciliation of Medications Prior to Discharge

A resident's discharge medications may differ from what the resident was receiving while residing in the facility. Facility staff must compare the medications listed in the discharge summary to medications the resident was taking while residing in the nursing home. Any discrepancies or differences found during the reconciliation must be assessed and resolved, and the resolution documented in the discharge summary, along with a rationale for any changes. For example, a resident who was receiving rehabilitative services may have required antibiotic

therapy postoperatively but does not need to continue the antibiotic at home. The discontinuation of the medication should be documented in the discharge summary.

Discharge instructions and accompanying prescriptions provided to the resident and if applicable, the resident representative must accurately reflect the reconciled medication list in the discharge summary.

Post-Discharge Plan of Care

The post-discharge plan of care details the arrangements that facility staff have made to address the resident's needs after discharge, and includes instructions given to the resident and his or her representative, if applicable. The post-discharge plan of care must be developed with the participation of the Interdisciplinary team and the resident and, with the resident's consent, the resident's representative. At the resident's request, a representative of the local contact agency may also be included in the development of the post-discharge plan of care. The post-discharge plan of care should show what arrangements have been made regarding:

- *Where the resident will live after leaving the facility;*
- *Follow-up care the resident will receive from other providers, and that provider's contact information;*
- *Needed medical and non-medical services (including medical equipment);*
- *Community care and support services, if needed; and*
- *When and how to contact the continuing care provider.*

Instructions to residents discharged to home

For residents discharged to their home, the medical record should contain documentation that written discharge instructions were given to the resident and if applicable, the resident representative. These instructions must be discussed with the resident and resident representative and conveyed in a language and manner they will understand.

KEY ELEMENTS OF NONCOMPLIANCE

To cite deficient practice at F661, the surveyor's investigation will generally show that the facility failed to do one or more of the following:

- *Prepare a discharge summary that includes all of the following:*
  - *A recapitulation (containing all required components) of the resident's stay;*
  - *A final summary of the resident's status (that includes the items listed in §483.20(b)(1));*
  - *A reconciliation of all pre and post discharge medications;*
  - *A discharge plan of care (containing all required components);* ***or***
- *Reconcile the resident's pre-discharge medications with his/her post-discharge medications;* ***or***
- *Convey the discharge summary to the continuing care provider or receiving facility at the time of discharge*

DEFICIENCY CATEGORIZATION

An examples of Level 4, immediate jeopardy to resident health or safety, includes, but is not limited to:

- *A resident experienced a stroke during the SNF stay and was started on Coumadin. The resident was then discharged to another facility but the discharge summary did not include the new orders for Coumadin and PT/INR monitoring. The receiving facility did not start the resident on Coumadin and the resident experienced another stroke.*

An example of level 3, actual harm that is not immediate jeopardy includes, but is not limited to:

- *Review of a discharge summary for a discharged resident showed that the discharge summary did not contain necessary information about the resident's wound care care needs and arrangements for wound care after discharge. Investigation showed that the resident did not receive appropriate wound care at home because details of wound care received in the facility were not conveyed in the discharge summary. The facility's failure to provide instructions for the care of the wound in the discharge summary information caused the resident's wound to worsen at home resulting in readmission to a hospital.*

An example of Level 2, no actual harm with potential for than more than minimal harm that is not immediate jeopardy, includes, but is not limited to:

- *A resident was discharged to another facility closer to her family. The transferring facility did not send a complete discharge summary to the receiving facility until one week after the resident was admitted to the new facility. The receiving facility had to take additional time and use multiple sources to verify medications and other medical orders while waiting for a complete discharge summary. This placed the resident at risk for more than minimal harm due to the potential for inaccuracies in medication and other orders while waiting for a complete discharge summary.*

An example of Level 1, no actual harm with potential for no more than a minor negative impact on the resident, includes, but is not limited to:

- *The failure of the facility to provide in its recapitulation of the resident's stay, the most recent laboratory results (which were normal). This resulted in no negative impact to the resident.*

F675
§ 483.*24* Quality of life
Quality of life is a fundamental principle that applies to all care and services provided to facility residents. **Each resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, *consistent with the resident's* comprehensive assessment and plan of care.**

INTENT
The intent of this requirement is to specify the facility's responsibility to create and sustain an environment that humanizes and individualizes each resident's quality of life by:

- *Ensuring all staff, across all shifts and departments, understand the principles of quality of life, and honor and support these principles for each resident; and*

- *Ensuring that the care and services provided are person-centered, and honor and support each resident's preferences, choices, values and beliefs.*

DEFINITIONS §483.24
"Person Centered Care" *– For the purposes of this subpart, person-centered care means to focus on the resident as the locus of control and support the resident in making their own choices and having control over their daily lives. (Definitions - §483.5)*

"Pervasive" *For the purposes of this guidance, pervasive means spread through or embedded within every part of something.*

"Quality of Life" *An individual's "sense of well-being, level of satisfaction with life and feeling of self-worth and self-esteem. For nursing home residents, this includes a basic sense of satisfaction with oneself, the environment, the care received, the accomplishments of desired goals, and control over one's life."*

GUIDANCE* §483.*24
Noncompliance at F675 identifies outcomes which rise to the level of immediate jeopardy and reflect an environment of pervasive disregard for the quality of life of the facility's residents. This can include the cumulative effect of noncompliance at other regulatory tags on one or more residents. To cite noncompliance at F675, the survey team must have evidence that outcomes at other regulatory tags demonstrate a pervasive disregard for the principles of quality of life.

Principles of Quality of Life
According to the 1986 Institute of Medicine (IOM) published report "Improving the Quality of Care in Nursing Homes," principles of Quality of Life included:

- *A sense of well-being, satisfaction with life, and feeling of self-worth and self-esteem; and*
- *A sense of satisfaction with oneself, the environment, the care received, the accomplishments of desired goals, and control over one's life.*

The report also identified that a sense of well-being, self-esteem, and self-worth was enhanced by personal control over choices, such as mealtimes, activities, clothing, and bedtime; privacy during visits, and treatments; and "opportunities to engage in religious, political, civic, recreational or other social activities. Based upon the regulatory requirement stating that quality of life is an overarching principle that applies to all care and services, the principles as identified in the IOM report above, will be used for determining whether a resident's quality of life is being supported and or enhanced. Refer to this link for the entire IOM report: https://www.ncbi.nlm.nih.gov/books/NBK217548/#ddd00037

Facilities must create and sustain an environment that humanizes and promotes each resident's well-being, and feeling of self-worth and self-esteem. This requires nursing home leadership to establish a culture that treats each resident with respect and dignity as an individual, and addresses, supports and/or enhances his/her feelings of self-worth including personal control over choices, such as mealtimes, activities, clothing, and bedtime; privacy during visits, and treatments; and opportunities to engage in religious, political, civic, recreational or other social activities.

Effective November 28, 2017

Facility leadership must be aware of the culture that exists in its facility and may use various methods to assess the attitudes and values prevalent amongst staff. These methods include, reviewing complaints or grievances, which could reasonably impact a resident's quality of life, or allegations of abuse, neglect or mistreatment. In order to identify whether staff supports each resident's quality of life, leadership should observe and evaluate verbal and nonverbal interactions between staff and residents. Negative observations could include staff actions such as the following:

- *Verbalizing negative or condescending remarks, or refusing to provide individualized care to a resident due to his/her age, race, or cognitive or physical impairments, his/her political or cultural beliefs, or sexual preferences;*
- *Dehumanizing an individual through verbal and nonverbal actions such as talking to others over a resident without acknowledging his/her presence, treating the resident as if he/she were an object rather than a human being, mistreating, or physically, sexually or mentally abusing a resident.*

These types of staff actions and attitudes do not recognize nor value the individual. An individual's life experiences, values, needs, choices and relationships must not be diminished, to the extent possible, due to admission to a nursing home. Treating a nursing home resident in any manner that does not uphold a resident's sense of self-worth, dignity and individuality dehumanizes the resident and creates an environment that perpetuates an unhealthy, unsafe attitude towards the resident(s).

In order to achieve a culture and environment that supports quality of life, the facility must ensure that all staff, across all shifts and departments,, understand the principles of quality of life, and honor and support these principles for each resident and that the care and services that are provided by the facility are person-centered, and honor and support each resident's preferences, choices, values and beliefs.

The Link between Noncompliance at other Regulatory Tags and Noncompliance at Quality of Life

Quality of Life at F675 should not automatically be cited when noncompliance has been identified in Resident's Rights/Quality of Care/Abuse-Neglect or other regulatory tags, unless the cumulative effect of the noncompliance creates an environment that reflects a complete disregard of one or more residents' well-being, and rises to the level of Immediate Jeopardy.

See below for an example of noncompliance at F675 demonstrating the cumulative effect of noncompliance at other tags for multiple residents:

> *The facility failed to provide an environment which supported and enhanced each resident's quality of life, which was the result of the cumulative effect of noncompliance cited at dignity, abuse, staffing, and continence care. This noncompliance was found to be pervasive and created an environment reflecting a complete disregard of one or more residents' well-being and quality of life, which has caused or is likely to cause serious harm related to one or more residents' self-worth, self-esteem, and well-being.*

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A complaint investigation revealed facility staff members posted unauthorized videos and photographs on social media of several residents during bathing, going to the bathroom, and grooming, including nude photos and photos of genitalia. As a result, the residents suffered public humiliation and dehumanization. Facility staff interviewed were aware of this abuse, but did not report to administration due to fear of retaliation by the perpetrators and fear of losing their jobs.

During a resident council meeting, several residents reported that they heard staff describing the photos, laughing about the postings and had seen staff passing around cell phones. As a result, the residents stated that they were afraid to take a shower or bath, and extremely uncomfortable when requesting assistance to go to the bathroom because they thought it might happen to them, and that they had shared these concerns with other resident's in the facility. (Refer to noncompliance cited at 483.12, F600 – Abuse)
When discussing going to the bathroom, the residents stated that in addition to being afraid of asking for help, when they did, there were not enough staff to answer call lights. They said that staff would ignore their call light, walk by or would answer the light and leave without assisting the residents. This had resulted in episodes of incontinence of urine and feces, which they stated was extremely embarrassing, humiliating and degrading to them. (Refer to noncompliance cited at 483.10(a)(1), F550 – Dignity; 483.35, F725 – Insufficient Staff, Nursing Services; and 483.25(e)(1), F690 – Incontinence, Quality of Care.)

Several residents stated that they were afraid to ask for staff assistance for the need to use the bathroom, based on their fear related to the postings on social media. In addition, they stated that when they were receiving care, if staff pulled out a cell phone, they didn't know if staff were taking and posting pictures of them.
When asked if these concerns had been reported to the administration, the residents stated that they identified the issue with the call lights and not enough staff multiple times during council meetings, but that the administration only said, we will look into it, and nothing was done. They said they were afraid to report the cell phone concerns. One resident said that an aide told him/her that if they didn't quit complaining to the administrator, no one would help them and they would be transferred to another facility. When the resident began to cry, the aide laughed and walked out of the room, verbally taunting him/her for crying.

See below for an example of noncompliance at F675 demonstrating the cumulative effect of noncompliance at other tags for one resident:

The facility failed to provide an environment which supported one resident's quality of life, which was the result of the cumulative effect of noncompliance cited at 483.10(a), Dignity, and 483.10(b)(2), Freedom from discrimination, F550; 483.12(a) Abuse; 483.10(h), Personal Privacy – F583; 483.10(f), Self-Determination - F561; 483.21(b), Comprehensive, Person-Centered Care Planning - F656; and 483.60(c)(4), Menus and Nutritional Adequacy – F803. This complete disregard of the residents' quality of life, caused serious harm related to her self-worth, self-esteem, and well-being.

Effective November 28, 2017

The surveyor identified a resident who was admitted 6 weeks ago, and had religious beliefs which differed from the resident population in the nursing home, and those of the staff. During interviews, the resident and her family reported that staff continually made derogatory remarks about the resident's culture/religion to each other within earshot of the resident, or while in the room providing ADL care to the resident. This occurred during all shifts. Additionally, the resident reported that discriminatory remarks were made by housekeeping and dietary staff as well. The resident's family reported this was particularly worse on weekends when facility leadership were not in the building. The family members reported they would take turns visiting the resident on weekends, to support the resident and assist with her care. When asked if this was reported to facility management, the resident said her family had reported it to the Administrator on several occasions, but that nothing had changed. Interview with the Administrator revealed that an in-service was planned for the future. (Refer to noncompliance cited at 483.10(a)(1), Dignity, and 483.10(b)(2) Freedom from Discrimination - F550, 483.12(a), Abuse – F600)

The resident described frequent occurrences of disregard of her personal privacy including not covering her body completely, allowing full view of her arms, legs and buttocks when transporting her to the shower. The surveyor observed, on one occasion, staff not pulling the privacy curtain when assisting her to dress, resulting in anyone walking in the hallway being able to view her as she was dressed. (Refer to noncompliance cited at 483.10(h), Personal Privacy – F583)

On multiple occasions, the resident reported that she was assigned a male care giver, which is against her religious belief that a person of the opposite sex cannot provide care. On these occasions, the resident would tearfully refuse to get dressed, or call her family to assist her. On at least one occasion, the resident was forced to receive a shower with the assistance of a male aide, which resulted in the resident crying uncontrollably until her family arrived. Progress notes in her medical record noted this occasion as the resident becoming uncontrollable while receiving a shower. Additionally, when dressing her for the day, staff would not cover her hair, arms and legs, and would say that her scarf was missing, only to be found when her family arrived. On interview, staff said they were unaware that this was a violation of her religion. This noncompliance resulted in the resident frequently refusing to shower, or, according to family, calling her family, begging for them to come get her dressed. (Refer to noncompliance cited at 483.10(f), Self-Determination - F561.)

The surveyor observed the meal tray set up and found it did not honor the resident's preferences identified on the meal tray card and care plan. The resident reported that this happened on most days, and even if she requested an alternative, she would be given a food item that was prohibited according to her religion, and therefore, she would not eat that meal. The resident's family stated that they frequently brought food in to the resident because she could not eat what was brought to her.

On interview, dietary staff stated they did not have the time to prepare a special diet for this one resident, and stated to the surveyor, "They should have thought of that before

they came to this country." Additionally, the dietary staff reported that he/she was not aware of the dietary requirements of this resident's religion. An interview with the consulting dietitian revealed that he/she was not aware that this resident had been admitted to the facility, and she agreed that the menu did not meet this resident's religious preferences. (Refer to noncompliance cited at 483.60(c)(4), Menus and Nutritional Adequacy – F803)

Review of the resident's care plans revealed that there was no identification of this resident's preferences or dietary requirements related to her religion. (Refer to noncompliance cited at 483.21(b), Comprehensive, Person-Centered Care Plan – F656

As the result of cumulative effect of the noncompliance identified, this resident suffered loss of religious and cultural identity, had ongoing feelings of extreme sadness and humiliation, and expressed a wish to die.

F676
§483.24(a) ***Based on the comprehensive assessment of a resident and consistent with the resident's needs and choices, the facility must provide the necessary care and services to ensure that a*** **resident's abilities in activities of daily living do not diminish unless circumstances of the individual's clinical condition demonstrate that such diminution was unavoidable. This includes** ***the facility ensuring that:***

§483.24(a)(1) A resident is given the appropriate treatment and services to maintain or improve his or her ***ability to carry out the activities of daily living, including those specified in paragraph (b) of this section …***

§483.24(b) Activities of daily living.
The facility must provide care and services in accordance with paragraph (a) for the following activities of daily living:

§483.24(b)(1) ***Hygiene*** **–bath*ing*, dress*ing*, groom*ing*,** ***and oral care,***

§483.24(b)(2) ***Mobility*****—transfer and ambula*tion, including walking*,**

§483.24(b)(3) ***Elimination*****-toilet*ing*,**

§483.24(b)(4) ***Dining*****-eat*ing*, i*ncluding meals and snacks,***

§483.24(b)(5) ***Communication, including***
(i) Speech,
(ii) Language,
(iii) Other functional communication systems.

See Guidance at F677

Effective November 28, 2017

F677
§483.24(a)(2) **A resident who is unable to carry out activities of daily living receives the necessary services to maintain good nutrition, grooming, and personal and oral hygiene; and**

DEFINITIONS
*"**Oral care"** refers to the maintenance of a healthy mouth, which includes not only teeth, but the lips, gums, and supporting tissues. This involves not only activities such as brushing of teeth or oral appliances, but also maintenance of oral mucosa.*

"Speech, language or other functional communication systems" refers to the resident's ability to effectively communicate requests, needs, opinions, and urgent problems; to express emotion, to listen to others and to participate in social conversation whether in speech, writing, gesture, behavior, or a combination of these (e.g., a communication board or electronic augmentative communication device).

"Assistance with the bathroom" *refers to the* resident's *ability to* use the toilet room (or commode, bedpan, urinal); transfer on/off the toilet, *clean themselves*, change *absorbent* pads *or briefs*, manage ostomy or catheter, and adjust clothes.

"Transfer" refers to resident's ability to move between surfaces - to/from: bed, chair, wheelchair, and standing positions. (Excludes to/from bath/toilet.)

GUIDANCE
The *existence* of a clinical diagnosis shall not justify a decline in a resident's ability to perform ADLs unless the resident's clinical picture reflects the normal progression of the disease/ condition has resulted in an unavoidable decline in the resident's ability to perform ADLs. Conditions which may demonstrate an unavoidable decline in the resident's ability to perform ADLs include but are not limited to the following:

- The natural progression of *a debilitating* disease *with known functional decline;*
- The onset of *an acute episode causing* physical or mental disability while the *resident is* receiving care to restore or maintain functional abilities; and
- The resident's or his/her representative's decision to refuse care and treatment to restore or maintain functional abilities after efforts by the facility to *inform and educate about the benefits/risks of the proposed care and treatment;* counsel and/or offer alternatives to the resident or representative. *The decision to refuse care and treatment must* be documented in the clinical record. *Documentation must include* interventions identified on the care plan and *in place to* minimize or decrease functional loss that were refused by the *resident or resident's representative* and any interventions that were substituted *with consent of the resident and/or representative* to minimize further decline. ***NOTE**: In some cases, residents with dementia may resist the manner in which care is being provided, or attempted, which can be misinterpreted as declination of care. In some cases the resident with dementia does not understand what is happening, or may be fearful of unfamiliar staff, or may be anxious or frustrated due to inability to communicate. Facility staff are responsible to attempt to identify the underlying cause of the "refusal/declination" of care.*

- Note also that depression is a potential cause of excess disability and, where appropriate, therapeutic interventions should be initiated. *Follow up if the resident shows signs/symptoms of depression even if not indicated on his or her MDS.*

If it is determined that the resident's inability to perform ADLs occurred after admission due to an unavoidable decline, such as the progression of the resident's disease process, surveyors must still determine that interventions to assist the resident are identified and implemented immediately.

Appropriate treatment and services includes all care provided to residents by staff, contractors, or volunteers of the facility to maximize the *resident's functional* abilities. This includes pain relief and control, especially when it is causing a decline or a decrease in the quality of life of the resident.

NOTE: For evaluating a resident's ADLs and determining whether a resident's abilities have declined, improved, or stayed the same within the last twelve months, the following definitions as specified in the State's Resident Assessment Instrument (RAI) Manual *are used in reference to the Assessment Reference Date (ARD)*:

- **Independent** – Resident completed activity with no help or oversight every time during the 7-day look-back period.
- **Supervision** – Oversight, encouragement or cueing provided 3 or more times during the last 7 days.
- **Limited Assistance** - Resident highly involved in activity and received physical help in guided maneuvering of limb(s) or other non-weight bearing assistance 3 or more times during the last 7-days.
- **Extensive Assistance** - While resident performed part of activity over the last 7 days, help of following type(s) was provided 3 or more times;
    a. Weight-bearing support provided 3 or more times; or
    b. Full staff performance of activity during part (but not all) of last 7 days.
- **Total Dependence** - Full staff performance of an activity with no participation by resident for any aspect of the ADL activity. Resident was unwilling or unable to perform any part of the activity over entire 7-day look-back period.

PROCEDURES §483.24*(b)(1, 3-5)*

Use the Activities of Daily Living Critical Element (CE) Pathway, along with the above interpretive guidelines *when determining if facility practices* are in place to identify, evaluate, and intervene to, maintain, improve, *or prevent an avoidable decline in* ADLs. In addition, use this pathway for the resident who is unable to perform ADLs.

*Briefly review the most recent comprehensive assessment, care plan, physician orders, a*s well as *ADL documentation/flow sheets on various shifts, to identify whether the facility has:*

- *Recognized and assessed an inability to perform ADLs, or a risk for decline in any ability they have to perform ADLs;*
- *Developed and implemented interventions in accordance with the resident's assessed needs, goals for care, preferences, and recognized standards of practice that address the identified limitations in ability to perform ADLs;*

- *Monitored and evaluated the resident's response to care plan interventions and treatment; and*
- *Revised the approaches as appropriate.*

***NOTE**: For concerns related to facility failure to provide care, services, equipment or assistance to a resident with limited mobility, refer to F688, Mobility.*

F678

§483.24(a)(3) Personnel provide basic life support, including CPR, to a resident requiring such emergency care prior to the arrival of emergency medical personnel and subject to related physician orders and the resident's advance directives.

INTENT §483.24(a)(3)

To ensure that each facility is able to and does provide emergency basic life support immediately when needed, including cardiopulmonary resuscitation (CPR), to any resident requiring such care prior to the arrival of emergency medical personnel in accordance with related physicians orders, such as DNRs, and the resident's advance directives.

DEFINITIONS §483.24(a)(3)

***"Advance directive"** is defined as a written instruction, such as a living will or durable power of attorney for health care, recognized under State law (whether statutory or as recognized by the courts of the State), relating to the provision of health care when the individual is incapacitated. 42 C.F.R. §489.100. Some States also recognize a documented oral instruction.*

***"Basic life support"** is a level of medical care which is used for victims of life-threatening illnesses or injuries until they can be given full medical care at a hospital, and may include recognition of sudden cardiac arrest, activiation of the emergency response system, early cardiopulmonary resuscitation, and rapid defibrillation with an automatied external defibrillator, if available.*

***"Cardiopulmonary resuscitation (CPR)"** refers to any medical intervention used to restore circulatory and/or respiratory function that has ceased.*

*"**Code Status**" refers to the level of medical interventions a person wishes to have started if their heart or breathing stops.*

*"**Do Not Resuscitate(DNR) Order**" refers to a medical order issued by a physician or other authorized non-physician practitioner that directs healthcare providers not to administer CPR in the event of cardiac or respiratory arrest. Existence of an advance directive does not imply that a resident has a DNR order. The medical record should show evidence of documented discussions leading to a DNR order.*

GUIDANCE §483.24(a)(3)

In keeping with the requirement at §483.24 to "provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of the resident" facilities must ensure that properly trained personnel (and certified in CPR for

Effective November 28, 2017

Healthcare Providers) are available immediately (24 hours per day) to provide basic life support, including cardiopulmonary resuscitation (CPR), to residents requiring emergency care prior to the arrival of emergency medical personnel, and subject to accepted professional guidelines, the resident's advance directives, and physician orders.

The American Heart Association (AHA) publishes guidelines every five years for CPR and Emergency Cardiovascular Care (ECC). These guidelines reflect global resuscitation science and treatment recommendations. In the guidelines, AHA has established evidenced-based decision-making guidelines for initiating CPR when cardiac or respiratory arrest occurs in or out of the hospital.

The AHA urges all potential rescuers to initiate CPR unless a valid Do Not Resuscitate (DNR) order is in place; obvious clinical signs of irreversible death (e.g., rigor mortis, dependent lividity, decapitation, transection, or decomposition) are present; or initiating CPR could cause injury or peril to the rescuer.

If a resident experiences a cardiac or respiratory arrest and the resident does not show obvious clinical signs of irreversible death (e.g. rigor mortis, dependent lividity, decapitation, transection, or decomposition), facility staff must provide basic life support, including CPR, prior to the arrival of emergency medical services,

- *in accordance with the resident's advance directives and any related physician order, such as code status, or*
- *in the absence of advance directives or a DNR order.*

Facilities must have systems in place supported by policies and procedures to ensure there are an adequate number of staff present at all times who are properly trained and/or certified in CPR for Healthcare Providers to be able to provide CPR until emergency medical services arrives.

Additionally, facilities should have procedures in place to document a resident's choices regarding issues like CPR. Physician orders to support these choices should be obtained as soon as possible after admission, or a change in resident preference or condition, to facilitate staff in honoring resident choices. Facility policy should also address how resident preferences and physician orders related to CPR and other advance directive issues are communicated throughout the facility so that staff know immediately what action to take or not take when an emergency arises. Resident wishes expressed through a resident representative, as defined at 483.5, must also be honored, although, again physician orders should be obtained as soon as possible.

Facility staff should verify the presence of advance directives or the resident's wishes with regard to CPR, upon admission. This may be done while doing the admission assessment. If the resident's wishes are different than the admission orders, or if the admission orders do not address the resident's code status and the resident does not want to receive CPR, facility staff should immediately document the resident's wishes in the medical record and contact the physician to obtain the order.

While awaiting the physician's order to withhold CPR, facility staff should immediately document discussions with the resident or resident representative, including, as appropriate, a resident's wish to refuse CPR. At a minimum, a verbal declination of CPR by a resident, or if applicable a resident's representative, should be witnessed by two staff members, though individual States may have more specific requirements related to documenting verbal directives. While the physician's order is pending, staff should honor the documented verbal wishes of the resident or the resident's representative, regarding CPR.

Advance Directives

The right to formulate an advance directive applies to each and every resident and facilities must inform residents of their option to formulate advance directives. If a resident has a valid Advance Directive, the facility's care must reflect the resident's wishes as expressed in their Directive, in accordance with state law. (Refer to 483.10(c)(6), F578, Residents' Right to Formulate an Advance Directive.)

***NOTE**: The presence of an Advance Directive does not absolve the facility from giving supportive and other pertinent care, including CPR and other basic life support that is not prohibited by the Advance Directive. The presence of a "Do Not Resuscitate" (DNR) order is not sufficient to indicate the resident is declining other appropriate treatment and services. It only indicates that the resident should not be resuscitated if respirations and/or cardiac function ceases.*

Facility Policies

Facility policies should address the provision of basic life support and CPR, including:

- *Directing staff to initiate CPR when cardiac or respiratory arrest occurs for residents who do not show obvious clinical signs of irreversible death and:*
  - *Who have requested CPR in their advance directives, or*
  - *Who have not formulated an advance directive or,*
  - *Who do not have a valid DNR order.*
- *Ensuring staff receive certification in performance of CPR (CPR for Healthcare Providers).*

Facility policies must not limit staff to only calling 911 when cardiac or respiratory arrest occurs. Prior to the arrival of EMS, nursing homes must provide basic life support, including initiation of CPR, to a resident who experiences cardiac or respiratory arrest in accordance with that resident's advance directives or in the absence of advance directives or a DNR order. CPR-certified staff must be available at all times to provide CPR when needed.

The presence of a facility-wide "no CPR" policy interferes with a resident's right to formulate an advance directive and should be cited at §483.10(c)(6), F578, Residents' Right to formulate an Advance Directive. Surveyors should attempt to determine if there were residents who could have been negatively affected by the facility's policy, which should be cited at 483.24(a)(3), F678.

Effective November 28, 2017

CPR Certification
Staff must maintain current CPR certification for Healthcare Providers through a CPR provider whose training includes hands-on practice and in-person skills assessment; online-only certification is not acceptable. CPR certification that includes an online knowledge component, yet still requires an in-person demonstration and skills assessment to obtain certification or recertification, is acceptable.

For concerns related to the qualifications of staff performing CPR, the survey team should also consider §483.21(b)(3)(ii), Services Provided by Qualified Persons, F659.

INVESTIGATIVE PROTOCOL:
Procedure
Record Review
Ask to review the facility policies for:

- *CPR*
- *Advance Directives and/or*
- *Code Status*

Review facility policies to ensure:

- *Staff are directed to initiate CPR when cardiac or respiratory arrest occurs for residents who do not show obvious clinical signs of irreversible death and:*
  - *who have requested CPR in their Advance Directive; or*
  - *who have not formulated an Advance Directive; or*
  - *who do not have a valid DNR order;*
- *Staff are expected to be certified in CPR for Healthcare Providers;*

Review facility records verifying staff certification in CPR for Healthcare Providers
Review the resident's medical record to determine if:

- *The resident has an advanced directive in place. If so:*
  - *Does the resident's code status reflect their wishes as recorded in their Advance Directive?*
  - *Does the MDS indicate that the resident has an advanced directive?*
- *The interdisciplinary team has reviewed the Advanced Directive on a regular basis with the resident, or representative to ensure that it is current?*

Interview
Interview the resident or their representative to determine:

- *If they have formulated an Advance Directive (compare resident wishes to physician's orders);*
- *If staff review the Advance Directive at least quarterly (with care planning) to see if it still reflects the resident's wishes.*

Interview nursing staff to determine:

- *How they know each resident's code status;*
- *Who is responsible for performing CPR;*

KEY ELEMENTS OF NONCOMPLIANCE:
To cite deficient practice at F678, the surveyor's investigation will generally show that the facility failed to do any one of the following:

- *Provide basic life support, including CPR to a resident who required emergency life support and/or resuscitative care; or*
- *Ensure availability of staff who can provide CPR.*
- *Have appropriate policies directing staff when to initiate basic life support;*
- *Ensure staff is familiar with facility policies related to CPR;*
- *Ensure staff knows how to confirm residents' code status in an emergency; and*
- *Ensure staff maintain current CPR certification for healthcare providers through a CPR provider whose training includes hands-on practice and in-person skills assessment.*

DEFICIENCY CATEGORIZATION §483.24(a)(3)
In addition to actual or potential physical harm, always consider whether psychosocial harm has occurred when determining severity level. (See Appendix P, Section IV, E, Psychosocial Outcome Severity Guide).

Examples of Severity Level 4 Noncompliance Immediate Jeopardy to Resident Health or Safety include, but are not limited to:
Failure to provide, or a delay in providing, CPR to a resident with no advance directive, who collapsed in the dining room.

Facility implementation of a No CPR policy resulting in psychosocial harm to residents who became distraught that they would have to relocate or have to sign a DNR.

Severity Level 3 Considerations: Actual Harm that is Not Immediate Jeopardy
CMS believes that noncompliance related to any of the key elements listed above with an actual or potential outcome to one or more residents would result in Immediate Jeopardy, therefore no example of level 3 severity is given.

Severity Level 2 Considerations: No Actual Harm, with Potential for More than Minimal Harm, that is Not Immediate Jeopardy
Noncompliance that results in no more than minimal physical, mental, and/or psychosocial discomfort to the resident, and/or has the potential (not yet realized) to compromise the resident's ability to maintain and/or reach his/her highest practicable physical, mental, and/or psychosocial wellbeing.

An example of a resident outcome that demonstrates severity at Level 2 may include, but is not limited to:
Failure to ensure all facility staff received training in CPR for Healthcare Providers, resulting in some staff responsible for providing CPR not receiving the correct CPR training.

Severity Level 1 Considerations: No Actual Harm, with Potential for Minimal Harm
Noncompliance that has the potential for causing no more than a minor negative impact on the resident(s).

Severity Level 1 does not apply for this regulatory requirement because the failure of the facility to be able to provide basic life support, including CPR, by properly trained staff in accordance

with facility policies, advance directives and related physician's orders creates the potential for more than minimal harm.

F679
***§483.24(c)* Activities.**
§483.24(c)*(1) The facility must provide, *based on the comprehensive assessment and care plan and the preferences of each resident,* an ongoing program *to support residents in their choice* of activities, *both facility-sponsored group and individual activities and independent activities,* designed to meet the interests *of* and *support* the physical, mental, and psychosocial well-being of each resident, *encouraging both independence and interaction in the community.

INTENT *§483.24(c)*
To ensure that facilities implement an *ongoing resident centered* activities program that incorporates *the resident's* interests, hobbies *and cultural* preferences which is integral to maintaining and/or improving a resident's physical, mental, and psychosocial well-being *and independence. To create opportunities for each resident to have a meaningful life by supporting his/her domains of wellness (security, autonomy, growth, connectedness, identity, joy and meaning).*

DEFINITIONS *§483.24(c)*
"Activities" refer to any endeavor, other than routine ADLs, in which a resident participates that is intended to enhance her/his sense of well-being and to promote or enhance physical, cognitive, and emotional health. These include, but are not limited to, activities that promote self-esteem, pleasure, comfort, education, creativity, success, and independence.

NOTE: ADL-related activities, such as manicures/pedicures, hair styling, and makeovers, may be considered part of the activities program.

GUIDANCE §483.24(c)
Research findings and the observations of positive resident outcomes confirm that activities are an integral component of residents' lives. Residents have indicated that daily life and involvement should be meaningful. Activities are meaningful when they reflect a person's interests and lifestyle, are enjoyable to the person, help the person to feel useful, and provide a sense of belonging. *Maintaining contact and interaction with the community is an important aspect of a person's well-being and facilitates feelings of connectedness and self- esteem. Involvement in community includes interactions such as assisting the resident to maintain his/her ability to independently shop, attend the community theater, local concerts, library, and participate in community groups.*

Activity Approaches for Residents with *Dementia*
All residents have a need for engagement in meaningful activities. For residents with dementia, the lack of engaging activities can cause boredom, loneliness and frustration, resulting in distress and agitation. Activities must be individualized and customized based on the resident's previous lifestyle (occupation, family, hobbies), preferences and comforts.
https://www.caringkindnyc.org/_pdf/CaringKind-PalliativeCareGuidelines.pdf

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The facility may have identified a resident's pattern of behavioral symptoms and may offer activity interventions, whenever possible, prior to the behavior occurring. Once a behavior escalates, activities may be less effective or may even cause further stress to the resident (some behaviors may be appropriate reactions to feelings of discomfort, pain, or embarrassment, such as aggressive behaviors exhibited by some residents with dementia during bathing[16]).

Examples of activities-related interventions that a facility may provide to try to minimize distressed behavior may include, but are not limited, to the following:

For the resident who *exhibits unusual amounts of energy or* walking *without purpose*:

- Providing a space and environmental cues that encourages physical exercise, decreases exit-*seeking* behavior and reduces extraneous stimulation (such as seating areas spaced along a walking path or garden; a setting in which the resident may manipulate objects; or a room with a calming atmosphere, for example, using music, light, and rocking chairs);
- Providing aroma(s)/aromatherapy that is/are pleasing and calming to the resident; and
- Validating the resident's feelings and words; engaging the resident in conversation about who or what they are seeking; and using one-to-one activities, such as reading to the resident or looking at familiar pictures and photo albums.

For the resident who engages in behaviors not conducive with a therapeutic home like environment:

- Providing a calm, non-rushed environment, with structured, familiar activities such as folding, sorting, and matching; using one-to-one activities or small group activities that comfort the resident, such as their preferred music, walking quietly with the staff, a family member, or a friend; eating a favorite snack; looking at familiar pictures;
- Engaging in exercise and movement activities; and
- Exchanging self-stimulatory activity for a more socially-appropriate activity that uses the hands, if in a public space.

For the resident who exhibits behavior that require a less stimulating environment to discontinue behaviors not welcomed by others sharing their social space:

- Offering activities in which the resident can succeed, that are broken into simple steps, that involve small groups or are one-to-one activities such as using the computer, that are short and repetitive, and that are stopped if the resident becomes overwhelmed (reducing excessive noise such as from the television);
- Involving in familiar occupation-related activities. (A resident, if they desire, can do paid or volunteer work and the type of work would be included in the resident's plan of care,

such as working outside the facility, sorting supplies, delivering resident mail, passing juice and snacks, refer to §*483.10(e)(8) Resident Right to Work*);

- Involving in physical activities such as walking, exercise or dancing, games or projects requiring strategy, planning, and concentration, such as model building, and creative programs such as music, art, dance or physically resistive activities, such as kneading clay, hammering, scrubbing, sanding, using a punching bag, using stretch bands, or lifting weights; and
- Slow exercises (e.g., slow tapping, clapping or drumming); rocking or swinging motions (including a rocking chair).

For the resident who goes through others' belongings:

- Using normalizing life activities such as stacking canned food onto shelves, folding laundry; offering sorting activities (e.g., sorting socks, ties or buttons); involving in organizing tasks (e.g., putting activity supplies away); providing rummage areas in plain sight, such as a dresser; and
- Using non-entry cues, such as "Do not disturb" signs or removable sashes, at the doors of other residents' rooms; providing locks to secure other resident's belongings (if requested).

For the resident who has withdrawn from previous activity interests/customary routines and isolates self in room/bed most of the day:

- Providing activities just before or after meal time and where the meal is being served (out of the room);
- Providing in-room volunteer visits, music or videos of choice;
- Encouraging volunteer-type work that begins in the room and needs to be completed outside of the room, or a small group activity in the resident's room, if the resident agrees; working on failure-free activities, such as simple structured crafts or other activity with a friend; having the resident assist another person;
- Inviting to special events with a trusted peer or family/friend;
- Engaging in activities that give the resident a sense of value (e.g., intergenerational activities that emphasize the resident's oral history knowledge);
- Inviting resident to participate on facility committees;
- Inviting the resident outdoors; and
- Involving in gross motor exercises (e.g., aerobics, light weight training) to increase energy and uplift mood.

For the resident who excessively seeks attention from staff and/or peers: Including in social programs, small group activities, service projects, with opportunities for leadership.

For the resident who lacks awareness of personal safety, such as putting foreign objects in her/his mouth or who is self-destructive and tries to harm self by cutting or hitting self, head banging, or causing other injuries to self:

- Observing closely during activities, taking precautions with materials (e.g., avoiding sharp objects and small items that can be put into the mouth);
- Involving in smaller groups or one-to-one activities that use the hands (e.g., folding towels, putting together PVC tubing);

- Focusing attention on activities that are emotionally soothing, such as listening to music or talking about personal strengths and skills, followed by participation in related activities; and
- Focusing attention on physical activities, such as exercise.

For the resident who has delusional and hallucinatory behavior that is stressful to her/him:

- Focusing the resident on activities that decrease stress and increase awareness of actual surroundings, such as familiar activities and physical activities; offering verbal reassurance, especially in terms of keeping the resident safe; and acknowledging that the resident's experience is real to her/him.

The outcome for the resident, the decrease or elimination of the behavior, either validates the activity intervention or suggests the need for a new approach.
The facility may use, but need not duplicate, information from other sources, such as the RAI/*MDS* assessment, including the CAAs, assessments by other disciplines, observation, and resident and family interviews. Other sources of relevant information include the resident's lifelong interests, spirituality, life roles, goals, strengths, needs and activity pursuit patterns and preferences. This assessment should be completed by or under the supervision of a qualified professional.

NOTE: Some residents may be independently capable of pursuing their own activities without intervention from the facility. This information should be noted in the assessment and identified in the plan of care.

Surveyors need to be aware that some facilities may take a non-traditional approach to activities. In *nursing homes where culture change philosophy has been adopted,* all staff may be trained as nurse aides *or "universal workers,"* (workers with primary role but multiple duties outside of primary role)and *may be* responsible to provide activities, *which* may resemble those of a private home. *The provision of activities should not be confined to a department, but rather may involve all staff interacting with residents.*

Residents, staff, and families should interact in ways that reflect daily life, instead of in formal activities programs. Residents may be more involved in the ongoing activities in their living area, such as care-planned approaches including chores, preparing foods, meeting with other residents to choose spontaneous activities, and leading an activity. It has been reported that, "some culture changed homes might not have a traditional activities calendar, and instead focus on community life to include activities." Instead of an "activities director," some homes have a Community Life Coordinator, a Community Developer, or other title for the individual directing the activities program.

For more information on activities in homes changing to a resident-directed culture, the following websites are available as resources: www.pioneernetwork.net; www.qualitypartnersri.org; and www.edenalt.org.

Effective November 28, 2017

INVESTIGATIVE SUMMARY
Use the Activities Critical Element pathway and the guidance above to investigate concerns related to activities which are based on the resident's comprehensive assessment and care plan, and meet the resident's interests and preferences, and support his or her physical, mental, and psychosocial well-being.

F680
§483.24(c)**(2) The activities program must be directed by a qualified professional who is a qualified therapeutic recreation specialist or an activities professional who—**

- ***(i)*** **Is licensed or registered, if applicable, by the State in which practicing; and**
- ***(ii)*** **Is:**
  - ***(A) E*****ligible for certification as a therapeutic recreation specialist or as an activities professional by a recognized accrediting body on or after October 1, 1990; or**
  - ***(B)*** **Has 2 years of experience in a social or recreational program within the last 5 years, *one* of which was full-time in a *therapeutic* activities program; or**
  - ***(C)*** **Is a qualified occupational therapist or occupational therapy assistant; or**
  - ***(D)*** **Has completed a training course approved by the State.**

INTENT §483.*2*4(*c*)(*2*)
The intent of this regulation is to ensure that the activities program is directed by a qualified professional.

DEFINITIONS §483.*2*4(*c*)(*2*)
"Recognized accrediting body" refers to those organizations that certify, register, or license therapeutic recreation specialists, activity professionals, or occupational therapists.

Activities Director Responsibilities

An activity director is responsible for directing the development, implementation, supervision and ongoing evaluation of the activities program. This includes the completion and/or directing/delegating the completion of the activities component of the comprehensive assessment; and contributing to and/or directing/delegating the contribution to the comprehensive care plan goals and approaches that are individualized to match the skills, abilities, and interests/preferences of each resident.

Directing the activity program includes scheduling of activities, both individual and groups, implementing and/or delegating the implementation of the programs, monitoring the response and/or reviewing/evaluating the response to the programs to determine if the activities meet the assessed needs of the resident, and making revisions as necessary.

NOTE: Review the qualifications of the activities director if there are concerns with the facility's compliance with the activities requirement at §483.*24*(*c*)(1), F*679*, or if there are concerns with the direction of the activity programs.

A person is a qualified professional under this regulatory tag if they meet the qualifications (if applicable) of §483.*2*4(*c*)(*2*)(i), <u>and</u> one (or more) of the qualifications of §483.*2*4(*c*)(*2*)(ii).

Effective November 28, 2017

KEY ELEMENTS OF NONCOMPLIANCE **§483.*2*4(*c*)(*2*)**
To cite deficient practice at F680, the surveyor's investigation will generally show that the facility failed to ensure the activities program is directed by a qualified professional, who:

- *Is licensed or registered, (if applicable); and*
  - *Is eligible for certification as a therapeutic recreation specialist, or as an activities professional by a recognized accrediting body on or after October 1, 1990; or*
  - *Has 2 years of experience in a social or recreational program with the last 5 years, one of which was full-time in a therapeutic activities program; or*
  - *Is a qualified occupational therapist or occupational therapy assistant; or*
  - *Has completed a training course approved by the state.*

NOTE*: F680* is a tag that is absolute, which means the facility must have a qualified activities professional to direct the provision of activities to the residents. Thus, it is cited if the facility is non-compliant with the regulation, whether or not there have been any negative outcomes to residents. *In determining the Scope and Severity, surveyors must consider the extent to which non-compliance at F679 is attributed to the lack of an activity director or the lack of qualifications of the activity director.*

F684
§ 483.25 Quality of care
Quality of care is a fundamental principle that applies to all treatment and care provided to facility residents. Based on the **comprehensive assessment** ***of a resident, the facility must ensure that*** **resident*s*** **receive** ***treatment and*** **care** ***in accordance with professional standards of practice, the*** **comprehensive** ***person-centered care plan, and the residents' choices, including but not limited to the following:***

INTENT
To ensure facilities identify and provide needed care and services that are resident centered, in accordance with the resident's preferences, goals for care and professional standards of practice that will meet each resident's physical, mental, and psychosocial needs.

DEFINITIONS
"Highest practicable physical, mental, and psychosocial well-being" is defined as the highest possible level of functioning and well-being, limited by the individual's recognized pathology and normal aging process. Highest practicable is determined through the comprehensive resident assessment and by recognizing and competently and thoroughly addressing the physical, mental or psychosocial needs of the individual.

"Hospice Care" *means a comprehensive set of services described in Section 1861(dd)(l) of the Act, identified and coordinated by an interdisciplinary group (IDG) to provide for the physical, psychosocial, spiritual, and emotional needs of a terminally ill patient and/or family members, as delineated in a specific patient plan of care. (42 CFR 418.3)*

"Palliative care*" means patient and family-centered care that optimizes quality of life by anticipating, preventing, and treating suffering. Palliative care throughout the continuum of*

illness involves addressing physical, intellectual, emotional, social, and spiritual needs and to facilitate patient autonomy, access to information, and choice. (§418.3)

"Terminally ill" *means that the individual has a medical prognosis that his or her life expectancy is 6 months or less if the illness runs its normal course. (§418.3)*

GUIDANCE

NOTE: *Although Federal requirements dictate the completion of RAI assessments according to certain time frames, standards of good clinical practice dictate that the clinical assessment process is more fluid and should be ongoing. The lack of ongoing clinical assessment and identification of changes in condition, to meet the resident's needs between required RAI assessments should be addressed at 483.35 Nursing Services, F726 (competency and skills to identify and address a change in condition), and the relevant outcome tag, such as 483.12 Abuse, 483.24 Quality of Life, 483.25 Quality of Care, and/or 483.40 Behavioral Health.*
Use guidance at F684 for review of concerns which have caused or have a potential to cause a negative outcome to a resident's physical, mental, or psychosocial health or well-being that is not specifically addressed by any other tag at 483.25. Additionally, F684 contains guidance for end of life and hospice care.

Nursing homes must place priority on identifying what each resident's highest practicable well-being is in each of the areas of physical, mental and psychosocial health.
Each resident's care plan must reflect person-centere care, and include resident choices, preferences, goals, concerns/needs, and describe the services and care that is to be furnished to attain or maintain, or improve the resident's highest practicable physical, mental and pschosoial well-being. For concerns related to the resident's comprehensive care plan, see F656, 483.21(b) Comprehensive Care Plans.

The following sections describe some, but not all of the care needs that are not otherwise covered in the remaining tags of § 483.25, Quality of Care.

I. Review of a Resident with Non Pressure-Related Skin Ulcer/Wound.

Residents may develop various types of skin ulceration. At the time of the assessment and diagnosis of a skin ulcer/wound, the clinician is expected to document the clinical basis (e.g., underlying condition contributing to the ulceration, ulcer edges and wound bed, location, shape, condition of surrounding tissues) which permit differentiating the ulcer type, especially if the ulcer has characteristics consistent with a pressure ulcer, but is determined not to be one. This section differentiates some of the different types of skin ulcers/wounds *that are not considered to be pressure ulcers*:

NOTE: Guidance regarding pressure ulcers is found at 42 CFR 483.25 *(b)(1)F686 Skin Integrity – Pressure Ulcers*. Use *this tag F684* for issues regarding non-pressure related skin ulcers/wounds. *Kennedy Terminal Ulcers are considered to be pressure ulcers that generally occur at the end of life. For concerns related to Kennedy Terminal Ulcers, refer to F686, 483.25(b) Pressure Ulcers.*

- ***Arterial Ulcer:*** An arterial ulcer is ulceration that occurs as the result of arterial occlusive disease when non-pressure related disruption or blockage of the arterial blood flow to an area causes tissue necrosis. Inadequate blood supply to the extremity may initially present as intermittent claudication. Arterial/Ischemic ulcers may be present in individuals with moderate to severe peripheral vascular disease, generalized arteriosclerosis, inflammatory or autoimmune disorders (such as arteritis), or significant vascular disease elsewhere (e.g., stroke or heart attack). The arterial ulcer is characteristically painful, usually occurs in the distal portion of the lower extremity and may be over the ankle or bony areas of the foot (e.g., top of the foot or toe, outside edge of the foot). The wound bed is frequently dry and pale with minimal or no exudate. The affected foot may exhibit: diminished or absent pedal pulse, coolness to touch, decreased pain when hanging down (dependent) or increased pain when elevated, blanching upon elevation, delayed capillary fill time, hair loss on top of the foot and toes, toenail thickening;
- ***Diabetic Neuropathic Ulcer:*** A diabetic neuropathic ulcer requires that the resident be diagnosed with diabetes mellitus and have peripheral neuropathy. The diabetic ulcer characteristically occurs on the foot, e.g., at mid-foot, at the ball of the foot over the metatarsal heads, or on the top of toes with Charcot deformity ; *and*
- ***Venous or Stasis Ulcer:*** A venous ulcer (previously known as a stasis ulcer) is an open lesion of the skin and subcutaneous tissue of the lower leg, often occurring in the lower leg around the medial ankle. Venous ulcers are reported to be the most common vascular ulceration and may be difficult to heal, may occur off and on for several years, and may occur after relatively minor trauma. The ulcer may have a moist, granulating wound bed, may be superficial, and may have minimal to copious serous drainage unless the wound is infected. The resident may experience pain that may increase when the foot is in a dependent position, such as when a resident is seated with her or his feet on the floor. Recent literature implicates venous hypertension as a causative factor. Venous hypertension may be caused by one (or a combination of) factor(s) including: loss of (or compromised) valve function in the vein, partial or complete obstruction of the vein (e.g., deep vein thrombosis, obesity, malignancy), and/or failure of the calf muscle to pump the blood (e.g., paralysis, decreased activity). Venous insufficiency may result in edema and induration, dilated superficial veins, dry scaly crusts, dark pigmented skin in the lower third of the leg, or dermatitis. The pigmentation may appear as darkening skin, tan or purple areas in light skinned residents and dark purple, black or dark brown in dark skinned residents. Cellulitis may be present if the tissue is infected.

II. Review of a Resident at or Approaching End of Life and/or Receiving Hospice Care and Services

Assessment

The resident must receive a comprehensive assessment to provide direction for the development of the resident's care plan to address the choices and preferences of the resident who is nearing the end of life. In addition, in order to promote the physical, mental, and psychosocial well-being of a resident who is approaching the end of life, the facility and the resident's attending physician/practitioner, should, to the extent possible:

- *Identify the resident's prognosis and the basis for that prognosis; and*
- *Initiate discussions/considerations regarding advance care planning and resident choices*

to clarify goals and preferences regarding treatment including pain management and symptom control, treatment of acute illness, and choices regarding hospitalization.

Care Plan

The care plan must be based upon the resident assessment, choices and advance directives, if any. As the resident's status changes, the facility, attending practitioner and the resident representative, to the extent possible, must review and/or revise care plan goals and treatment choices. Based upon the resident's assessment, the care plan may include, but is not limited to addressing:

- *Oral Care - The care plan should include the provision of ongoing, consistent oral care including interventions, as necessary to provide comfort and prevent complications associated with dry mucous membranes and compromised dentition. (For concerns related to the provision of oral hygiene, refer to F676 or F677 - Activities of Daily Living, and for concerns related to dental care, refer to F790 and F791 - Dental Services.);*
- *Skin Integrity – The care plan should include, for a resident who has skin integrity issues or a pressure injury or is at risk of developing a pressure injury, approaches in accordance with the resident's choices, including, to the extent possible, attempting to improve or stabilize the skin integrity/tissue breakdown and to provide treatments if a pressure injury is present. (For concerns related to pressure injuries, refer to F686.);*
- *Medical Treatment/Diagnostic Testing - The resident and his/her representative and the attending practitioner may, based on resident choices/directives, make decisions on whether to continue medications, treatments and/or diagnostic tests. This must be included in the resident's record. (For concerns related to choice, care planning decisions and right to discontinue treatments, refer to F552 and F553.);*
- *Symptom Management - Symptom management may include controlling nausea, vomiting, uncomfortable breathing, agitation, and pain. Symptom management may include both pharmacological and nonpharmacological interventions consistent with the resident's choices and goals for comfort, dignity and desired level of alertness. (For concerns related to medications, refer to F758 psychotropic medications and F757 unnecessary medications.);*
- *Nutrition and Hydration- The resident may experience a decline in appetite or have difficulty eating or swallowing. Care plan interventions, regarding nutrition/hydration, must be based upon the resident's assessment, disease processes, and resident choices/directives and include amount, type, texture and frequency for food and fluids. Dietary restrictions and/or weight measurements may be revised/discontinued based upon resident/representative and attending practitioner decisions, and must be included in the medical record. If the resident's condition has declined to the point where he/she may no longer swallow food or fluids, the determination of whether to use artificial nutrition/hydration, based upon resident choices/directives, is made by the resident/ representative and the attending practitioner, and consistent with applicable State law and regulation. (For concerns related to nutrition, refer to F692, for concerns related to nutrition/hydration, and for concerns related to feeding tubes, refer to F693.); and/or*
- *Activities/Psychosocial Needs - Care plan interventions for activities must be based on the resident's assessment and include the resident's choices, personal beliefs, interests, ethnic/cultural practices and spiritual values, as appropriate. In addition, the resident's*

assessment may identify psychosocial needs, such as fear, loneliness, anxiety, or depression. Interventions to address the needs must be included in the plan of care. (For concerns related to the provision of activities, refer to F679. For concerns regarding medically related social services, refer to F745.)

For concerns related to developing and implementing the care plan, refer to F656, Comprehensive Care Plans; and for revision of care plans refer to F657, Comprehensive Care Plan Revision.

Resident Care Policies

The facility in collaboration with the medical director must develop and implement resident care policies that are consistent with current professional standards of practice for not only pain management and symptom control, but for assessing residents' physical, intellectual, emotional, social, and spiritual needs as appropriate. In addition, if the facility has a written agreement with a Medicare-certified hospice, the policies must identify the ongoing collaboration and communication processes established by the nursing home and the hospice. (Refer to F841 - §483.70(h) Medical Director, or for the written agreement, to F849, 483.70(o) Hospice Services)

***NOTE**: If the resident has elected or is revoking the Medicare hospice benefit, a Significant Change in Status Assessment (SCSA) must be conducted as noted in the "Long Term Care Facility Resident Assessment Instrument User's Manual" (Version 3.0) Chapter 2:*

- *If a resident was admitted on the hospice benefit (i.e. the resident is coming into the facility having already elected the hospice benefit), the facility completes the required MDS admission assessment;*
- *If a terminally ill resident elects the hospice benefit after admission, a SCSA must be performed regardless of whether an MDS assessment was recently conducted on the resident. This is to ensure a coordinated care plan between the hospice and nursing home is in place; and*
- *A SCSA is required to be performed when a resident is receiving hospice services and decides to discontinue those services (revocation of the hospice benefit). (Refer to F637 significant change in status assessment)*

Hospice Care and Services Provided by a Medicare-certified Hospice

Hospice care and services are based upon a written agreement between the nursing home and the Medicare-certified hospice (hereafter referred to as hospice or hospice services). (See F849 - Hospice Services). This section discusses the collaborative services provided by the nursing home and the hospice for a resident who is receiving hospice care and services.

A nursing home resident at the end of life may choose to elect the Medicare hospice benefit, or may choose to continue to receive the care and services provided by the nursing home. The resident considering election of the hospice benefit must meet the hospice eligibility requirements. According to 42 CFR §418.20, in order to be eligible to elect hospice care under Medicare, an individual must be -

(a) Entitled to Part A of Medicare; and
(b) Certified as being terminally ill in accordance with §418.22.

***NOTE**: Hospice is also an optional state plan benefit in the Medicaid program. If a resident who receives Medicaid chooses to elect the hospice benefit, the physician must provide written certification that the individual is terminally ill. (Refer to SSA Sec. 1905(o)(1)(A). [42 U.S.C. 1396d(o)(1)(A)]) If the resident is eligible for both Medicare and Medicaid, he/she must elect the hospice benefit simultaneously under both programs; and if the resident chooses to revoke the hospice benefit, he/she must revoke the benefit simultaneously under both of the programs.*

There is no requirement that a nursing home offer hospice services. Although a resident may meet the eligibility requirements and may choose to elect the hospice benefit, the nursing home may or may not have an arrangement with a hospice to provide hospice care and services. If the nursing home has an agreement with a hospice, it must, consistent with F552, inform each resident before or at the time of admission, and periodically during the resident's stay, of hospice services available in the nursing home.

If a nursing home allows one or more hospice providers to provide services, there must be a written agreement between each hospice and the nursing home that describes their responsibilities prior to the hospice initiating care for the resident. (For the written agreement refer to F849 - Hospice Services.)

If the resident chooses to elect the hospice benefit, but has not chosen a hospice provider, and the nursing home does not have an agreement with a hospice provider:

- *If the resident wishes, the nursing home must assist the resident with a transfer to another facility or appropriate setting where hospice services are provided; or*
- *The nursing home may choose to establish a written agreement with a hospice.*

Coordinated Care Plan

The nursing home retains primary responsibility for implementing those aspects of care that are not related to the duties of the hospice. It is the nursing home's responsibility to continue to furnish 24-hour room and board care, meeting the resident's personal care and nursing needs. The facility's services must be consistent with the care plan developed in coordination with the hospice, and the facility must offer the same services to its residents who have elected the hospice benefit as it furnishes to its residents who have not elected the hospice benefit. Therefore, the nursing home resident should not experience any lack of services or personal care because of his or her status as a hospice patient. This includes what would normally be provided to a resident in the nursing home, including but not limited to the following: conducting the comprehensive assessments which includes the Resident Assessment Instrument (RAI), providing personal care, activities, medication administration, required physician visits, monthly medication regimen review, support for activities of daily living, social services as appropriate, nutritional support and services, and monitoring the condition of the resident. The facility is required to develop and update the care plan in accordance with Federal, State or local laws governing the facility.

The hospice retains primary responsibility for the provision of hospice care and services, based upon the resident's assessments, including but not limited to the following: providing medical direction and management of the resident; nursing,(including assigning a hospice aide as needed to support the resident's ongoing care); counseling (including spiritual, dietary, and

bereavement); social work; providing medical supplies, durable medical equipment, and drugs necessary for the palliation of pain and symptoms associated with the terminal illness and related conditions; and all other hospice services that are necessary for the care of the resident's terminal illness and related conditions. See 42 C.F.R. § 418.112(c)(6).

***NOTE**: If there is an issue related to the provision of care by the hospice, the survey team may request the written agreement and review to see the steps the nursing home has taken to resolve the resident care issues. The written agreement should include how differences are resolved between the nursing home and the hospice, and the nursing home and hospice liaisons may need to be interviewed regarding the identified concerns. If there are concerns related to the provision of care based upon the failure of the implementation of the written agreement or the lack of a written agreement, refer to F849.*

The resident/representative must be included in the development of the care plan, which must reflect the resident's choices to the extent possible. In order to address communication regarding the resident's care between the nursing home and the hospice, the nursing home must designate a staff person to participate in the ongoing communication and include the resident representative in decision-making. The nursing home should provide the name of the designated staff member/or designee to the resident/representative for ongoing communication regarding care or concerns. (Refer to F849 - Designated member of Interdisciplinary Group (IDG))

In order to provide continuity of care, the hospice, nursing home, and resident/representative must collaborate in the development of a coordinated care plan which includes, but is not limited to, the following:

- *Resident/representative choices regarding care;*
- *The hospice philosophy of care and all services necessary for the palliation and management of the terminal illness and related conditions;*
- *Measurable goals and interventions based on comprehensive and ongoing assessments;*
- *Interventions that address, as appropriate, the identification of timely, pertinent non-pharmacologic and pharmacological interventions to manage pain and other symptoms of discomfort;*
- *The hospice portion that governs the actions of the hospice and describes the services that are needed to care for the resident;*
- *Identification of the services the nursing home will continue to provide; and*
- *The identification of the provider responsible for performing specific services/functions that have been agreed upon.*

The structure of the care plan is established by the nursing home and the hospice. The care plan may be divided into two portions, one maintained by the nursing home and the other maintained by the hospice. The nursing home and the hospice must be aware of the location and content of the coordinated care plan (which includes the nursing home portion and the hospice portion) and the plan must be current and internally consistent in order to assure that the needs of the resident for both hospice care and nursing home care are met at all times. Any changes to the plan(s) must be discussed and approved by the nursing home, hospice staff and, to the extent possible, the resident and/or representative.

Effective November 28, 2017

As the condition of the resident declines, the hospice and nursing home must continue a joint collaborative effort, which includes ongoing communication with and input from the resident/ representative, to assure that the care provided addresses concerns as identified in the ongoing assessments.

Physician Services

When a hospice patient is a resident of a nursing home, that resident's hospice care plan must be established and maintained in consultation with the resident's attending physician/practitioner, representatives of the nursing home and the resident/representative, to the extent possible. (See F710 – Physician supervision of care) In a nursing home, a physician's assistant may not act as the hospice attending physician, however, the resident's attending physician at the nursing home may delegate tasks to a physician's assistant. See F714 – physician delegation of tasks.

***NOTE**: For informational purposes, the definition of an attending physician as identified in the hospice federal regulations is provided below. This clarifies that a doctor of medicine, osteopathy or nurse practitioner, if meeting the listed requirements, may function as the "attending physician" in a hospice. The hospice regulations do not provide for a physician assistant to function in this category.*

> *§418.3 Definitions. For the purposes of this part — "Attending physician" means a —*
> *(1)(i) Doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he or she performs that function or action; or*
> *(ii) Nurse practitioner who meets the training, education, and experience requirements as described in §410.75 (b) of this chapter.*
> *(2) Is identified by the individual, at the time he or she elects to receive hospice care, as having the most significant role in the determination and delivery of the individual's medical care.*

Communication

Nursing home staff must immediately contact and communicate with the hospice staff regarding any significant changes in the resident's status, clinical complications or emergent situations. These situations may include but are not limited to changes in cognition or sudden unexpected decline in condition, a fall with a suspected fracture or adverse consequences to a medication or therapy, or other situations requiring a review or revision to the care plan. The immediate notification to hospice does not change the requirement that a nursing home also immediately notify the resident's attending physician/practitioner and the family resident representative of significant changes in condition or a need to change the care plan. (Refer to F580 - Notification of Changes) Prior to care plan or order changes, the hospice and the resident's attending physician/practitioner may need to collaborate to address this change and to assure the resident's immediate needs and treatment decisions are met, including situations which could require a potential transfer to an acute care setting. This decision making must be consistent with the resident's wishes. (Refer to F849 - Hospice Services.) Additionally, the communication of necessary information to the receiving provider must include those items required at 483.15(c)(2)(iii), F622.

If there is a conflict between the hospice and the resident's attending physician/practitioner regarding the care plan, there must be communication between the hospice and the nursing home regarding the issue. This communication should be timely and include the hospice medical director and the nursing home medical director as well as other pertinent hospice and facility staff, as needed.

The care of the resident receiving hospice services must reflect ongoing communication and collaboration between the nursing home and the hospice staff. It is essential that a communication process be established between the nursing home and the hospice to be used 24-hours a day and that it include how the communication will be documented to reflect concerns and responses. (Refer to F849 - which requires that the written agreement specify the process for hospice and nursing home communication of necessary information regarding the resident's care.)

Review of Facility Practices/Written Agreement for Hospice Services
Any concerns identified by the survey team related to end of life and/or care provided by a hospice should trigger a review of the facility's policies and procedures on end of life and hospice care and/or related policies (e.g., advance directives). In addition, the survey team should request a copy of the written agreement between the nursing home and the hospice. If there is a failure to develop and or implement portions of the written agreement with a hospice, refer to F849 - Hospice Services.

***NOTE**: If a resident is receiving services from a Medicare-certified hospice and:*

- *The hospice was advised of concerns by the nursing home and failed to address and resolve issues related to coordination of care or implementation of appropriate services; and/or*
- *The hospice failed to provide services in accordance with the coordinated plan of care, regardless of notice from the facility;*

The survey team must refer the complaint to the State agency responsible for oversight of hospice, identifying the specific resident(s) involved and the concerns identified. If the hospice was advised of the concerns, and failed to resolve issues related to the management of a resident's care, coordination of care, or implementation of appropriate services, review the appropriate portions of F849 regarding the written agreement and determine whether there is a failure by the nursing home related to the implementation of the agreement.

INVESTIGATIVE PROTOCOL for F684 – Quality of Care
Use
Use the General Critical Element (CE) Pathway, or if applicable, the Hospice and End of Life Care and Services CE Pathway, along with the above interpretive guidelines, or applicable professional standards of practice for investigating concerns related to the facility's requirement to provide treatment and care in accordance with professional standards of practice, the comprehensive person-centered care plan, and the residents' choices – for which there is no other Quality of Care tag that would address the issue.

Effective November 28, 2017

***Summary of Investigative* Procedure**

Briefly review the *most recent comprehensive* assessment*s*, comprehensive care plan and orders to identify whether the facility has recognized and *assessed concerns or resident care needs under investigation.* If the resident has been in the facility for less than 14 days (before completion of all the *Resident Assessment Instrument (*RAI) is required), *review the baseline care plan which must be completed within 48 hours to* determine if the facility is *providing appropriate care and services based on information available at the time of admission*.

This information will guide observations *and interviews* to be made *in order to corroborate concerns identified*. *Make note of whether the comprehensive care plan is evaluated and revised based on the resident's response to interventions. Always observe for visual cues of psychosocial distress and harm (see Appendix P, Guidance on Severity and Scope Levels and Psychosocial Outcome Severity Guide).*

During the investigation, identify *the extent to which the* facility *has developed and implemented* interventions *in accordance with the resident's needs, goals for care and professional standards of practice for the specific condition or concern being investigated.* In any instance in which the surveyor has identified a lack of improvement or a decline, it must be determined whether this was unavoidable or avoidable. In order to make a determination of unavoidable decline or failure to reach highest practicable well-being, the facility must have:

- Conducted an accurate and comprehensive assessment (see §483.20 *Resident Assessment*) including evaluating the resident's clinical condition and risk factors for the concern being investigated;
- Based on *information gathered through resident assessments, with resident/representative input, d*eveloped a person centered care plan, defined and implemented interventions that are consistent with resident needs, goals, and recognized standards of practice;
- *Implemented the care plan, and monitored resident responses to the interventions; and*
- Provided ongoing review and revision of the *care plan and* interventions as necessary.

If the facility has not done one or more of the above bulleted items, and a decline or failure to reach his/her highest practicable well-being occurred, this would be considered an avoidable decline.

NOTE: *During the investigation of services provided to a resident from a Medicare-certified hospice determine whether:*

- *The hospice was advised of concerns by the nursing home and failed to address and resolve issues related to coordination of care or implementation of appropriate services; and/or*
- *The hospice failed to provide services in accordance with the coordinated care plan, regardless of notice from the facility.*

The survey team must refer the above concerns as complaints to the State agency responsible for oversight of hospice, identifying the specific resident(s) involved and the concerns identified. If the hospice was advised of the concerns, and failed to resolve issues related to the management of a resident's care, coordination of care, or

implementation of appropriate services, review the appropriate portions of F849 regarding the written agreement and determine whether there is a failure by the nursing home related to the implementation of the agreement.

KEY ELEMENTS OF NONCOMPLIANCE

To cite deficient practice at F684, the surveyor's investigation will generally show that the facility failed to do any one of the following:

- *Provide needed care or services resulting in an actual or potential decline in one or more residents' physical, mental, and/or psychosocial well-being;*
- *Provide needed care or services (i.e., manage symptoms) resulting in one or more residents' failure to improve and/or attain their highest practicable physical, mental, and/or psychosocial well-being;*
- *Recognize and/or assess risk factors placing the resident at risk for specific conditions and/or problems;*
- *Implement resident-directed care and treatment consistent with the resident's comprehensive assessment and care plan, preferences, choices, rights, advance directives (if any, and if applicable, according to State law), goals, physician orders, and professional standards of practice, causing a negative outcome, or placing the resident at risk for specific conditions and/or problems.;*
- *Monitor, evaluate the resident's response to interventions, and/or revise the interventions as appropriate, causing a negative outcome, or placing the resident at risk for specific conditions and/or problems; and*
- *Inform and educate the resident who decides to decline care about risks/benefits of such declination; and offer alternative care options and take steps to minimize further decline, causing a negative outcome, or placing the resident at risk for specific conditions and/or problems.*

NOTE: *Most noncompliance related to the failure to provide care and services needed for residents to attain or maintain the highest practicable physical, mental, and psychosocial well-being can also be cited at other regulations (e.g., assessment, care planning, accommodation of needs, and physician supervision). Surveyors should evaluate compliance with these regulations and cite deficiencies at F684 only when other regulations do not address the deficient practice.* *Refer to F697 for pain management, and if there is a failure to develop and or implement portions of the written agreement with a hospice, refer to F849 - Hospice Services.*

DEFICIENCY CATEGORIZATION

In addition to actual or potential physical harm, always consider whether psychosocial harm has occurred when determining severity level (See Appendix P, Section IV, E, Psychosocial Outcome Severity Guide).

Examples of Severity Level 4 Noncompliance Immediate Jeopardy to Resident Health or Safety include but are not limited to:

- *The facility failed to promptly identify and intervene for an acute change in a resident's condition related to congestive heart failure (CHF), resulting in the family calling 911 to transport the resident to the hospital. The resident was admitted to the hospital with*

respiratory distress, pulmonary edema, and complications of CHF.(Also cross-referenced and cited at F580, Notification of Changes.)

- *As a result of the facility's continuous or repeated failure to implement comfort measures in accordance with the care plan, the resident experienced serious harm related to uncontrolled vomiting and nausea.*

Examples of Severity Level 3 Noncompliance Actual Harm that is Not Immediate Jeopardy include, but are not limited to:

- *The facility failed to provide care for a resident with a stasis ulcer as identified on the resident's care plan and physician's orders, resulting in worsening of the stasis ulcer, as evidenced by a large area of the skin surrounding the ulcer being reddened, swollen and, according to the nurse, warm to touch. There was exudate and slough on the wound bed, and according to measurements, the wound had increased in size.*
- *The facility failed to implement a resident's hospice/nursing home coordinated care plan that specified the resident not being transferred to the hospital for treatment. The facility transferred the resident to the hospital for treatment related to a urinary tract infection even though the resident and the coordinated care plan indicated the resident did not wish to be hospitalized and preferred treatment at the facility. The facility did not contact the hospice prior to initiating the transfer to the hospital. The resident experienced increased pain during the transfer to the hospital and continued to express emotional distress (tearful/crying) over the transfer.*
- *The resident had requested and the care plan included a symptom management plan with the use of medication to reduce the resident's symptoms but not to the point that the resident was symptom free so that the resident could be alert and able to participate in visits with family/friends. However, the facility failed to administer the medications as indicated in the plan of care. The resident experienced lethargy and somnolence and was unable to converse/relate to family/friends during visits.*

Examples of Severity Level 2 Noncompliance: No Actual Harm, with Potential for More than Minimal Harm, that is Not Immediate Jeopardy include, but are not limited to:
Failure to follow physician orders to obtain daily weights for a resident with a diagnosis of congestive heart failure, as evidenced by no documented daily weights on three consecutive weekends. Although this noncompliance resulted in no actual harm to the resident, it has a potential for more than minimal harm if the practice is not corrected.

The resident receiving the hospice benefit was on a pain management program utilizing opioids. The resident was experiencing episodic minimal discomfort related to the facility's failure to consistently implement the bowel management plan as identified in the coordinated care plan.

Severity Level 1 Noncompliance: No Actual Harm, with Potential for Minimal Harm
Failure to provide appropriate care and services to meet the resident's physical, mental and/or psychosocial needs places the resident at risk for more than minimal harm. Therefore, Severity Level 1 does not apply for this regulatory requirement.

Effective November 28, 2017

F685
§483.25*(a)* Vision and hearing
To ensure that residents receive proper treatment and assistive devices to maintain vision and hearing abilities, the facility must, if necessary, assist the resident—

§483.25*(a)(1)* In making appointments, and

§483.25*(a)(2)* By arranging for transportation to and from the office of a practitioner specializing in the treatment of vision or hearing impairment or the office of a professional specializing in the provision of vision or hearing assistive devices.

INTENT
The intent of this regulation is to ensure the facility assists the resident in gaining access to vision and hearing services by making appointments and by arranging for transportation.

DEFINITIONS
Assistive devices to maintain vision include, *but are not limited to,* glasses, contact lenses, magnifying *lens or other devices that are used by the resident*.

Assistive devices to maintain hearing include*, but are not limited to,* hearing aids*, and amplifiers.*

INTERPRETIVE* GUID*ANCE
This requirement does not mean that the facility must provide refraction, glasses, contact lenses *or other assistive devices,* conduct comprehensive audiological evaluations (*other than the screening that is* a part of the required assessment in §483.20(b)) or provide hearing aids *or other devices*.

The facility's responsibility is to assist residents and their *representatives* in locating and utilizing any available resources (e.g., Medicare or Medicaid program payment, local health organizations offering items and services which are available free to the community) for the provision of the services the resident needs. This includes making appointments and arranging transportation to obtain needed services.

In situations where the resident has lost their device, facilities must assist residents and their representative in locating resources, as well as in making appointments, and arranging for transportation to replace the lost devices.

Investigative Summary:
Use the Activities of Daily Living and Communication-Sensory Critical Element (CE) Pathways along with the above interpretive guidelines when determining if the facility meets requirements to ensure that residents receive proper treatment and assistive devices to maintain vision and hearing abilities.

Summary of Vision and Hearing Investigative Procedure
Briefly review the most recent comprehensive assessments, comprehensive care plan, and physician orders to determine if the facility assists residents in gaining access to vision and

hearing services by making appointments, and arranging for transportation. Observations, interviews, and record reviews should be utilized to corroborate concerns identified. If the resident has been in the facility for less than 14 days (before completion of all the Resident Assessment Instrument (RAI) is required), review the baseline care plan which must be completed within 48 hours to determine if the facility is providing appropriate care and services based on information available at the time of admission.

F686
§483.25(b) ***Skin Integrity***
§483.25(b)(1) Pressure ***ulcers.***
Based on the comprehensive assessment of a resident, the facility must ensure that—

(i) ***A resident receives care, consistent with professional standards of practice, to prevent pressure ulcers and*** **does not develop pressure ulcers unless the individual's clinical condition demonstrates that they were unavoidable; and**

(ii) A resident ***with*** **pressure** ***ulcers*** **receives necessary treatment and services,** ***consistent with professional standards of practice*****, to promote healing, prevent infection and prevent new ulcers from developing.**

INTENT
The intent of this requirement is that the resident does not develop pressure *ulcers/injuries (PU/PIs)* unless clinically unavoidable and that the facility provides care and services *consistent with professional standards of practice* to:

- Promote the prevention of pressure *ulcer/injury* development;
- Promote the healing of existing pressure *ulcers/injuries* (including prevention of infection to the extent possible); and
- Prevent development of additional pressure *ulcer/injury***.**

NOTE: *CMS is aware of the array of terms used to describe alterations in skin integrity due to pressure. Some of these terms include: pressure ulcer, pressure injury, pressure sore, decubitus ulcer and bed sore. Clinicians may use and the medical record may reflect any of these terms, as long as the primary cause of the skin alteration is related to pressure. For example, the medical record could reflect the presence of a Stage 2 pressure injury, while the same area would be coded as a Stage 2 pressure ulcer on the MDS.*

CMS often refers to the National Pressure Ulcer Advisory Panel's (NPUAP) terms and definitions, which it has adapted, within its patient and resident assessment instruments and corresponding assessment manuals, which includes the Minimum Data Set (MDS). We intend to continue our adaptation of NPUAP terminology for coding the resident assessment instrument while retaining current holistic assessment instructions definitions and terminology. The adapted terminology was used in the development of this guidance.

Additional information can be found on the NPUAP website at https://www.npuap.org/resources/educational-and-clinical-resources.

NOTE*: References to non-CMS/HHS sources or sites on the Internet included above or later in this document are provided as a services and do not constitute or imply endorsement of these*

organizations or their programs by CMS or the U.S. Department of Health and Human Services. CMS is not responsible for the content of pages found at these sites. URL addresses were ccurrent at the date of this publication.

DEFINITIONS

Definitions are provided to clarify clinical terms related to pressure *injuries* and their evaluation and treatment.

"Pressure Ulcer/Injury (PU/PI)" *refers to localized damage to the skin and/or underlying soft tissue usually over a bony prominence or related to a medical or other device. A pressure injury will present as intact skin and may be painful. A pressure ulcer will present as an open ulcer, the appearance of which will vary depending on the stage and may be painful. The injury occurs as a result of intense and/or prolonged pressure or pressure in combination with shear. The tolerance of soft tissue for pressure and shear may also be affected by skin temperature and moisture, nutrition, perfusion, co-morbidities and condition of the soft tissue.*

Avoidable/Unavoidable

- "Avoidable" means that the resident developed *a pressure ulcer/injury* and that the facility did not do one or more of the following: evaluate the resident's clinical condition and risk factors; define and implement interventions that are consistent with resident needs, resident goals, and *professional* standards of practice; monitor and evaluate the impact of the interventions; or revise the interventions as appropriate.
- "Unavoidable" means that the resident developed *a pressure ulcer/injury* even though the facility had evaluated the resident's clinical condition and risk factors; defined and implemented interventions that are consistent with resident needs, goals, and *professional* standards of practice; monitored and evaluated the impact of the interventions; and revised the approaches as appropriate.

Colonized/Infected

- "Colonized" refers to the presence of micro-organisms on the surface or in the tissue of a wound without the signs and symptoms of an infection.
- "Infected" refers to the presence of micro-organisms in sufficient quantity to overwhelm the defenses of viable tissues and produce the signs and symptoms of infection.

Debridement- Debridement is the removal of devitalized/necrotic tissue and foreign matter from a wound to improve or facilitate the healing process. Debridement methods may include a range of treatments such as the use of enzymatic dressings to surgical debridement in order to remove tissue or matter from a wound to promote healing.

Eschar/Slough

- *"Eschar" is dead or devitalized tissue that is hard or soft in texture; usually black, brown, or tan in color, and may appear scab-like. Necrotic tissue and eschar are usually firmly adherent to the base of the wound and often the sides/ edges of the wound.*
- *"Slough" is non-viable yellow, tan, gray, green or brown tissue; usually moist, can be soft, stringy and mucinous in texture. Slough may be adherent to the base of the wound or present in clumps throughout the wound bed.*

Exudate

- "Exudate" is any fluid that has been forced out of the tissues or its capillaries because of inflammation or injury. It may contain serum, cellular debris, bacteria and leukocytes.
- "Purulent exudate/drainage/discharge" is any product of inflammation that contains pus (e.g., leukocytes, bacteria, and liquefied necrotic debris).
- "Serous drainage or exudate" is watery, clear, or slightly yellow/tan/pink fluid that has separated from the blood and presents as drainage.

Friction/Shearing

- "Friction" is the mechanical force exerted on skin that is dragged across any surface.
- "Shearing" occurs when layers of skin rub against each other or when the skin remains stationary and the underlying tissue moves and stretches and angulates or tears the underlying capillaries and blood vessels causing tissue damage.

Granulation Tissue - "Granulation tissue" is the pink-red moist tissue that fills an open wound, when it starts to heal. It contains new blood vessels, collagen, fibroblasts, and inflammatory cells.

Tissue tolerance *is the ability of the skin and its supporting structures to endure the effects of pressure, without adverse effects. Tissue tolerance affects the length of time a resident can maintain a position without suffering a pressure ulcer/injury.*

Tunnel/Sinus Tract/Undermining - The terms tunnel and sinus tract are often used interchangeably.

- A "tunnel" is a passageway of tissue destruction under the skin surface that has an opening at the skin level from the edge of the wound.
- A "sinus tract" is a cavity or channel underlying a wound that involves an area larger than the visible surface of the wound.
- "Undermining" is the destruction of tissue or ulceration extending under the skin edges (margins) so that the pressure ulcer is larger at its base than at the skin surface. Undermining often develops from shearing forces and is differentiated from tunneling by the larger extent of the wound edge involved and the absence of a channel or tract extending from the pressure ulcer under the adjacent intact skin.

GUIDANCE
STAGING
Staging of a PU/PI is performed to indicate the characteristics and extent of tissue injury, and should be conducted according to professional standards of practice.

NOTE: *Regardless of the staging system or wound definitions used by the facility, the facility is responsible for completing the MDS utilizing the staging guidelines found in the RAI Manual.*

Stage 1 Pressure Injury: Non-blanchable erythema of intact skin
Intact skin with a localized area of non-blanchable erythema (redness). In darker skin tones, the PI may appear with persistent red, blue, or purple hues. The presence of blanchable erythema or

changes in sensation, temperature, or firmness may precede visual changes. Color changes of intact skin may also indicate a deep tissue PI (see below).

Stage 2 Pressure Ulcer: Partial-thickness skin loss with exposed dermis
Partial-thickness loss of skin with exposed dermis, presenting as a shallow open ulcer. The wound bed is viable, pink or red, moist, and may also present as an intact or open/ruptured blister. Adipose (fat) is not visible and deeper tissues are not visible. Granulation tissue, slough and eschar are not present. This stage should not be used to describe moisture associated skin damage including incontinence associated dermatitis, intertriginous dermatitis (inflammation of skin folds), medical adhesive related skin injury, or traumatic wounds (skin tears, burns, abrasions).

Stage 3 Pressure Ulcer: Full-thickness skin loss
Full-thickness loss of skin, in which subcutaneous fat may be visible in the ulcer and granulation tissue and epibole (rolled wound edges) are often present. Slough and/or eschar may be visible but does not obscure the depth of tissue loss. The depth of tissue damage varies by anatomical location; areas of significant adiposity can develop deep wounds. Undermining and tunneling may occur. Fascia, muscle, tendon, ligament, cartilage and/or bone are not exposed. If slough or eschar obscures the wound bed, it is an Unstageable PU/PI.

Stage 4 Pressure Ulcer: Full-thickness skin and tissue loss
Full-thickness skin and tissue loss with exposed or directly palpable fascia, muscle, tendon, ligament, cartilage or bone in the ulcer. Slough and/or eschar may be visible on some parts of the wound bed. Epibole (rolled edges), undermining and/or tunneling often occur. Depth varies by anatomical location. If slough or eschar obscures the wound bed, it is an unstageable PU/PI.

Unstageable Pressure Ulcer: Obscured full-thickness skin and tissue loss
Full-thickness skin and tissue loss in which the extent of tissue damage within the ulcer cannot be confirmed because the wound bed is obscured by slough or eschar. Stable eschar (i.e. dry, adherent, intact without erythema or fluctuance) should only be removed after careful clinical consideration and consultation with the resident's physician, or nurse practitioner, physician assistant, or clinical nurse specialist if allowable under state licensure laws. If the slough or eschar is removed, a Stage 3 or Stage 4 pressure ulcer will be revealed. If the anatomical depth of the tissue damage involved can be determined, then the reclassified stage should be assigned. The pressure ulcer does not have to be completely debrided or free of all slough or eschar for reclassification of stage to occur.

Other staging considerations include:

- ***Deep Tissue Pressure Injury (DTPI): Persistent non-blanchable deep red, maroon or purple discoloration***
  Intact skin with localized area of persistent non-blanchable deep red, maroon, purple discoloration due to damage of underlying soft tissue.. This area may be preceded by tissue that is painful, firm, mushy, boggy, warmer or cooler as compared to adjacent tissue. These changes often precede skin color changes and discoloration may appear differently in darkly pigmented skin. This injury results from intense and/or prolonged pressure and shear forces at the bone-muscle interface. The wound may evolve rapidly

to reveal the actual extent of tissue injury, or may resolve without tissue loss. If necrotic tissue, subcutaneous tissue, granulation tissue, fascia, muscle or other underlying structures are visible, this indicates a full thickness pressure ulcer. Once a deep tissue injury opens to an ulcer, reclassify the ulcer into the appropriate stage. Do not use DTPI to describe vascular, traumatic, neuropathic, or dermatologic conditions.

- ***Medical Device Related Pressure Ulcer/Injury:*** *Medical device related PU/PIs result from the use of devices designed and applied for diagnostic or therapeutic purposes. The resultant pressure injury generally conforms to the pattern or shape of the device. The injury should be staged using the staging system.*
- ***Mucosal Membrane Pressure Ulcer/Injury:*** *Mucosal membrane PU/PIs are found on mucous membranes with a history of a medical device in use at the location of the injury. Due to the anatomy of the tissue, these ulcers cannot be staged.*

PREVENTION OF PRESSURE *ULCERS/NJURIES*

A pressure ulcer/injury (PU/PI) can occur wherever pressure has impaired circulation to the tissue. *A facility must:*

- *Identify whether the resident is at risk for developing or has a PU/PI upon admission and thereafter;*
- *Evaluate resident specific risk factors and changes in the resident's condition that may impact the development and/or healing of a PU/PI;*
- *Implement, monitor and modify interventions to attempt to stabilize, reduce or remove underlying risk factors; and*
- *If a PU/PI is present, provide treatment to heal it and prevent the development of additional PU/PIs.*

The first step in *the* prevention *of PU/PIs,* is the identification of the resident at risk of developing *PU/PIs*. This is followed by implementation of appropriate individualized interventions and monitoring for the effectiveness of the interventions.

ASSESSMENT

An admission evaluation helps identify residents at risk of developing a PU/PI, and residents with existing *PU/PIs.* Because a resident at risk can develop a *PU/PI* within hours of the onset of pressure, the at-risk resident needs to be identified and have interventions implemented promptly to attempt to prevent *PU/PI.* The admission evaluation helps define those initial care approaches.

In addition, the admission evaluation may identify pre-existing signs suggesting that tissue damage has already occurred and additional tissue loss may occur. *For example, a deep* tissue *pressure injury identified on admission* could lead to the appearance of an unavoidable Stage *3* or *4* pressure *ulcer. A* Stage *1 PI can progress* to an *ulcer* with eschar or exudate within days after admission. Some situations, which may have contributed to this tissue damage *prior to admission*, include pressure resulting from immobility during hospitalization or surgical procedures, during prolonged ambulance transport, or while waiting to be assisted after a debilitating event, such as a fall or a cerebral vascular accident.

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It may be harder to identify erythema in a resident with darkly pigmented skin, *putting those residents* more at risk for developing *PU/PIs*. It may be necessary, in darker skinned *residents* to focus more on other evidence of *PU/PI* development such as *changes in sensation, skin temperature or firmness*.

Multiple factors, including pressure intensity, pressure duration, and tissue tolerance, significantly affect the potential for the development and healing of *PUs/PIs*. The comprehensive assessment, which includes the RAI, evaluates the resident's intrinsic risks, the resident's skin condition, *and* other factors (including causal factors) which place the resident at risk for *the development of or hinder the healing of PU/PIs. An individual may also have various intrinsic risks due to aging, such as decreased subcutaneous tissue and lean muscle mass, decreased skin elasticity, and impaired circulation or sensation.*

The comprehensive assessment should address those factors that have been identified as having an impact on the development, treatment and/or healing of *PU/PIs*, including, at a minimum: risk factors, pressure points, under-nutrition and hydration deficits, and moisture and the impact of moisture on skin. The assessment also helps identify the resident who has multi-system organ failure or an end-of-life condition or who is refusing care and treatment. If the resident is refusing care, an evaluation of the basis for the refusal, and the identification and evaluation of potential alternatives is indicated.

Risk Factors

Not all risk factors are fully modifiable or can be completely addressed. Some risk factors, such as a permanent lack of sensation to an area, may not be modifiable. Some potentially modifiable risk factors, such as malnutrition or uncontrolled blood sugars, may take time to correct, despite prompt intervention. Other risk factors, such as pressure, can be modified promptly. Many studies and professional *literature* identify risk factors that increase a resident's susceptibility to develop or to not heal pressure *PU/PIs.*

Examples of these risk factors include, but are not limited to:

- Impaired/decreased mobility and decreased functional ability;
- Co-morbid conditions, such as end stage renal disease, thyroid disease or diabetes mellitus;
- Drugs such as steroids that may affect healing;
- Impaired diffuse or localized blood flow, for example, generalized atherosclerosis or lower extremity arterial insufficiency;
- Resident refusal of some aspects of care and treatment;
- Cognitive impairment;
- Exposure of skin to urinary and fecal incontinence;
- Under nutrition, malnutrition, and hydration deficits; and
- *The presence of a previously* healed *PU/PI. The history of any healed PU/PI, its origin, treatment,* its stages [if known] is *important assessment information,* since areas of healed Stage *3* or *4 PU/PIs* are more likely to have recurrent breakdown.

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Although the requirements do not mandate the use of any specific assessment tool (other than the RAI), many validated instruments are available to aid in assessing the risk for developing PU/PIs. It is important to keep in mind that research has shown that in a skilled nursing facility, 80 percent of PU/PIs develop within two weeks of admission and 96 percent develop within three weeks of admission. (Reference: Lyder CH, Ayello EA. Pressure Ulcers: A Patient Safety Issue. In: Hughes RG, editor. Patient Safety and Quality: An Evidence-Based Handbook for Nurses. Rockville (MD): Agency for Healthcare Research and Quality (US); 2008 Apr. Chapter 12. Available from: http://www.ncbi.nlm.nih.gov/books/NBK2650/)

Many clinicians *utilize* a standardized pressure *ulcer/injury* risk assessment tool to assess a resident's *PU/PI* risks upon admission, weekly for the first four weeks after admission, then *monthly* or whenever there is a change in the *resident's condition*.

A resident's risk may increase due to an acute illness or condition change (e.g., upper respiratory infection, pneumonia, or exacerbation of underlying congestive heart failure) and may require additional evaluation. *The frequency of assessment should be based upon each resident's specific needs.*

Regardless of any resident's total risk score *on an assessment tool*, clinicians *are* responsible *for evaluating each existing and potential risk factor for developing a pressure injury and determining the resident's overall risk. It is acceptable if the clinician's assessment places the resident at a higher risk level than the overall score of the assessment tool based on assessment factors that are not captured by the tool. Documentation of the clinician's decision should be placed in the medical record.*

Pressure Points and Tissue Tolerance

Assessment of a resident's skin condition helps define prevention strategies. The skin assessment should include an evaluation of the skin integrity and tissue tolerance (ability of the skin and its supporting structures to endure the effects of pressure without adverse effects) after pressure to that area has been reduced or redistributed. *The measurement of tissue tolerance can be done in a variety of ways and the method chosen for use in the facility should be identified.*

Tissue closest to the bone may be the first tissue to undergo *changes related to pressure*. *PU/PIs* are usually located over a bony prominence, such as the sacrum, heel, the greater trochanter, ischial tuberosity, fibular head, scapula, and ankle (malleolus).

An at-risk resident who sits too long *in one position may* be more prone to *developing an ulcer/injury over the* ischial *tuberosity*. Slouching in a chair may predispose an at-risk resident to pressure ulcers/*injuries* of the spine, scapula, or elbow. Elbow pressure *injury* is often related to arm rests or lap boards. Friction and shearing are also important factors in tissue ischemia, necrosis and *PU/PI* formation.

PU/PIs may develop at other sites where pressure has impaired the circulation to the tissue, such as pressure from positioning or use of medical devices *applied for diagnostic or therapeutic purposes. The resultant PU/PI generally conforms to the pattern or shape of the device. Mucosal membrane PU/PIs are found on mucous membranes with a history of a medical device in use at*

the location of the injury. Due to the anatomy of mucous membranes, these ulcers cannot be staged.

PU/PIs on the sacrum and heels are most common. PU/PIs may also develop from pressure on an ear lobe related to positioning of the head; on areas (*for example,* nares, urinary meatus, extremities) caused by tubes, casts, orthotics, braces, cervical collars, or other medical devices; pressure on the labia or scrotum related to positioning (*for example*, against a pommel type cushion); the foot related to ill-fitting shoes causing blistering; or on legs, arms and fingers due to contractures or deformity.

Nutrition and Hydration

Adequate nutrition and hydration are essential for overall functioning. Nutrition provides vital energy and building blocks for all of the body's structures and processes. Any organ or body system may require additional energy or structural materials for repair or function. The skin is the body's largest organ system. It may affect, and be affected by, other body processes and organs. Skin condition reflects overall body function *therefore, the presence of* skin breakdown may be the most visible evidence of a *health issue.*

Weight reflects a balance between intake and utilization of energy. Significant unintended weight loss may indicate under-nutrition or worsening health status. Weight stability (in the absence of fluid excess or loss) is a useful indicator of overall caloric balance. Severely impaired organs (heart, lungs, kidneys, liver, etc.) may be unable to use nutrients effectively. A resident with a *PU/PI* who continues to lose weight either needs additional caloric intake or correction (where possible) of conditions that are creating a hypermetabolic state. Continuing weight loss and failure of a *PU/PI* to heal despite reasonable efforts to improve caloric and nutrient intake may indicate the resident is in multi-system failure or an end-stage or end-of-life condition warranting an additional assessment of the resident's overall condition.

Before instituting a nutritional care plan, it helps to summarize resident specific evidence, including: severity of nutritional compromise, rate of weight loss or appetite decline, probable causes, the individual's prognosis and projected clinical course, and the resident's wishes and goals. Because there are no wound-specific nutritional measures, the interdisciplinary team should develop nutritional goals for the whole person *and address nutritional status and needs in the care plan as appropriate.*

NOTE: Although some laboratory tests may help clinicians evaluate nutritional issues in a resident with *PU/PIs* , no laboratory test is specific or sensitive enough to warrant serial/repeated testing. *A* practitioner may order test(s) that provide useful additional information or help with management of treatable conditions *at their discretion*

Water is essential to maintain adequate body functions. As a major component of blood, water dissolves vitamins, minerals, glucose, amino acids, etc.; transports nutrients into cells; removes waste from the cells; and helps maintain circulating blood volume as well as fluid and electrolyte balance. It is critical that each resident at risk for hydration deficit or imbalance, including the resident *who has* or *is* at risk of developing *a PU/PI*, be identified and *assessed to determine appropriate interventions*.

***NOTE*:** The surveyor should refer to the Guidance at 42 CFR 483.25*(g), F692, Assisted Nutrition and Hydration,* for investigation of potential non-compliance with the nutrition and hydration requirements. A low albumin level combined with the facility's lack of supplementation, for example, is not by itself sufficient to cite a *nutrition related* deficiency.

Moisture

Both urine and feces contain substances that may irritate the epidermis and may make the skin more susceptible to breakdown *and moisture-related skin damage*. Fecal incontinence may pose a greater threat to skin integrity, due to bile acids and enzymes in the feces. Irritation or maceration resulting from prolonged exposure to urine and feces may hasten skin breakdown, and moisture may make skin more susceptible to damage from friction and shear during repositioning.

It may be difficult to differentiate dermatitis related to incontinence from partial thickness *PU/PI*. This differentiation should be based on the clinical evidence and review of presenting risk factors. The dermatitis may occur in the area where the incontinence brief or underpad has been used.

Prevention and Treatment Strategies

The comprehensive assessment should provide the basis for defining approaches to address residents at risk of developing or already having a *PU/PI*. A determination that a resident is at risk *for* develop*ing* a *PU/PI* has significant implications for preventive and treatment strategies, but does not by itself indicate that development of a *PU/PI* was unavoidable. Effective prevention and treatment are based upon consistently providing routine and individualized interventions.

Based upon the assessment and the resident's clinical condition, choices and identified needs, basic or routine care *c*ould include, *but is not limited to,* interventions to:

- Redistribute pressure (such as repositioning, protecting *and/or offloading* heels, etc.);
- Minimize exposure to moisture and keep skin clean, especially of fecal contamination;
- Provide appropriate, pressure-redistributing, support surfaces;
- Provide non-irritating surfaces; and
- Maintain or improve nutrition and hydration status, where feasible. Adverse drug reactions related to the resident's drug regimen may worsen risk factors for development of, or for non-healing *PU/PIs* (for example, by causing lethargy or anorexia or creating/increasing confusion) and should be identified and addressed. These interventions should be incorporated into the plan of care and revised as the condition of the resident indicates.

Resident Choices

In the context of the resident's choices, clinical condition, and physician input, the resident's *care plan* should establish relevant goals and approaches to stabilize or improve co-morbidities, such as attempts to minimize clinically significant blood sugar fluctuations, and other interventions aimed at limiting the effects of risk factors associated with *PU/PIs*. Alternatively,

facility staff and practitioners should document clinically valid reasons why such interventions were not appropriate or feasible.

In order for a resident to exercise his or her right appropriately to make informed choices about care and treatment or to decline treatment, the facility and the resident (or *if applicable,* the resident representative) must discuss the resident's condition, treatment options, expected outcomes, and consequences of refusing treatment. The facility is expected to address the resident's concerns and offer relevant alternatives, if the resident has declined specific treatments. (See §483.10*(c), F552, Planning and implementing care*.)

Pressure Injuries at End of Life

Residents at the end of life, in terminal stages of an illness or having multiple system failures may have written directions for his or her treatment goals (or a decision has been made by the resident's representative, in accordance with State law). The facility's care must reflect *the* resident's *goals for care and* wishes as expressed in *a valid Advance* Directive, *if one was formulated,* in accordance with *S*tate law. However, the presence of an Advance Directive does not absolve the facility from giving supportive and other pertinent care *that is* not prohibited by the *resident's* Advance Directive. *It is important for surveyors to understand that when a* facility has implemented individualized approaches for end-of-life care in accordance with the resident's wishes, the development, continuation, or worsening of a PU/PI may be considered unavoidable. If the facility has implemented appropriate efforts to stabilize the resident's condition (or indicted why the condition cannot or should not be stabilized) and has provided care to prevent or treat existing PU/PIs (including pertinent, routine, lesser aggressive approaches, such as, cleaning, turning, repositioning), the PU/PI may be considered unavoidable and consistent with regulatory requirements.

The Kennedy Terminal Ulcer (KTU) *The facility is responsible for accurately assessing and classifying an ulcer as a KTU or other type of PU/PI and demonstrate that appropriate preventative measures were in place to prevent non-KTU pressure ulcers.*

KTUs have certain characteristics which differentiate them from pressure ulcers such as the following:

- *KTUs appear suddenly and within hours;*
- *Usually appear on the sacrum and coccyx but can appear on the heels, posterior calf muscles, arms and elbows;*
- *Edges are usually irregular and are red, yellow, and black as the ulcer progresses, often described as pear, butterfly or horseshoe shaped; and*
- *Often appear as an abrasion, blister, or darkened area and may develop rapidly to a Stage 2, Stage 3, or Stage 4 injury.*

Repositioning

Repositioning *or relieving constant pressure* is a common, effective intervention for an individual with a *PU/PI* or who is at risk of developing one. Assessment of a resident's skin integrity after pressure has been reduced or redistributed should guide the development and implementation of repositioning plans. Such plans should be addressed in the comprehensive *care plan* consistent with the resident's need and goals. Repositioning is critical for a resident

who is immobile or dependent upon staff for repositioning, *as the resident is unable to make small movements on their own that would help to relieve prolonged pressure to one area*. The care plan for a resident at risk of friction or shearing during repositioning may require the use of lifting devices for repositioning. Positioning the resident on an existing *PU/PI* should be avoided since it puts additional pressure on tissue that is already compromised and may impede healing.

Determine repositioning frequency with consideration to the individual's:

- *Level of activity and mobility,*
- *General medical condition,*
- *Overall treatment objectives,*
- *Skin condition, and*
- *Comfort.*

The resident's skin condition and general comfort should be regularly assessed. The efficacy of repositioning must be monitored and revisions to the care plan considered, if the individual is not responding as expected to the repositioning interventions.

Facilities should consider the following repositioning issues:

1. *The time an individual spends seated in a chair without pressure relief should be limited. Seated individuals should be repositioned so as to maintain stability and full range of activities. An acceptable seated posture minimizes the pressure and shear exerted on the skin and soft tissues, which may involve using pressure relieving devices/cushions or adjusting the seat tilt, foot rests, elevated leg rests and other support devices to prevent prolonged pressure to areas of the body that may be at particular risk for developing a PU/PI.*
2. *If able, the resident should be taught to shift his or her weight while sitting in a chair.* A resident who can change positions independently may need supportive devices to facilitate position changes. The resident also may need instruction about why repositioning is important and how to do it, encouragement to change positions regularly, and monitoring of frequency of repositioning.
3. Many clinicians recommend a position change "off - loading" hourly for dependent residents who are sitting or who are in a bed or a reclining chair with the head of the bed or back of the chair raised 30 degrees or more. *The resident may require more frequent position changes based on an assessment of their skin condition or their comfort. A "microshift," meaning a small change in the resident's position for a short period of time, may not be adequate since this approach does not allow sufficient capillary refill and tissue perfusion for a resident at risk of developing PU/PI's. Ongoing monitoring of the resident's skin integrity and tissue tolerance is critical to prevent development or deterioration of PU/PI's.*
4. Wheelchairs are often used for transporting residents, but they may severely limit repositioning options and increase the risk of *PU/PI* development. Therefore, wheelchairs with sling seats may not be optimal for prolonged sitting during activities or meals, etc. However, available modifications to the seating can provide a more stable surface and provide better pressure reduction.
5. The care plan for a resident who is reclining and is dependent on staff for repositioning should address position changes to maintain the resident's skin integrity. This may include repositioning at least every 2 hours or more frequently depending upon the resident's

condition and *specific needs.* Depending on the individualized assessment, more frequent repositioning may be warranted for individuals who are at higher risk for *PU/PI* development or who show evidence that repositioning at 2-hour intervals is inadequate. With rare exception (*such as when* both sacral and ischial *PU/PI's* are present) the resident should not be placed directly on the greater trochanter for more than momentary placement. Elevating the head of the bed or the back of a reclining chair to or above a 30 degree angle creates pressure comparable to that exerted while sitting, and requires the same considerations regarding repositioning as those for a dependent resident who is seated.

Support Surfaces and Pressure Redistribution

Pressure redistribution refers to the function or ability to distribute a load over a surface or contact area. Redistribution results in shifting pressure from one area to another and requires attention to all affected areas. Pressure redistribution has incorporated the concepts of both pressure reduction and pressure relief.

Appropriate support surfaces or devices should be chosen by matching a device's potential therapeutic benefit with the resident's specific situation; *such as* multiple injuries, limited turning surfaces, ability to maintain position. The effectiveness of pressure redistribution devices (*such as* gel *mattresses*, air fluidized mattresses, and low loss air mattresses) is based on their potential to address the individual resident's risk, the resident's response to the product, and the characteristics and condition of the product. For example, an overinflated overlay product, or one that "bottoms out" *(when the overlay is underinflated or loses inflation creating* less than one inch between the resident and support material) is unlikely to effectively reduce the pressure risk. These products are more likely to reduce pressure effectively if they are used in accord with the manufacturer's instructions. The effectiveness of each product used needs to be evaluated on an ongoing basis. Surveyors should consider the following pressure redistribution issues:

- Static pressure redistribution devices (*such as a* gel mattress) may be indicated when a resident is at risk for *PU/PI* development or delayed healing. A specialized pressure redistribution cushion or surface, for example, might be used to extend the time a resident is sitting in a chair; however, the cushion does not eliminate the necessity for periodic repositioning *and skin assessment.*
- Dynamic pressure reduction surfaces may be helpful when:
    - The resident cannot assume a variety of positions without bearing weight on a *PU/PI*;
    - The resident completely compresses a static device that has retained its original integrity; or
    - The *PU/PI* is not healing as expected, and it is determined that pressure may be contributing to the delay in healing.
- Because the heels and elbows have relatively little surface area, it is difficult to redistribute pressure on these two surfaces. Therefore, it is important to pay particular attention to reducing the pressure on these areas for the resident at risk in accord with resident's overall goals and condition. Pillows used to support the entire lower leg may effectively raise the heel from contact with the bed, but use of the pillows needs to take into account the resident's other conditions. The use of donut-type cushions is not recommended by the clinicians.

- A resident with severe flexion contractures also may require special attention to effectively reduce pressure on bony prominences or prevent breakdown from skin-to-skin contact.

Some products serve mainly to provide comfort and reduce friction and shearing forces, e.g., sheepskin, heel and elbow protectors. Although these products are not effective at redistributing pressure, they (in addition to pillows, foam wedges, or other measures) may be employed to prevent bony prominences from rubbing together *or on other surfaces, such as armrests, the bed, or side rails*.

Monitoring
Staff should remain alert to potential changes in the skin condition and should evaluate, *report and* document changes *as soon as identified*. For example, a resident's complaint about pain or burning at a site where there has been pressure or observation during the resident's bath that there is a change in skin condition should be reported so that the resident may be evaluated further.

After completing a thorough evaluation, the interdisciplinary team should develop a relevant care plan *that includes measurable goals for prevention and management of PU/PIs with appropriate* interventions. Many clinicians recommend evaluating skin condition (skin color, moisture, temperature, integrity, and turgor) at least weekly, or more often if indicated, such as when the resident is using a medical device that may cause pressure. Defined interventions should be implemented and monitored for effectiveness.

Assessment and Treatment of Pressure *Ulcers/Injuries*
It is important that each existing *PU/PI* be identified, whether present on admission or developed after admission, and that factors that influenced its development, the potential for development of additional *PU/PIs* or the deterioration of the *PU/PIs* be recognized, assessed and addressed. Any new *PU/PI* suggests a need to reevaluate the adequacy of *prevention measures in* the *resident's care plan*.

When assessing the *PU/PI* itself, it is important *that documentation addresses*:

- The type of *injury* (pressure-related versus non-pressure-related) because interventions may vary depending on the specific type of *injury*;
- The *PU/PI's* stage;
- A *description of* the *PU/PI's* characteristics;
- The progress toward healing and *identification of* potential complications;
- If infection is present;
- *The presence of pain, what was done to address it, and the effectiveness of the intervention*; and
- *A description of* dressings and treatments.

Types of Injuries
Three of the more common types of *skin injuries* are pressure, vascular insufficiency/ischemia (venous stasis and arterial ischemic ulcers) and neuropathic. See §483.2*5*, F*684*, *Quality of Care*, for definition and description of *injury* types other than *PU/PIs*.

Effective November 28, 2017

At the time of the assessment, clinicians (physicians, advance practice nurses, physician assistants, and certified wound care specialists, etc.) should document the clinical basis (for example, type of skin injury, location, shape, edges and wound bed, condition of surrounding tissues) for any determination that an *injury* is not pressure-related, especially if the *injury* has characteristics consistent with a pressure *injury*, but is determined not to be one.

Pressure *Ulcer/Injury* Characteristics

It is important that the facility have a system in place to assure that the protocols for daily monitoring and for periodic documentation of measurements, terminology, frequency of assessment, and documentation are implemented consistently throughout the facility.

When a *PU/PI*is present, daily monitoring, (with accompanying documentation, when a complication or change is identified), should include:

- An evaluation of the *PU/PI*, if no dressing is present;
- An evaluation of the status of the dressing, if present (whether it is intact and whether drainage, if present, is or is not leaking);
- The status of the area surrounding the *PU/PI* (that can be observed without removing the dressing);
- The presence of possible complications, such as signs of increasing area of ulceration or soft tissue infection (for example: increased redness or swelling around the wound or increased drainage from the wound); and
- Whether pain, if present, is being adequately controlled.

The amount of observation possible will depend upon the type of dressing that is used, since some dressings are meant to remain in place for several days, according to manufacturers' guidelines.

With each dressing change or at least weekly (and more often when indicated by wound complications or changes in wound characteristics), an evaluation of the *PU/PIshould* be documented. At a minimum, documentation should include the date observed and:

- Location and staging;
- Size (perpendicular measurements of the greatest extent of length and width of the *PU/PI*), depth; and the presence, location and extent of any undermining or tunneling/sinus tract;
- Exudate, if present: type (such as purulent/serous), color, odor and approximate amount;
- Pain, if present: nature and frequency (e.g., whether episodic or continuous);
- Wound bed: Color and type of tissue/character including evidence of healing (e.g., granulation tissue), or necrosis (slough or eschar); and
- Description of wound edges and surrounding tissue (e.g., rolled edges, redness, hardness/induration, maceration) as appropriate.

Photographs may be used to support this documentation, if the facility has developed a protocol consistent with professional standards *and issues related to resident privacy and dignity are considered and maintained.*

Effective November 28, 2017

Healing Pressure *Ulcers/Injuries*

Ongoing evaluation and research have indicated that *PU/PIs*do not heal in a reverse sequence, that is, the body does not replace the types and layers of tissue (muscle, fat and dermis) that were lost during development. *The healing process varies depending on the stage of the pressure injury.*

There are different types of clinical documentation to describe the progression of the healing *PU/PI.* Facilities *are required to* use the RAI. Directions on describing *PU/PIs* can be found in the RAI manual – these are intended for coding purposes of the MDS. (**NOTE**: Information on coding for the MDS is located on the CMS MDS website (*http://www.cms.gov/NursingHomeQualityInits/45_NHQIMDS30TrainingMaterials.asp#TopOfPage*)

It is important to evaluate and modify interventions for a resident with an existing PU/PI such as the following:

- *Residents with PU/PIs on the sacrum/coccyx or ischia should limit sitting to three times a day in periods of 60 minutes or less. Consult a seating specialist to prescribe an appropriate seating surface and/or positioning techniques to avoid or minimize pressure on the PU/PI. While sitting is important for overall health, every effort should be made to avoid or minimize pressure on the PU/PI.*
- *Residents with an ischial injury should not be seated in a fully erect posture in chair or in bed. Modify sitting time schedules and re-evaluate the seating surface and the individual's posture if the PI worsens or fails to improve.*

If a *PU/PI* fails to show some evidence of progress toward healing within 2-4 weeks, the area and the resident's overall clinical condition should be reassessed. Re-evaluation of the treatment plan includes determining whether to continue or modify the current interventions. Results may vary depending on the resident's overall condition and interventions/treatments used. The complexity of the resident's condition may limit responsiveness to treatment or tolerance for certain treatment modalities. The clinicians, if deciding to retain the current regimen, should document the rationale for continuing the present treatment *to explain* why some, or all, of the plan's interventions remain relevant despite little or no apparent healing.

Pressure *ulcers/injuries* may progress or may be associated with complications, such as infection of the soft tissues around the wound (cellulitis), infection of the bone (osteomyelitis), infection of a joint (septic arthritis), abscess, spread of bacteria into the bloodstream (bacteremia/septicemia), chronic infection, or development of a sinus tract. Sometimes these complications may occur despite apparent improvement in the *PU/PI* itself. The physician's involvement is integral whenever significant changes in the nature of the wound or overall resident condition are identified.

Infections

A PU/PI infection may be acute or chronic. In acute wounds, the classic signs of inflammation (redness, edema, pain, increased exudate, and periwound surface warmth) persist beyond the normal time frame of three to four days. In residents who are immunosuppressed, the signs of inflammation often are diminished or masked because of an ineffective immune response. Often the only observable symptom of infection is a complaint of pain.

All chronic wounds, including PU/PIs, have bacteria. Since bacteria reside in non-viable tissue, debridement of this tissue and wound cleansing are important to reduce bacteria and avoid adverse outcomes such as sepsis.
The first sign of infection may be a delay in healing and an increase in exudates. In a chronic wound, the signs of infection may be more subtle. Signs may include the following:

- *Increase in amount or change in characteristics of exudate,*
- *Decolorization and friability of granulation tissue,*
- *Undermining,*
- *Abnormal odor,*
- *Epithelial bridging (a bridge of epithelial tissue across a wound bed) at the base of the wound, or*
- *Sudden pain.*

The physician diagnosis of infections present in a PU/PI are based on resident history and clinical findings, such as a wound culture. Pus, slough or necrotic tissue should not be cultured. Findings such as an elevated white blood cell count, bacteremia, sepsis, or fever may signal an infection related to a *PU/PI* area or a co-existing infection from a different source. *The treatment of an infection will depend on the type of infection present.*

Pain
The assessment and treatment of a resident's pain are integral components of *PU/PI* prevention and management. Pain that interferes with movement and/or affects mood may contribute to immobility and contribute to the potential for developing or for delayed healing or non-healing of an already existing *PU/PI*. *Refer to §483.25(k), F697, for additional guidance related to Pain Management.*

Dressings and Treatments
Determination of the need for *treatment for a PU/PI is* based upon the individual practitioner's clinical judgment, facility protocols, and current professional standards of practice.

Product selection should be based upon the relevance of the specific product to the identified *PU/PI*(s) characteristics, the treatment goals, and the manufacturer's recommendations for use. Current literature does not indicate significant advantages of any single specific product over another, but does confirm that not all products are appropriate for all *PU/PIs*. Wound characteristics should be assessed throughout the healing process to assure that the treatments and dressings being used are appropriate to the nature of the wound.

Evidenced-based practice suggests that *PU/PI* dressing protocols may use clean technique rather than sterile, but that appropriate sterile technique may be needed for those wounds that recently have been surgically debrided or repaired. *Clean technique (also known as non-sterile) involves approved hand hygiene and glove use, maintaining a clean environment by preparing a clean field, using clean instruments, and preventing direct contamination of materials and supplies. Clean technique is considered most appropriate for long-term care; for residents who are not at high risk for infection; and for residents receiving routine dressings for chronic wounds such as venous ulcers, or wounds healing by secondary intention with granulation tissue.*

A facility should be able to show that its treatment protocols are based upon current professional standards of practice and are in accord with the facility's policies and procedures as developed with the medical director's review and approval.

INVESTIGATIVE PROTOCOL

Use

Use the Pressure Ulcer Critical Element (CE) Pathway, along with the above interpretive guidelines when determining if the facility meets requirements to ensure a resident receives care consistent with professional standards of practice, to prevent pressure ulcers/injuries development, prevent the development of additional pressure ulcers/injuries, and to promote the healing of existing pressure ulcers/injuries.

Summary of Skin Integrity Investigative Procedure

Briefly review the comprehensive assessments, care plans, and physician orders to identify whether the facility has practices in place to identify if a resident is at risk for a pressure ulcer/injury, evaluate a resident for pressure ulcers/injuries, and intervene to prevent and/or heal pressure ulcers. During this review, identify the extent to which the facility has developed and implemented interventions in accordance with ensuring a resident receives care consistent with professional standards of practice. If the resident has been in the facility for less than 14 days (before completion of all the *Resident Assessment Instrument (*RAI) is required), *review the baseline care plan which must be completed within 48 hours to* determine if the facility is *providing appropriate care and services based on information available at the time of admission*. This information will guide observations and interviews to be made to corroborate concerns identified.

KEY ELEMENTS OF NONCOMPLIANCE

To cite deficient practice at F686, the surveyor's investigation will generally show that the facility failed to do one or more of the following:

- *Provide preventive care, consistent with professional standards of practice, to residents who may be at risk for development of pressure injuries; or*
- *Provide treatment, consistent with professional standards of practice, to an existing pressure injury; or*
- *Ensure that a resident did not develop an avoidable PU/PI.*

NOTE*: To cite F686, it is not necessary to prove that a PU/PI developed. F686 can be cited when it has been determined that the provider failed to implement interventions to prevent the development of a PU/PI for a resident identified at risk.*

DEFICIENCY CATEGORIZATION

In addition to actual or potential physical harm, always consider whether psychosocial harm has occurred when determining severity level (See Appendix P, Section IV, E, Psychosocial Outcome Severity Guide).

Examples of Severity Level 4 Noncompliance: Immediate Jeopardy to Resident Health or Safety include but are not limited to:

- *The facility failed to implement interventions to prevent PU/PI development for a resident who was admitted without PU/PIs, but who had multiple co-morbidities and was totally dependent on staff, placing her at increased risk for PU/PI development; and failed to provide ongoing skin assessments for the same resident. The resident developed a stage 4 pressure ulcer on her heel within three weeks of her admission.*
- Development of avoidable Stage IV pressure ulcer(s): As a result of the facility's non-compliance, permanent tissue damage (whether or not healing occurs) has compromised the resident, increasing the potential for serious complications including osteomyelitits and sepsis.
- Admitted with a Stage IV pressure ulcer(s) that has shown no signs of healing or shows signs of deterioration: As a result of the facility's non-compliance, a Stage IV pressure ulcer has shown signs of deterioration or a failure to progress towards healing with an increased potential for serious complications including osteomyelitis and sepsis.
- Stage III or IV pressure ulcers with associated soft tissue or systemic infection: As a result of the facility's failure to assess or treat a resident with an infectious complication of a pressure ulcer. (See discussion in guidelines and definitions that distinguishes colonization from infection.)
- Extensive failure in multiple areas of pressure ulcer care: As a result of the facility's extensive noncompliance in multiple areas of pressure ulcer care, the resident developed recurrent and/or multiple, avoidable Stage III or Stage IV pressure ulcer(s).

Examples of Severity Level 3 Noncompliance Actual Harm that is not Immediate Jeopardy include but are not limited to:

- *The facility failed to provide necessary equipment, interventions, monitoring, and care, for a resident who was identified to be at risk for developing PU/PIs due to the presence of contractures and had no PU/PIs upon admission. The facility's occupational therapist (OT) assessed the resident and provided a pressure relieving device for use on the resident's left hand, which was to be in place at all times except when daily hygiene was being provided. The interventions were not recorded on the resident's care plan. During observation and interviews with staff, the assistive device was unable to be located and was not in use. This resulted in the resident developing a Stage 3 pressure injury.*
- The development of avoidable Stage III pressure ulcer(s): As a result of the facility's non-compliance, Stage III pressure ulcers occurred, which are open wounds in which damage has occurred into the subcutaneous level and may be painful.
- The development of recurrent or multiple avoidable Stage II pressure ulcer(s): As a result of the facility's non-compliance, the resident developed multiple and/or recurrent avoidable Stage II ulcers.
- Failure to implement the comprehensive care plan for a resident who has a pressure ulcer: As a result of a facility's failure to implement a portion of an existing plan related to pressure ulcer care, such as failure to provide for pressure redistribution, or inappropriate treatment/dressing changes, a wound increased in size or failed to progress towards healing as anticipated, or the resident experienced untreated pain.

Examples of Severity Level 2 Noncompliance No Actual Harm with Potential for More Than Minimal Harm that is Not Immediate Jeopardy include but are not limited to:

- *The facility failed to assure that a resident with a healed Stage 1 /PI in the coccyx area received care to prevent the development of another PU/PI. The resident's care plan identified the use of a pressure-relieving device while up in the chair and repositioning every 30 minutes. During observations, the pressure relieving device was not present on the seat of the wheelchair but staff did reposition resident every 30 minutes. The device was available, but the staff person interviewed stated that although it was usually on his wheelchair, it had not been placed that day. The resident's skin was intact and did not indicate the presence of a stage 1 /PI based on observation, but the likelihood existed of a PU/PI developing as a result of not implementing care as identified in the plan of care.*
- *The facility failed to assess the skin condition of a resident who used continual oxygen for management of a chronic respiratory disease. The resident's oxygen was provided via nasal cannula and the resident voiced discomfort and irritation with the tubing on his nares. There was a small reddened area where the tubing contacted the nares. The resident had mentioned this to the staff, but was not addressed, and the resident continued to experience discomfort and irritation.*
- The development of a single avoidable Stage II pressure ulcer that is receiving appropriate treatment: As a result of the facility's non-compliance, a resident developed an avoidable Stage II pressure ulcer.
- The development of an avoidable Stage I pressure ulcer: As a result of the facility's non-compliance, a resident developed an avoidable Stage I pressure ulcer.
- Failure to implement an element of the care plan for a resident who has a pressure ulcer however, there has been no evidence of decline or failure to heal.
- Failure to recognize or address the potential for developing a pressure ulcer: As a result of the facility's non-compliance, staff failed to identify the risks, develop a plan of care and/or consistently implement a plan that has been developed to prevent pressure ulcers.

Severity Level 1: No Actual Harm with Potential for Minimal Harm
The failure of the facility to provide appropriate care and services to prevent pressure *ulcers/injuries* or heal existing pressure *ulcers/injuries* is more than minimal harm. Therefore, Severity Level 1 does not apply for this regulatory requirement.

POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION
During the investigation of F*686*, the surveyor may have determined at concerns may also be present with related outcome, process and/or structure requirements. The surveyor is cautioned to investigate these related requirements before determining whether non-compliance may be present. Some examples of related requirements that should be considered include *§483.20 Resident Assessment, §483.21 Comprehensive Person-Centered Care Planning, §483.24 Quality of Life, §483.30 Physician Services, §483.35 Nursing Services, §483.70 Administration, and §483.75 QAPI.*

F687
§483.25(b)(2) Foot care.
To ensure that residents receive proper treatment and care to maintain mobility and good foot health, the facility must:
(i) Provide foot care and treatment, in accordance with professional standards of practice, including to prevent complications from the resident's medical condition(s) and

(ii) If necessary, assist the resident in making appointments with a qualified person, and arranging for transportation to and from such appointments.

INTENT
To ensure that the foot care provided is consistent with professional standards of practice and to clarify that foot care includes treatment to prevent complications from conditions such as diabetes, peripheral vascular disease, or immobility. Also includes assisting the resident in making necessary appointments with qualified healthcare providers such as podiatrists and arranging transportation to and from appointments.

GUIDANCE
Facilities are responsible for providing the necessary treatment and foot care to residents. Treatment also includes preventive care to avoid podiatric complications in residents with diabetes and circulatory disorders who are prone to developing foot problems. Foot care that is provided in the facility, such as toe nail clipping for residents without complicating disease processes, must be provided by staff who have received education and training to provide this service within professional standards of practice. Residents requiring foot care who have complicating disease processes must be referred to qualified professionals as listed below.

Facilities are also responsible for providing residents access to qualified professionals who can treat foot disorders, by making necessary appointments and arranging transportation. Examples include podiatrist, Doctor of Medicine, *and* Doctor of Osteopathy. *Foot disorders which may require treatment include,* but *are* not limited to: corns, neuromas, calluses, *hallux valgus* (bunions), *digiti flexus (hammertoe)*, heel spurs, and nail disorders. *The facility is also responsible for assisting residents in making appointments and arranging transportation to obtain needed services.*

PROBES: For residents selected for review *determine the following*:

- *According to the medical record, does the resident have a diagnosis or condition that poses a risk to foot health (e.g., diabetes, peripheral vascular disease, ingrown toenails)?*
- *Does the comprehensive care plan adequately address the resident's risk with appropriate interventions?*
- *Observe resident's feet for lack of nail care, presence of calluses, and/or other foot problems.*
- *Are residents with foot concerns seen either within the facility or community by a qualified foot care specialist? Do residents with mobility concerns have foot care concerns, and did the facility address these concerns?*
- *Are qualified healthcare providers available to see residents either in the facility or in the community?*
- *What preventive foot care do staff provide and to what resident population?*
- *Are staff performing foot care to the resident when needed and ordered?*

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F688
§483.25(*c) Mobility.*
§483.25(*c)*(1) The facility must ensure that a resident who enters the facility without limited range of motion does not experience reduction in range of motion unless the resident's clinical condition demonstrates that a reduction in range of motion is unavoidable; and

§483.25(*c)*(2) A resident with limited range of motion receives appropriate treatment and services to increase range of motion and/or to prevent further decrease in range of motion.

§483.25(*c)(3) A resident with limited mobility receives appropriate services, equipment, and assistance to maintain or improve mobility with the maximum practicable independence unless a reduction in mobility is demonstrably unavoidable.*

To review the impact of the physical, mental, and/or psychosocial aspects of the resident's ability to maintain, improve or prevent avoidable decline in range of motion and mobility, the surveyor must review the provision of care and services and implementation of interventions under this tag .

INTENT *483.25(c)*
The intent of this regulation *(F688)* is to ensure that *the facility provides the services, care and equipment to assure that:*

- *A resident maintains, and/or improves to his/her highest level of range of motion (ROM) and mobility, unless a reduction is clinically unavoidable; and*
- *A resident with limited range of motion and mobility maintains or improves function unless reduced Range of Motion (ROM)/mobility is unavoidable based on the resident's clinical condition.*

DEFINITIONS §*483.25(c)*
***"Active ROM"** means the performance of an exercise to move a joint without any assistance or effort of another person to the muscles surrounding the joint.*

***"Active Assisted ROM"** means the use of the muscles surrounding the joint to perform the exercise but requires some help from the therapist or equipment (such as a strap).*
Mobility refers to all types of movement, including walking, movement in a bed, transferring from a bed to a chair, all with or without assistance or moving about an area either with or without an appliance (chair, walker, cane, crutches, etc.).

***"Muscle atrophy"** means the wasting or loss of muscle tissue.*

***"Passive ROM"** means the movement of a joint through the range of motion with no effort from the patient.*

"Range of motion (ROM)" means the full movement potential of a joint.

Effective November 28, 2017

GUIDANCE §*483.25(c)*

***Assessment for Range of Motion*:**

The resident's comprehensive assessment should include and measure, as appropriate, a resident's current extent of movement of his/her joints and the identification of limitations, if any and opportunities for improvement. The assessment should address whether the resident had previously received treatment and services for ROM and whether he/she maintained his/her ROM, whether the ROM declined, and why the treatment/services were stopped. In addition, the assessment should address, for a resident with limited ROM, if he/she is not receiving services, the reason for the services to not be provided..

The resident-specific, comprehensive assessment should identify individual risks which could impact the resident's range of motion including, but not limited to:

- *Immobilization (e.g., bedfast, reclining in a chair or remaining seated in a chair/wheelchair);*
- *Neurological conditions causing functional limitations such as cerebral vascular accidents, multiple sclerosis, Amyotrophic Lateral Sclerosis (ALS) or Lou Gehrig's disease, Guillain-Barre syndrome, Muscular Dystrophy***,** *or cerebral palsy, etc.***;***
- *Any condition where movement may result in pain, spasms or loss of movement such as cancer, presence of pressure ulcers, arthritis, gout, late stages of Alzheimer's, contractures, dependence on mechanical ventilation, etc.; or*
- *Clinical conditions such as immobilized limbs or digits because of injury, fractures, or surgical procedures including amputations.*

Assessment for Mobility:

The resident's comprehensive assessment should include and measure, as appropriate, a resident's current mobility status, the identification of limitations, if any and opportunities for improvement. The MDS tool provides an assessment of the resident's ability for movement including to and from the lying position, turning and side to side movement in bed, positioning of the body, transfers between surfaces such as to and from bed or chair, standing, and walking. The resident's comprehensive assessment should also address whether the resident had previously received treatment and services for mobility and whether he/she maintained his/her mobility, whether there was a decline, and why the treatment/services were stopped. In addition, the assessment should address, for a resident with limited mobility, if he/she is not receiving services, the reason for the services to not be provided. In addition, the resident specific comprehensive assessment may identify individual risks which could impact the resident's mobility including, but not limited to include the risk factors in the above section for range of motion.

Care Plan for ROM and/or Mobility

Based upon the comprehensive assessment, the resident's care plan must include specific interventions, exercises and/or therapy to maintain or improve the ROM and mobility, or to prevent, to the extent possible, declines or further declines in the resident's ROM or mobility. The resident/representative must be included in the development of the restorative/rehabilitative care plan and provided the risks and benefits of the treatments. The comprehensive assessment must identify the current status of the resident's ROM and mobility capabilities, which must be used to develop interventions. The decision on what type of treatments includes an evaluation of

the cognitive ability of the resident to be able to independently participate, whether the resident requires assistance due to medical condition or cognitive impairments or loss of ability to follow treatment instructions. Care plan interventions may be delivered through the facility's restorative program, or as ordered by the attending practitioner, through specialized rehabilitative services. (Also see F825 for specialized rehabilitative services.)

Based upon the assessment, the care plan interventions must include the provision of necessary equipment and/or services necessary, adapting the environment to meet the needs of the resident, the use of equipment for bed mobility, walkers, canes, splints, braces or other rehabilitative equipment as prescribed by the attending practitioner and/or as allowed by state law, and PT/OT. Examples of interventions may include treatments such as active, passive, and/or active-assisted ROM, muscle strengthening and stretching exercises, land and/or water based activities, and/or specific physical and/or occupational therapies.

The care plan must identify the type of treatments, frequency, and duration, as well as the measurable objectives and resident goals. The measurable objectives describe what the resident is expected to achieve, such as mobility goals, and/or ROM measurements to be achieved within a specific timeframe. This enables the interdisciplinary team to determine progress including whether or not a resident has been able to maintain or increase range of motion and/or mobility. The facility must assure that the care plan provides for increasing and/or promoting independence to the extent clinically possible for the resident in the areas of both ROM and mobility. The care plan must address the presence of any contractures and interventions required, and any dependence and/or declines in mobility and ROM.

In some clinical conditions, a decline/reduction in ROM and/or mobility may occur even though the facility provides ongoing assessment, appropriate resident specific care planning and provides ongoing preventive care and interventions. Documentation must reflect the attempts made by the facility to implement the care plan and revise interventions to address the changing needs of the resident. In this type of situation, declines in ROM/mobility may be considered to be unavoidable.

The comprehensive assessment may identify specific resident risks for complications. Examples of complications that may be related to decreased ROM and/or mobility may include, but are not limited to, the following:

- *Pain;*
- *Skin integrity issues;*
- *Deconditioning including decreased muscle strength and atrophy;*
- *Unsteady gait and balance resulting in potential falls and fractures;*
- *Contractures; or*
- *Respiratory and circulatory complications, such as postural hypotension, deep vein thrombosis, pneumonia; potential urinary incontinence, bowel constipation/impactions, etc.*

The care plan should reflect the specific resident risks for complications and include interventions to mitigate, to the extent possible, the potential complications. If resident specific complications related to a decrease in ROM/mobility are present, the care plan must provide

interventions to address the complications.

In some clinical conditions, a decline/reduction in ROM and/or mobility may occur even though the facility provides ongoing assessment, appropriate resident specific care planning and provides ongoing preventive care and interventions. Documentation must reflect the attempts made by the facility to implement the care plan and revise interventions to address the changing needs of the resident. In this type of situation, declines in ROM/mobility may be considered to be unavoidable.

Administrative Review
The facility must develop resident care policies in collaboration with the medical director, director of nurses, and as appropriate, physical/occupational therapy consultant. This includes policies on restorative/rehabilitative treatments/services, based on professional standards of practice, including who may provide specific treatments and modalities according to applicable State law and/or practice acts. Refer to F841, Medical Director. These policies should also address equipment use, cleaning, and storage.

In situations where the survey team has concerns related to patterns or widespread noncompliance within the requirements for Mobility, please see guidance at §483.75, QAPI/QAA.

KEY ELEMENTS OF NONCOMPLIANCE
To cite deficient practice at F688, the surveyor's investigation will generally show that the facility failed to provide treatment/services, equipment, supplies and/or assistance to:

- *Prevent an avoidable reduction of ROM and/or mobility in residents admitted with full ROM and/or mobility status; or*
- *Increase ROM or mobility status or prevent further avoidable reduction of ROM and mobility; or*
- *Maintain or improve ROM/mobility.*

INVESTIGATIVE SUMMARY
Use - *Use the Positioning, Mobility & Range of Motion (ROM) Critical Element (CE) Pathway, along with the above interpretive guidelines when determining if the facility provides the necessary care and services to meet the resident's needs.*

Summary of Procedure
Briefly review the most recent comprehensive assessments, comprehensive care plan and orders to identify whether the facility has assessed and developed an individualized care plan based on professional standards of practice and provided by qualified, competent staff. During this review, identify the extent to which the facility has implemented interventions in accordance with the resident's needs, goals for care and professional standards of practice, consistently across all shifts. This information will guide observations and interviews to be made in order to corroborate concerns identified.

NOTE*: Always observe for visual cues of psychosocial distress and harm (see Appendix P, Guidance on Severity and Scope Levels and Psychosocial Outcome Severity Guide).*

Effective November 28, 2017

F689
§483.25(d) Accidents.
The facility must ensure that –
§483.25(d)(1) The resident environment remains as free of accident hazards as is possible; and

§483.25(d)(2)Each resident receives adequate supervision and assistance devices to prevent accidents.

INTENT: 483.25*(d)*
The intent of this requirement is to ensure the facility provides an environment that is free from accident hazards over which the facility has control and provides supervision and assistive devices to each resident to prevent avoidable accidents. This includes:

- Identifying hazard(s) and risk(s);
- Evaluating and analyzing hazard(s) and risk(s);
- Implementing interventions to reduce hazard(s) and risk(s); and
- Monitoring for effectiveness and modifying interventions when necessary.

DEFINITIONS *483.25(d)*
Definitions are provided to clarify terms related to providing supervision and other interventions to prevent accidents.

"Accident" refers to any unexpected or unintentional incident, which results or may result in injury or illness to a resident. This does not include *other types of harm, such as* adverse outcomes that are a direct consequence of treatment or care that is provided in accordance with current professional standards of practice (e.g., drug side effects or reaction).

"Avoidable Accident" means that an accident occurred because the facility failed to:

- Identify environmental hazards and/or *assess* individual resident risk of an accident, including the need for supervision *and/or assistive devices*; and/or
- Evaluate/analyze the hazards and risks *and eliminate them, if possible, or, if not possible, identify and implement measures to reduce the hazards/risks as much as possible;* and/or
- Implement interventions, including adequate supervision *and assistive devices*, consistent with a resident's needs, goals, *care plan* and current professional standards of practice in order to eliminate the risk, if possible, and, if not, reduce the risk of an accident; and/or
- Monitor the effectiveness of the interventions and modify the care plan as necessary, in accordance with current professional standards of practice.

"Unavoidable Accident" means that an accident occurred despite *sufficient and comprehensive* facility *systems designed and implemented to*:

- Identify environmental hazards and individual resident risk of an accident, including the need for supervision; and
- Evaluate/analyze the hazards and risks *and eliminate them, if possible and, if not possible, reduce them as much as possible*;

- Implement interventions, including adequate supervision, consistent with the resident's needs, goals, care *plan*, and current professional standards of practice in order to *eliminate or* reduce the risk of an accident; and
- Monitor the effectiveness of the interventions and modify the interventions as necessary, in accordance with current professional standards of practice.

"Assistance Device or **Assistive Device"** refers to any item (e.g., fixtures such as handrails, grab bars, and *mechanical* devices/equipment such as *stand- alone or overhead* transfer lifts, canes, wheelchairs, *and walkers*, etc.) that is used by, or in the care of a resident to promote, supplement, or enhance the resident's function and/or safety.

NOTE: The currently accepted nomenclature refers to "assistive devices." Although the term "assistance devices" is used in the regulation, the Guidance provided in this document will refer to "assistive devices."

"Environment" *refers to any environment or area in the facility that is frequented by or accessible to residents, including (but not limited to) the residents' rooms, bathrooms, hallways, dining areas, lobby, outdoor patios, therapy areas and activity areas.*

"Fall" refers to unintentionally coming to rest on the ground, floor, or other lower level, but not as a result of an overwhelming external force (e.g., resident pushes another resident). An episode where a resident lost his/her balance and would have fallen, *if not for another person or if he or she had not caught him/herself,* is considered a fall. A fall without injury is still a fall. Unless there is evidence suggesting otherwise, when a resident is found on the floor, a fall is considered to have occurred (*refer to Resident Assessment Instrument User's Manual. Version 3.0, Chapter 3, page J-27)*.

"Hazards" refer to elements of the resident environment that have the potential to cause injury or illness.

- "Hazards over which the facility has control" are those hazards in the resident environment where reasonable efforts by the facility could influence the risk for resulting injury or illness.
- "Free of accident hazards as is possible" refers to being free of accident hazards over which the facility has control.

"Position change alarms" *are alerting devices intended to monitor a resident's movement. The devices emit an audible signal when the resident moves in a certain way. Types of position change alarms include chair and bed sensor pads, bedside alarmed mats, alarms clipped to a resident's clothing, seatbelt alarms, and infrared beam motion detectors.* [7] *Position change alarms do not include alarms intended to monitor for unsafe wandering such as door or elevator alarms.*

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7 Bressler, K., Redfern, R.E., and Brown, M.(2011). Elimination of position-change alarms in an Alzheimer's and dementia long-term care facility. Am J Alzheimers Dis Other Demen 26(8), 599.

Effective November 28, 2017

"Risk" refers to any external factor, *facility characteristic (e.g., staffing or physical environment)* or characteristic of an individual resident that influences the likelihood of an accident.

"Supervision/Adequate Supervision" refers to an intervention and means of mitigating the risk of an accident. Facilities are obligated to provide adequate supervision to prevent accidents. Adequate supervision is *determined by assessing the appropriate level and number of staff required, the competency and training of the staff, and the frequency of supervision needed. This determination is based on the* individual resident's assessed needs and identified hazards in the resident environment. Adequate supervision may vary from resident to resident and from time to time for the same resident.

***GUIDANCE** §483.25(d)*

OVERVIEW

Numerous and varied accident hazards exist in everyday life. Not all accidents are avoidable. The frailty of some residents increases their vulnerability to hazards in the resident environment and can result in life-threatening injuries. It is important that all facility staff understand the facility's responsibility, as well as their own, to ensure the safest environment possible for residents.

The facility is responsible for providing care to residents in a manner that helps promote quality of life. This includes respecting residents' rights to privacy, dignity and self-determination, and their right to make choices about significant aspects of their life in the facility.

An effective way for the facility to avoid accidents is to *develop a culture of safety and* commit to implementing systems that address resident risk and environmental hazards to minimize the likelihood of accidents. A facility with a commitment to safety:

- Acknowledges the high-risk nature of its population and setting;
- Develops *effective communication, including* a reporting system that does not place blame on the staff member for reporting resident risks and environmental hazards;
- *Engages all staff, residents and families in training on safety, and promotes ongoing discussions about safety with input from staff at all levels of the organization, as well as residents and families;*
- *Encourages the use of data to identify potential hazards, risks, and solutions related to specific safety issues that arise;*
- Directs resources to address safety concerns; and
- Demonstrates a commitment to safety at all levels of the organization.

A SYSTEMS APPROACH

Processes in a facility's interdisciplinary systematic approach may include:

- Identification of hazards, including inadequate supervision, and a resident's risks of potentially avoidable accidents in the resident environment;
- Evaluation and analysis of hazards and risks;

- Implementation of *individualized, resident-centered* interventions, including adequate supervision and assistive devices, to reduce individual risks related to hazards in the environment; and
- Monitoring for effectiveness and modification of interventions when necessary.

A key element of a systematic approach is the consistent application of a process to address identified hazards and/or risks. Risks may pertain to individual residents, groups of residents, or the entire facility. Hazards may include, but are not limited to, aspects of the physical plant, equipment, and devices that are defective or are not used properly (per manufacturer's specifications), are disabled/removed, or are not individually adapted or fitted to the resident's needs.

- An effective system not only *proactively* identifies environmental hazards and the resident's risk for an avoidable accident, but also *evaluates* the resident's need for supervision.

Identifying and addressing risks, including the potential for accidents, includes consideration of the environment, the resident's risk factors, and the need for supervision, care, and assistive devices. This will allow the facility to communicate information about observed hazards, identify resident-specific information, develop and implement an individualized *care plan based on the Resident Assessment Instrument (RAI)* to address each resident's needs and goals, and to monitor the results of the planned interventions. The *care plan* should strive to balance the resident's wishes with the potential impact on other residents.

A systematic approach *enables the facility to evaluate safety throughout its environment and among all staff, and make appropriate adjustments in training and competency testing as required. Each resident or representative and their family members and representatives should be aware of the risks and potential hazards related to falls and of various devices used to reduce fall risk. Furthermore, a systematic approach enables leadership and direct care staff to work together to revise policies and procedures, based on feedback from workers who are most familiar with the residents and care processes. Effective facility* system*s address how to:*

- *communicate* the observations of hazards,
- *record* resident specific information, *and*
- *monitor data related to care processes that potentially lead to accidents.*

Identification of Hazards and Risks

Identification of hazards and risks is the process through which the facility becomes aware of potential hazards in the resident environment and the risk of a resident having an avoidable accident. All staff (e.g., professional, administrative, maintenance, etc.) are to be involved in observing and identifying potential hazards in the environment, while taking into consideration the unique characteristics and abilities of each resident. The facility should make a reasonable effort to identify the hazards and risk factors for each resident. Various sources provide information about hazards and risks in the resident environment. These sources may include, but are not limited to, *Quality Assessment and Assurance (QAA)* activities, environmental rounds, MDS/*CAA*s data, medical history and physical exam, *facility assessment as required in F838*, and individual observation. This information is to be documented and communicated across all disciplines.

Effective November 28, 2017

Evaluation and Analysis
Evaluation and analysis is the process of examining data to identify specific hazards and risks and to develop targeted interventions to reduce the potential for accidents. Interdisciplinary involvement is a critical component of this process. Analysis may include, for example, considering the severity of hazards, the immediacy of risk, and trends such as time of day, location, etc.

Both the facility-centered and resident-directed approaches include evaluating hazards and accident risk data *which includes prior accidents/incidents*, analysis to identify the root causes of each hazard and accident risk, and identifying or developing interventions based on the severity of the hazards and immediacy of risk. Evaluations also look at trends such as time of day, location, etc.

Implementation of Interventions
Implementation refers to using specific interventions to try to reduce a resident's risks from hazards in the environment. The process includes: Communicating the interventions to all relevant staff, assigning responsibility, providing training as needed, documenting interventions (e.g., plans of action developed by the Quality Assurance Committee or care plans for the individual resident), and ensuring that the interventions are put into action.

Interventions are based on the results of the evaluation and analysis of information about hazards and risks and are consistent with professional standards, including evidence-based practice. Development of interim safety measures may be necessary if interventions cannot immediately be implemented fully.

Facility-based interventions may include, but are not limited to, educating staff, repairing the device/equipment, and developing or revising policies and procedures. Resident-directed approaches may include implementing specific interventions as part of the plan of care, supervising staff and residents, etc. Facility records document the implementation of these interventions.

Monitoring and Modification
Monitoring is the process of evaluating the effectiveness of *care plan* interventions. Modification is the process of adjusting interventions as needed to make them more effective in addressing hazards and risks.

Monitoring and modification processes include:

- Ensuring that interventions are implemented correctly and consistently;
- Evaluating the effectiveness of interventions;
- Modifying or replacing interventions as needed and
- Evaluating the effectiveness of new interventions.

An example of facility-specific modification is additional training of staff when equipment has been upgraded*, while a* resident-specific modification is revising the *care plan* to reflect the

resident's current condition and risk factors that may have changed since the previous assessment.

For example, a facility implements a position change alarm for a newly admitted resident with a history of falls. After completing a comprehensive assessment of the resident, facility staff identify the resident's routines and patterns, remove the alarm, implementing more individualized interventions that address the actual cause of why a resident may be changing position (e.g. has been in one position too long or is trying to reach for a personal item) which could lead to a fall.

Supervision

Supervision is an intervention and a means of mitigating accident risk. Facilities are obligated to provide adequate supervision to prevent accidents. Adequacy of supervision is defined by *type* and frequency, based on the individual resident's assessed needs, and identified hazards in the resident environment. Adequate supervision may vary from resident to resident and from time to time for the same resident. *Devices such as position change* alarms *may* help to monitor a resident's *movement temporarily*, but do not eliminate the need for adequate supervision.

The resident environment may contain temporary hazards (e.g., construction, painting, housekeeping activities, etc.) that warrant additional supervision or alternative measures such as barriers to prevent access to affected areas of the resident environment.

Adequate supervision to prevent accidents is enhanced when the facility:

- Accurately assesses a resident and/or the resident environment to determine whether supervision to avoid an accident is necessary; and/or
- Determines that supervision of the resident was necessary and provides supervision based on the individual resident's assessed needs and the risks identified in the environment.

Resident Smoking

Some facilities permit residents to smoke tobacco products. In these facilities, assessment of the resident's capabilities and deficits determines whether or not supervision is required. If the facility identifies that the resident needs assistance and supervision for smoking, the facility includes this information in the resident's *care plan*, and reviews and revises the plan periodically as needed.

The facility may designate certain areas for resident smoking. The facility must ensure precautions are taken for the resident's individual safety, as well as the safety of others in the facility. Such precautions may include smoking only in designated areas, supervising residents whose assessment and *care plans* indicate a need for assisted and supervised smoking, and limiting the accessibility of matches and lighters by residents who need supervision when smoking for safety reasons. Smoking by residents when oxygen is in use is prohibited, and any smoking by others near flammable substances is also problematic. Additional measures may include informing all visitors of smoking policies and hazards.

Guidance concerning resident smoking regulations can be found in NFPA 101, the Life Safety Code at 19.7.4, Smoking, including requirements for signage, prohibiting smoking by residents classified as not responsible, and disposal of smoking materials.

Resident-to-Resident Altercations

NOTE: *A resident to resident altercation should be reviewed as a potential situation of abuse which should be investigated* under the guidance for 42 CFR §483.*12, (F600). The surveyor should not automatically assume that abuse did not occur for a resident identified as having a cognitive impairment or mental disorder, as it does not preclude the resident from deliberate (willful) or non-accidental actions.* "Willful" *as defined at §483.5 and as used in the definition of "abuse," "means the individual must have acted deliberately, not that the individual must have intended to inflict injury or harm."* Even though a resident may have a cognitive impairment, he/she could still commit a willful act. *If during the investigation of an allegation of abuse, it is determined that the action was not willful, the surveyor must investigate whether the facility is in compliance with the requirement to maintain an environment as free of accident hazards as possible, and that each resident receives adequate supervision using guidance at this tag, F689, Accidents.*

It is important that a facility take reasonable precautions, including providing adequate supervision, when the risk of resident-to-resident altercation is identified, or should have been identified. Certain situations or conditions may increase the potential for such altercations, including, but not limited to:

- A history of aggressive behaviors including striking out, verbal outbursts, or negative interactions with other resident(s); and/or
- Behavior that *may* disrupt or annoy others such as constant verbalization (e.g., crying, yelling, calling out for help), making negative remarks, restlessness, repetitive behaviors, taking items that do not belong to them, going into others' rooms, drawers, or closets, and undressing in inappropriate areas. Although these behaviors may not be aggressive in nature, they may precipitate a negative response from others, resulting in verbal, physical, and/or emotional harm.

The facility is responsible for identifying residents who have a history of disruptive or intrusive interactions, or who exhibit other behaviors that make them more likely to be involved in an altercation. The facility should identify the factors (e.g., *pain, specific triggers in the* environment, etc.) that *increase the risks associated with* individual residents, including those that could trigger an altercation. The *interdisciplinary team* reviews the assessment along with the resident and/or his/her representative, in order to *address the underlying reasons for the behavioral manifestations and to* identify interventions to try to prevent altercations.

The interventions listed below include supervision and other actions that could address potential or actual negative interactions:

- Evaluating staffing levels to ensure adequate supervision (if it is adequate, it is meeting the resident's needs) *(refer to F725, §483.35(a)(1)(2), to evaluate staffing levels for any nursing services not related to behavioral health care or dementia care and F741,*

§483.40, for any staff caring for residents with dementia or a history of trauma and/or post-traumatic stress disorder);

- Evaluating staffing assignments to ensure consistent staff who are more familiar with the resident and who thus may be able to identify changes in a resident's condition and behavior;
- Providing safe supervised areas for unrestricted movement;
- Eliminating or reducing underlying causes of distressed behavior such as boredom and pain;
- Monitoring environmental influences such as temperatures, lighting, and noise levels; and

Ongoing staff training, competencies and supervision, including how to approach a resident who may be agitated, combative, verbally or physically aggressive, or anxious, and how and when to obtain assistance in managing a resident with behavior symptoms *(refer to F726, §483.35(a)(3)(4)(c), to evaluate staff competency for any nursing services not related to behavioral health care or dementia care and F741, §483.40, for any staff caring for residents with dementia or a history of trauma and/or post-traumatic stress disorder)*.

RISKS AND ENVIRONMENTAL HAZARDS

This section discusses common, but not all, potential risks and hazards found in the resident environment.

NOTE: The information included in the following sections is based on current professional standards of practice or "best practice" models as described in the literature.

The physical plant, devices, and equipment described in this section may not be hazards by themselves but can become hazardous when a vulnerable resident interacts with them. Some temporary hazards in the resident environment can affect most residents who have access to them (e.g., construction, painting, and housekeeping activities). Other situations may be hazardous only for certain individuals (e.g., accessible smoking materials).

In order to be considered hazardous, an element of the resident environment must be accessible to a vulnerable resident. Resident vulnerability is based on risk factors including the individual resident's functional status, medical condition, cognitive abilities, mood, and health treatments (e.g., medications). Resident vulnerability to hazards may change over time. Ongoing assessment helps identify when elements in the environment pose hazards to a particular resident.

Certain sharp items, such as scissors, kitchen utensils, knitting needles, or other items, may be appropriate for many residents but hazardous for others with cognitive impairments. Handrails, assistive devices, and any surface that a resident may come in contact with may cause injury, if the surface is not in good condition, free from sharp edges or other hazards *or not installed properly*.

Improper actions or omissions by staff can create hazards in the physical plant (e.g., building and grounds), environment, and/or with devices and equipment. Examples of such hazards might include fire doors that have been propped open, disabled locks or latches, nonfunctioning alarms,

buckled or badly torn carpets, cords on floors, irregular walking surfaces, improper storage and access to toxic chemicals, exposure to unsafe heating unit surfaces, and unsafe water temperatures. Other potential hazards may include furniture that is not appropriate for a resident (e.g., chairs or beds that are *not the proper height or width for the resident to transfer to and from safely* or unstable as to present a fall hazard) and lighting that is either inadequate or so intense as to create glare. Devices for resident care, such as pumps, ventilators, and assistive devices, may be hazardous when they are defective, disabled, or improperly used (i.e., used in a manner that is not per manufacturer's recommendations or current professional standards of practice).

Resident Vulnerabilities

The responsibility to respect a resident's choices is balanced by considering the resident's right to direct the care they receive with the potential impact of these choices on their well-being, other residents, and on the facility's obligation to protect residents from harm. The facility has a responsibility to educate a resident, family, and staff regarding significant risks related to a resident's choices. When a resident choice poses some risk, staff should work with the resident to understand reasons for the choice, and discuss options for the facility to honor the choice. For example, a resident may express a desire to use a cane instead of a walker or wheelchair in order to maintain dignity and self-esteem. This preference should be discussed to review potential positive and negative consequences of possible courses of action (including potential negative consequences that may result from preventing the choice) and to find ways to develop a care plan in which staff honor the choice while mitigating risks. For more information on care planning to mitigate risk, see A Process for Care Planning Resident Choice at http://www.ideasinstitute.org/PDFs/Process_for_Care_Planning_for_Residnet_Choice.pdf .

Verbal consent or signed consent/waiver forms do not eliminate a facility's responsibility to protect a resident from an avoidable accident, nor does it relieve the provider of its responsibility to assure the health, safety, and welfare of its residents. While Federal regulations affirm the resident's right to participate in care planning and to refuse treatment, the regulations do not create the right for a resident, or representative to demand the facility use specific medical interventions or treatments that the facility deems inappropriate. The regulations hold the facility ultimately accountable for the resident's care and safety.

Falls and unsafe wandering/elopement are of particular concern. The following section reviews these issues along with some common potential hazards.

Falls - The MDS defines a fall as unintentionally coming to rest on the ground, floor, or other lower level but not as a result of an overwhelming external force (e.g., resident pushes another resident). An episode where a resident lost his/her balance and would have fallen, if not for *another person or if he or she had not caught him/herself*, is considered a fall. A fall without injury is still a fall. Unless there is evidence suggesting otherwise, when a resident is found on the floor, a fall is considered to have occurred.

***NOTE**: Challenging a resident's balance and training him/her to recover from loss of balance is an intentional therapeutic intervention. The losses of balance that occur during supervised therapeutic interventions are not considered a fall.*

Some factors that may result in resident falls include, but are not limited to:

- *Environmental hazards, such as wet floors, poor lighting, incorrect bed height and/or width, or improperly fitted or maintained wheelchairs;*[8]
- *Unsafe or absent footwear;*
- *Underlying chronic medical conditions, such as arthritis, heart failure, anemia and neurological disorders;*
- *Acute change in condition such as fever, infection, delirium;*
- *Medication side effects;*
- *Orthostatic hypotension;*
- *Lower extremity weakness;*
- *Balance disorders;*
- *Poor grip strength;,*
- *Functional impairments (difficulty rising from a chair, getting on or off toilet, etc.);*
- *Gait disorders;*
- *Cognitive impairment;*
- *Visual deficits;*
- *Pain; and*
- *Incontinence.*

Muscle weakness and gait problems account for about 24% of nursing home falls and environmental hazards cause16% to 27% of falls for residents.[9]

Older persons have both a high incidence of falls and a high susceptibility to injury.[10] *Serious potential consequences of falls include physical injuries, pain, increased risk of death, impaired function, fear of falling, and self-imposed limitations on activities leading to social isolation.*[11] Evaluation of *all of* the causal factors leading to a resident fall *assists the facility in developing and implementing* relevant, consistent*, and individualized* interventions to prevent future occurrences. Proper actions following a fall include:

- Ascertaining if there were injuries, and providing treatment as necessary;
- Determining what may have caused or contributed to the fall, *including ascertaining what the resident was trying to do before he or she fell;*
- Addressing the *risk* factors for the fall *such as the resident's medical conditions(s), facility environment issues, or staffing issues*; and

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8 *Shorr, R.I., Chandler, M., Mion, L.C., Waters, T.M., Liu, M., Daniels, M.J., Kessler, L.A., and Miller, S.T. (2012). Effects of an intervention to increase bed alarm use to prevent falls in hospitalized patients. Annals of Internal Medicine 157(10), 698.*

9 *The Centers for Disease Control and Prevention. Falls in Nursing Homes. http://www.cdc.gov/homeandrecreationalsafety/falls/nursing.html.*

10 *Panel on Prevention of Falls in Older Persons, American Geriatrics Society and British Geriatrics. (2010). Summary of the updated American Geriatrics Society/British Geriatrics Society clinical practice guideline for prevention of falls in older persons. J Am Geriatr Soc, 2011, 59(1), 148-57.*

11 *Taylor, J.A., Parmelee, P., Brown, H., and Ouslander, J. The Falls Management Program: A Quality Improvement Initiative for Nursing Facilities. Agency for Healthcare Research and Quality, 2005, http://www.ahrq.gov/professionals/systems/long-term-care/resources/injuries/fallspx/fallspxmanual.html.*

- Revising the resident's plan of care and/or facility practices, as needed, to reduce the likelihood of another fall.

NOTE: A fall by a resident does not necessarily indicate a deficient practice because not every fall can be avoided.

***Position Change Alarms*:**
Facilities often implement position change alarms as a fall prevention strategy or in response to a resident fall. The alarms are designed to alert staff that the resident has changed position, increasing the risk for falling. However, the efficacy of alarms to prevent falls has not been proven and a study of hospitalized patients concluded these devices may only alert staff that a fall has already occurred. The same study also noted false alarms are a common problem leading to "alarm fatigue," where staff no longer respond to the sound of an alarm.[12] *A study on bed-exit alarms concluded the alarms are not a substitute for staff assisting residents and bed-exit alarms may not always function reliably for residents who weigh less than 100 pounds or who are restless.*[13] *Individual facility efforts to reduce use of alarms have shown falls actually decrease when alarms are eliminated, and replaced with other interventions such as purposeful checks to proactively address resident needs, adjusting staff to cover times of day when most falls occur, assessing resident routines, and making individualized environmental or care changes that suit each resident.*[14] *For example, brighter lighting might help a resident with macular degeneration ambulate more easily in his or her room but would cause glare and make walking more difficult for a resident with cataracts.*[15]

Facilities must implement comprehensive, resident-centered fall prevention plans for each resident at risk for falls or with a history of falls. While position change alarms are not prohibited from being included as part of a plan, they should not be the primary or sole intervention to prevent falls. If facility staff choose to implement alarms, they should document their use aimed at assisting the staff to assess patterns and routines of the resident. Use of these devices, like any care planning intervention, must be based on assessment of the resident and monitored for efficacy on an on-going basis. Position change alarms have been used to monitor a resident's movement in chairs or beds, etc. However, there must be sufficient staff and supervision to meet the resident's needs and staff must be vigilant in order to respond to alarms a timely manner. Alarms do not replace necessary supervision. Facilities must take steps to identify issues that place the resident at risk for falls and implement approaches to address those risks in a manner that enables the resident to achieve or maintain his or her highest practicable physical, mental, and psychosocial well-being.

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12 *Shorr, R.I., Chandler, M., Mion, L.C., Waters, T.M., Liu, M., Daniels, M.J., Kessler, L.A., and Miller, S.T. (2012). Effects of an intervention to increase bed alarm use to prevent falls in hospitalized patients. Annals of Internal Medicine 157(10), 698.*

13 *Capezuti, E., Brush, B.L., Lane, S., Rabinowitz, H.U., and Secic, M. (2009). Bed-exit alarm effectiveness. Arch Gerontol Geriatr 49(1) 27-31.*

14 *MASSPRO (n.d.). Nursing home alarm elimination program: It's possible to reduce falls by eliminating resident alarms. http://www.masspro.org/case-studies/elimalarmsrehab.pdf.*

15 *Becker, C., Rapp, K. (2010) Fall Prevention in Nursing Homes. Clinics in Geriatric Medicine 26(4)693-704.*

Wandering and Elopement - Wandering is random or repetitive locomotion. This movement may be goal-directed (e.g., the person appears to be searching for something such as an exit) or may be non-goal-directed or aimless. Non-goal-directed wandering requires a response in a manner that addresses both safety issues and an evaluation to identify root causes to the degree possible. Moving about the facility aimlessly may indicate that the resident is frustrated, anxious, bored, hungry, or depressed. *Goal-directed wandering may fulfill a resident's need for exercise or provide sensory stimulation. This goal directed wandering should also require staff supervision and a facility response to address safety issues.*

Wandering may become unsafe when a resident becomes overly tired or enters an area that is physically hazardous or that contains potential safety hazards (e.g., chemicals, tools, and equipment, etc.). Entering into another resident's room may lead to an altercation or contact with hazardous items.[16] *Unsafe wandering can be associated with an increased risk for falls and injuries.*

While *wander, door, or building* alarms can help to monitor a resident's activities, staff must be vigilant in order to respond to them in a timely manner. Alarms do not replace necessary supervision, *and require scheduled maintenance and testing to ensure proper functioning.*

Elopement occurs when a resident leaves the premises or a safe area without authorization (i.e., an order for discharge or leave of absence) and/or any necessary supervision to do so. A resident who leaves a safe area may be at risk of (or has the potential to experience) heat or cold exposure, dehydration and/or other medical complications, drowning, or being struck by a motor vehicle. Facility policies that clearly define the mechanisms and procedures for *assessing or identifying,* monitoring and managing residents at risk for elopement can help to minimize the risk of a resident leaving a safe area without authorization and/or appropriate supervision. In addition, the resident at risk should have interventions in their comprehensive plan of care to address the potential for elopement. Furthermore, a facility's disaster and emergency preparedness plan should include a plan to locate a missing resident.

Physical Plant Hazards

NOTE: *Refer to guidance at 483.70(e) (F838) for facility responsibilities regarding the facility's physical environment.*

Supervision and/or containment of hazards are needed to protect residents from harm caused by environmental hazards. Examples of such hazards can range from common chemical cleaning materials to those caused by adverse water temperatures or improper use of electrical devices.

Chemicals and Toxins - Various materials in the resident environment can pose a potential hazard to residents. Hazardous materials can be found in the form of solids, liquids, gases, mists, dusts, fumes, and vapors. The routes of exposure for toxic materials may include inhalation, absorption, or ingestion.

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16 Boltz, M. (2003). Litigation Issues Related To Wandering and Elopement. The John A. Hartford Foundation Institute for Geriatric Nursing, New York University, The Steinhardt School of Education, Division of Nursing. *Retrieved May 9, 2014 from http://www.nccdp.org/wandering.htm.*

For a material to pose a safety hazard to a resident, it must be toxic, caustic, or allergenic; accessible and available in a sufficient amount to cause harm. Toxic materials that may be present in the resident environment are unlikely to pose a hazard unless residents have access or are exposed to them. Some materials that would be considered harmless when used as designed could pose a hazard to a resident who accidentally ingests or makes contact with them.

Examples of materials that may pose a hazard to a resident include (but are not limited to):

- Chemicals used by the facility staff in the course of their duties (e.g., housekeeping chemicals) and chemicals or other materials brought into the resident environment by staff, other residents, or visitors;
- Drugs and therapeutic agents;
- Plants and other "natural" materials found in the resident environment or in the outdoor environment (e.g., poison ivy).

One source of information concerning the hazards of a material that a facility may obtain is *the* Material Safety Data Sheet (MSDS).[17] The Occupational Safety and Health Administration (OSHA) requires employers to have a MSDS available for all hazardous materials that staff use while performing their duties.[18] MSDSs are available on-line for numerous chemicals and non-toxic materials, and should be reviewed carefully to determine if the material is toxic and poses a hazard. Poison control centers are another source of information for potential hazards, including non-chemical hazards such as plants.

NOTE: Toxicological profiles for a limited number of hazardous materials are accessible on the Agency for Toxic Substances & Disease Registry Web site at http://www.atsdr.cdc.gov/.

Water Temperature - Water may reach hazardous temperatures in hand sinks, showers, tubs, *and any other source or location where hot water is accessible to a resident*. Burns related to hot water/liquids may also be due to spills and/or immersion. Many residents in long-term care facilities have conditions that may put them at increased risk for burns caused by scalding. These conditions include: decreased skin thickness, decreased skin sensitivity, peripheral neuropathy, decreased agility (reduced reaction time), decreased cognition or dementia, decreased mobility, and decreased ability to communicate.[19]

The degree of injury depends on factors including the water temperature, the amount of skin exposed, and the duration of exposure. Some States have regulations regarding allowable maximum water temperature. Table 1 illustrates damage to skin in relation to the temperature of the water and the length of time of exposure.[20]

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17 Agency for Toxic Substances & Disease Registry web site at *http://www.atsdr.cdc.gov/toxprofiles/index.asp*.

18 US Dept. of Labor, Occupational Safety and Health Standards, 29 CFR 1910.1200 (g)(1) and (2).

19 Katcher, L.K. (1981). Scald Burns from Hot Tap Water. Journal of Am Med Assoc., 246(11), 1219-1222.

20 Moritz, A.R., Henriques F.C. Jr. (1947). Studies of Thermal Injury: II. The Relative Importance of Time and Surface Temperatures in the Causation of Cutaneous Burns. Am J Pathology, 23, 695-720.

Table 1. Time and Temperature Relationship to Serious Burns

Water Temperature		Time Required for a 3rd Degree Burn to Occur
155°F	68°C	1 sec
148°F	64°C	2 sec
140°F	60°C	5 sec
133°F	56°C	15 sec
127°F	52°C	1 min
124°F	51°C	3 min
120°F	48°C	5 min
100°F	37°C	Safe Temperatures for Bathing (see Note)

NOTE: Burns can occur even at water temperatures below those identified in the table, depending on an individual's condition and the length of exposure.

Based upon the time of the exposure and the temperature of the water, the severity of the harm to the skin is identified by the degree of burn, as follows.[21]

- First-degree burns involve the top layer of skin (e.g., minor sunburn). These may present as red and painful to touch, and the skin will show mild swelling.
- Second-degree burns involve the first two layers of skin. These may present as deep reddening of the skin, pain, blisters, glossy appearance from leaking fluid, and possible loss of some skin.
- Third-degree burns penetrate the entire thickness of the skin and permanently destroy tissue. These present as loss of skin layers, often painless (pain may be caused by patches of first- and second-degree burns surrounding third-degree burns), and dry, leathery skin. Skin may appear charred or have patches that appear white, brown, or black.

Electrical Safety - Any electrical device, whether or not it needs to be plugged into an electric outlet, can become hazardous to the residents through improper use or improper maintenance. Electrical equipment such as electrical cords can become tripping hazards. Halogen lamps or heat lamps can cause burns or fires if not properly installed away from combustibles in the resident environment. The Life Safety Code prohibits the use of portable electrical space heaters in resident areas.

Extension cords should not be used to take the place of adequate wiring in a facility. If extension cords are used, the cords should be properly secured and not be placed overhead, under carpets or rugs, or anywhere that the cord can cause trips, falls, or overheat. Extension cords should be connected to only one device to prevent overloading of the circuit. The cord itself should be of a size and type for the expected electrical load and made of material that will not fray or cut easily.

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21 US Dept. of Health and Human Services. Centers for Disease Control and Prevention. Emergency Preparedness & Response. *Mass Casualties: Burns. Retrieved March 25, 2014 from http://www.bt.cdc.gov/masscasualties/burns.asp*

Electrical cords including extension cords should have proper grounding if required and should not have any grounding devices removed or not used if required.

Power strips may not be used as a substitute for adequate electrical outlets in a facility. Power strips may be used for a computer, monitor, and printer. Power strips are not designed to be used with medical devices in patient care areas. Precautions needed if power strips are used include: installing internal ground fault and over-current protection devices; preventing cords from becoming tripping hazards; and using power strips that are adequate for the number and types of devices used. Overload on any circuit can potentially cause overheating and fire. The use of ground fault circuit interruption (GFCIs) may be required in locations near water sources to prevent electrocution of staff or residents.[22]

The proper use of electric blankets and heating pads is essential to avoid thermal injuries. These items should not be tucked in or squeezed. Constriction can cause the internal wires to break. A resident should not go to sleep with an electric blanket or heating pad turned on. Manufacturer's instructions for use should be followed closely. Injuries and deaths have been related to burns and fires related to the use of heating pads. Most deaths are attributable to heating pads that generated fires, but most injuries are burns from prolonged use or inappropriate temperature setting. Prolonged use on one area of the body can cause a severe burn, even when the heating pad is at a low temperature setting.[23]

Lighting - The risk of an accident increases when there is insufficient light or too much light, which often results in glare. Vision among older persons varies widely; therefore, no single level of illumination can ensure safety for all residents. The proper amount of light depends on the resident's visual needs and the task he/she is performing. An older person typically needs more light to see. However, a resident with cataracts or glaucoma may be overly sensitive to bright light, and excessive lighting could make it more difficult to see clearly and thereby increase his/her fall risk.[24] Creating transitional zones between light and dark spaces helps to improve sight recovery and enable safer mobility. Providing extra visual cues that clearly define needed items or spaces in areas with limited or variable light can help to enable safe performance of tasks (e.g., turning on a light). Providing supplemental light near beds for patients who are mobile may assist in safe mobility at night.[25]

NOTE: Refer to guidance for 42 CFR 483.*10(i)(5), F584* for lighting issues related to *Resident Rights regarding adequate and comfortable lighting*.

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22 *Electrical Safety Foundation International Resource Library. Retrieved March 25, 2014 from http://www.esfi.org/index.cfm/page/Resource-Library/pid/10272.*

23 US Dept. of Health and Human Services. Food and Drug Administration. (December 12, 1995). Public Health Advisory: Hazards Associated with the Use of Electric Heating Pads. *http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/ucm242866.htm.*

24 Tideiksaar, R. (1998). Falls in Older Persons: Prevention and Management (2nd Edition). Baltimore, MD: Health Profession Press.

25 Warren, M. (2001), Occupational Therapy Practice Guidelines for Adults with Low Vision, The American Occupational Therapy Association, Inc.

Assistive Devices/Equipment Hazards

Assistive devices also can help to prevent accidents. Assistive devices and equipment can help residents move with increased independence, transfer with greater comfort, and feel physically more secure. However, there are risks associated with the use of such devices and equipment, *particularly if or when they are not properly maintained* and these risks need to be balanced with the benefits gained from their use. Training of staff, residents, family members and volunteers on the proper use of assistive devices/equipment is crucial to prevent accidents. It is also important to communicate clearly the approaches identified in the care plan to all staff, including temporary staff. It is important to train staff regarding resident assessment, safe transfer techniques, and the proper use of mechanical lifts including device weight limitations.

NOTE: The Safe Medical Devices Act of 1990 (SMDA) requires hospitals, nursing homes, and other user facilities to report deaths, serious illnesses, and injuries associated with the use of medical devices to manufacturers and the Food and Drug Administration.

Assistive Devices for Mobility - Mobility devices include all types of assistive devices, such as, but not limited to, canes, standard and rolling walkers, manual or non-powered wheelchairs, and powered wheelchairs. Three primary factors that may be associated with an increased accident risk related to the use of assistive devices include:

1. Resident Condition. Lower extremity weakness, gait disturbances, decreased range of motion, and poor balance may affect some residents. These conditions combined with cognitive impairment can increase the accident risks of using mobility devices. Unsafe behavior, such as failure to lock wheelchair brakes and trying to stand or transfer from a wheelchair unsafely, can result in falls and related injuries;
2. Personal Fit and Device Condition. Devices can pose a hazard if not fitted and/or maintained properly.[26] Personal fit, or how well the assistive device meets the individual needs of the resident, may influence the likelihood of an avoidable accident; and
3. Staff Practices. Mobility devices that a resident cannot readily reach may create a hazardous situation. Unsafe transfer technique used by staff may result in an accident. Inadequate supervision by staff of a resident during the initial trial period of assistive device use or after a change in the resident's functional status can increase the risk of falls and/or injury. Additionally, staff needs to ensure assistive devises properly fit the resident and the resident has received proper training in the use of the assistive device.

Assistive Devices for Transfer - Mechanical assistive devices for transfer include, but are not limited to, portable and stationary total body lifts, sit-to-stand devices, and transfer or gait belts. The resident assessment helps to determine the resident's degree of mobility and physical impairment and the proper transfer method; for example, whether one or more caregivers or a mechanical device is needed for a safe transfer. Residents who become frightened during transfer in a mechanical lift may exhibit resistance movements that can result in avoidable accidents. Communicating with the resident and addressing the resident's fear may reduce the risk.

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26 Taylor, J.A., Brown, A.K., Meredith, S., Ray, W.A. (2002). The fall reduction program: a comprehensive program for reduction of falls and injuries in long-term care residents. Nashville, TN: Department of Preventive Medicine, Vanderbilt University School of Medicine.

Factors that may influence a resident's risk of accident during transfer include staff availability, resident abilities, staff training and competency. The resident's ability to communicate and identify physical limitations or to aid in the transfer will help determine the need for an assistive device, such as a mechanical lift. *The Occupational Safety and Health Administration (OSHA) provides information and guidelines on identifying problems and implementing solutions relating to handling residents during transfers.*[27]

Devices Associated with Entrapment Risks - Devices can be therapeutic and beneficial; however, devices are not necessarily risk free so it is important to weigh the relative risks and benefits of using certain devices. For example, while physical restraints may be used to treat a resident's medical symptom, the devices may create a risk for entrapment. Physical restraints are defined *as any manual method, physical or mechanical device/equipment or material that meets all of the following criteria:*

- *Is attached or adjacent to a resident's body;*
- *Cannot be removed easily by the resident; and*
- *Restricts the resident's freedom of movement or normal access to his/her body.*

In 1992, the Food and Drug Administration (FDA) issued a Safety Alert entitled "Potential Hazards with Restraint Devices".[28] Serious injuries, as well as death, have been reported as a result of using physical restraints. Some physical restraints carry a risk of severe injury, strangulation, and asphyxiation. Restrained residents may be injured or die when they try to remove restraints, to ambulate while restrained, or due to an improperly fitted or used device.

Regardless of the purpose for use, bed rails (also referred to as "side rails," "bed side rails," and "safety rails") and other bed accessories (e.g. transfer bar, bed enclosures), while assisting with transfer and positioning, can increase resident safety risk. Bed rails include rails of various sizes (e.g., full length rails, half rails, quarter rails) that may be positioned in various locations on the bed. Residents most at risk for entrapment are those who are frail or elderly or those who have conditions such as agitation, delirium, confusion, pain, uncontrolled body movement, hypoxia, fecal impaction, acute urinary retention, etc. that may cause them to move about the bed or try to exit from the bed. The timeliness of assistance in using the bathroom, appropriateness of positioning, and other care-related activities can contribute to the risk of entrapment. *The FDA provides detailed information about bed rails, including recommendations for health care providers.*[29]

Entrapment may occur when a resident is caught between the mattress and bed rail or in the bed rail itself. Technical issues, such as the proper sizing of mattresses, fit and integrity of bed rails

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27 *US Department of Labor, , Occupational Safety & Health Administration. Guidelines for Nursing Homes (Revised March 2009), https://www.osha.gov/ergonomics/guidelines/nursinghome/final_nh_guidelines.html.*

28 US Dept. of Health and Human Services. Food and Drug Administration. (July 15, 1992). FDA Safety Alert: Potential Hazards with Restraint Devices.

29 *US Dept. of Health and Human Services. Food and Drug Administration, Bed Rail Safety, http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/HospitalBeds/ucm123676.htm.*

or other design elements (e.g., wide spaces between bars in the bed rails) can also affect the risk of resident entrapment.[30]

NOTE: *§483.25(n) (F700) requires that facilities attempt appropriate alternatives before installing bed rails.* Refer to § 483.*90(d)*(3) *(F909)* for *guidance regarding inspection and maintenance issues related to bed rails.*

The use of a specialty air-filled mattress or a therapeutic air-filled bed may also present an entrapment risk that is different from rail entrapment with a regular mattress. The high compressibility of an air-filled mattress compared to a regular conventional mattress requires appropriate precautions when used for a resident at risk for entrapment. An air-filled mattress compresses on the side to which a person moves, thus raising the center of the mattress and lowering the side. This may make it easier for a resident to slide off the mattress or against the rail. Mattress compression widens the space between the mattress and rail. When a resident is between the mattress and rail, the mattress can re-expand and press the chest, neck, or head against the rail. While using air therapy to prevent and treat pressure ulcer/injuries, facilities should also take precautions to reduce the risk of entrapment. Precautions may include following manufacturer equipment alerts and increasing supervision.[31]

NOTE: §483.*12 (F604)*, applies to the use of physical restraints. §483.25*(d)*, *This tag, F689,* applies to assistive devices that create hazards (e.g., devices that are defective; not used properly or according to manufacturer's specifications; disabled or removed; not provided or do not meet the resident's needs (poor fit or not adapted); and/or used without adequate supervision when required). *§483.25(n) (F700) applies to the installation of bed rails.*

KEY ELEMENTS OF NONCOMPLIANCE

To cite deficient practice at F689, the surveyor's investigation will generally show that the facility failed to do one or more of the following:

- *Identify and eliminate all known and foreseeable accident hazards in the resident's environment, to the extent possible; or*
- *To the extent possible, reduce the risk of all known or foreseeable accident hazards that cannot be eliminated; or*
- *Provide appropriate and sufficient supervision to each resident to prevent an avoidable accident; or*
- *Provide assistance devices necessary to prevent an avoidable accident from occurring.*

INVESTIGATIVE SUMMARY

Use

Use the Accidents Critical Element (CE) Pathway along with the above interpretive guidelines when determining if the facility meets the requirements to ensure that the resident's environment

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30 *US Dept. of Health and Human Services, Food and Drug Administration, Recommendations for Consumers and Caregivers about Bed Rails. http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/ConsumerProducts/BedRailSafety/ucm362843.htm.*

31 Miles, S. (June 2002). Death between bedrails and air pressured mattresses. J Am Geriatr Soc, 50(6), 1124-50(6), 1124-5..

remains as free from accident hazards as possible and that each resident receives adequate supervision and assistance devices to prevent accidents.

Summary of Accident and Supervision Investigative Procedure
Observe the general environment of the facility to determine if the facility provides an environment that is free from accident hazards over which the facility has control and provides supervision and assistive devices to each resident to prevent avoidable accidents. During observation of the facility, the survey team should observe the environment for the presence of potential/actual hazards. For a resident with an identified concern, briefly review the assessment and plan of care to determine whether the facility identified resident risks and implemented interventions as necessary.

If the resident has been in the facility for less than 14 days (before completion of all the *Resident Assessment Instrument (*RAI) is required), *review the baseline careplan which must be completed within 48 hours to* determine if the facility is *providing appropriate care and services based on information available at the time of admission*.

DEFICIENCY CATEGORIZATION
In addition to actual or potential physical harm, always consider whether psychosocial harm has occurred when determining severity level (See Appendix P, Section IV, E, Psychosocial Outcome Severity Guide).

Examples of Severity Level 4 Noncompliance Immediate Jeopardy to Resident Health or Safety include, but are not limited to:

- *The facility failed to keep corrosive cleaning supplies out of the reach of ambulatory residents with dementia, resulting in one resident ingesting drain opener and sustaining esophageal damage.*
- *The facility failed to provide supervision to a unit which had ambulatory cognitively impaired residents. The facility failed to keep these residents from gaining access to the employee locker room. When the surveyor conducted her tour of the facility, she found a confused resident who was trapped in the employee locker room.*

Examples of Severity Level 3 Noncompliance Actual Harm that is Not Immediate Jeopardy include, but are not limited to:

- *The facility failed to apply a smoking apron to a resident while smoking, which was necessary and documented on the care plan. The resident sustained a 2nd degree burn after the cigarette fell onto his/her lap.*
- *The facility failed to use a two-person transfer, as determined necessary by the comprehensive, during a transfer from the resident's bed to wheelchair, resulting in the resident falling to the floor, sustaining a laceration requiring sutures.*

Examples of Severity Level 2 Noncompliance No Actual Harm with Potential for More Than Minimal Harm that is Not Immediate Jeopardy include, but are not limited to:

- *The facility failed to remove clutter and building materials from a construction area, immediately adjacent to a walkway used by residents and their families, creating a hazard which poses a risk for more than minimal harm.*

- *The facility failed to reassess the resident and his fall risks, determine root causes of fall, and revise the care plan interventions if indicated, for a resident who fell, sustaining only a bruised forehead.*

Severity Level 1 Noncompliance No Actual Harm with Potential for Minimal Harm

The failure of the facility to provide a safe environment and adequate supervision places residents at risk for more than minimal harm. Therefore, Severity Level 1 does not apply for this regulatory requirement.

F690
§483.25*(e)* Incontinence.
§483.25*(e)*(1) The facility must ensure that a resident who *is continent of bladder and bowel on admission receives services and assistance to maintain continence unless his or her clinical condition is or becomes such that continence is not possible to maintain.*

§483.25*(e)(2)For a resident with urinary incontinence, based on the resident's comprehensive assessment, the facility must ensure that—*

(i) A resident who enters the facility without an indwelling catheter is not catheterized unless the resident's clinical condition demonstrates that catheterization was necessary;

(ii) A resident who enters the facility with an indwelling catheter or subsequently receives one is assessed for removal of the catheter as soon as possible unless the resident's clinical condition demonstrates that catheterization is necessary and

(iii) A resident who is incontinent of bladder receives appropriate treatment and services to prevent urinary tract infections and to restore *continence to the extent possible*.

§483.25*(e)(3) For a resident with fecal incontinence, based on the resident's comprehensive assessment, the facility must ensure that a resident who is incontinent of bowel receives appropriate treatment and services to restore as much normal bowel function as possible.*

INTENT
The intent of this requirement is to ensure that:

- *Each resident who is continent of bladder and bowel receives the necessary services and assistance to maintain continence, unless it is clinically not possible.*
- Each resident who is incontinent of urine is identified, assessed and provided appropriate treatment and services to achieve or maintain as much normal bladder function as possible;
- *A resident who is incontinent of bowel is identified, assessed and provided appropriate treatment and services to restore as much normal bowel function as possible;*
- An indwelling catheter is not used unless there is valid medical justification *for catheterization* and *the catheter* is discontinued as soon as clinically warranted;
- Services are provided to restore or improve normal bladder function to the extent possible, after the removal of the *indwelling* catheter; and

- A resident, with or without *an indwelling* catheter, receives the appropriate care and services to prevent *urinary tract* infections to the extent possible.

DEFINITIONS
"Bacteremia" is the presence of bacteria in the bloodstream.

"Bacteriuria" is defined as the presence of bacteria in the urine.

"Continence" r*efers to any void that occurs voluntarily, or as the result of prompted, assisted, or scheduled use of the bathroom.*

"Sepsis" *is the body's overwhelming and life-threatening response to an infection which can lead to tissue damage, organ failure, and death.*

"Urinary Incontinence" is the involuntary loss or leakage of urine.

"Urinary Retention" is the inability to completely empty the urinary bladder by micturition.

"Urinary Tract Infection (UTI)" is a clinically detectable condition associated with invasion by disease causing microorganisms of some part of the urinary tract, including the urethra (urethritis), bladder (cystitis), ureters (ureteritis), and/or kidney (pyelonephritis). An infection of the urethra or bladder is classified as a lower tract UTI and infection involving the ureter or kidney is classified as an upper tract UTI.

GUIDANCE 483.25(e)
A resident who is continent of bladder *on admission must receive care, including assistance, and services to maintain continence unless his/her clinical condition is or becomes such that continence is not possible to maintain. If a resident is admitted with incontinence of bladder, he/she* receives appropriate treatment and services to prevent urinary tract infections and to restore as much normal bladder function as possible.

Urinary incontinence generally involves a number of transitory or progressive factors that affect the bladder and/or the urethral sphincter. Any condition, medication, or factor that affects lower urinary tract function, bladder capacity, urination, or the ability to toilet can predispose residents to urinary incontinence and may contribute to incomplete bladder emptying.

Assessment
A resident should be assessed at admission regarding continence status and whenever there is a change in urinary tract function, *such as if a resident is admitted who is continent of urine, and subsequently becomes incontinent. The identification of reversible and irreversible (e.g., bladder tumors, spinal cord disease) causes of incontinence, including the type of incontinence, provides direction for the development of appropriate interventions*. It is important that staff, when completing the comprehensive assessment, consider the following:

- Prior history of *bladder functioning, including status of continence, history of* urinary incontinence, including onset, duration and characteristics, precipitants of urinary incontinence, associated symptoms (e.g., dysuria, polyuria, hesitancy) and previous

treatment and/or management, including the response to the interventions and the occurrence of persistent or recurrent UTI;

- Voiding patterns (such as frequency, volume, nighttime or daytime, quality of stream) and, for those already experiencing urinary incontinence, voiding patterns over several days;
- Medication review, particularly those that might affect continence, such as medications with anticholinergic properties (may cause urinary retention and possible overflow incontinence), sedative/hypnotics (may cause sedation leading to functional incontinence), diuretics (may cause urgency, frequency, overflow incontinence), narcotics, alpha-adrenergic agonists (may cause urinary retention in men) or antagonists (may cause stress incontinence in women) calcium channel blockers (may cause urinary retention);
- Patterns of fluid intake, such as amounts, time of day, alterations and potential complications, such as decreased or increased urine output;
- Use of urinary tract stimulants or irritants (e.g., frequent caffeine intake);
- Pelvic and rectal examination to identify physical features that may directly affect urinary continence, such as prolapsed uterus or bladder, prostate enlargement, significant constipation or fecal impaction, use of a urinary catheter, atrophic vaginitis, distended bladder, or bladder spasms;
- Functional and cognitive capabilities that could enhance urinary continence and limitations that could adversely affect continence, such as impaired cognitive function or dementia, impaired immobility, decreased manual dexterity, the need for task segmentation, decreased upper and lower extremity muscle strength, decreased vision, pain with movement;
- Type and frequency of physical assistance necessary to assist the resident to access the toilet, commode, urinal, etc. and the types of prompting needed to encourage urination;
- Pertinent diagnoses such as congestive heart failure, stroke, diabetes mellitus, obesity, and neurological disorders (e.g., Multiple Sclerosis, Parkinson's Disease or tumors) that could affect the urinary tract or its function);
- Identification of and/or potential of developing complications such as skin irritation or breakdown;
- Tests or studies indicated to identify the type(s) of urinary incontinence (e.g., post-void residual(s) for residents who have, or are at risk of, urinary retention, results of any urine culture if the resident has clinically significant systemic or urinary symptoms), or evaluations assessing the resident's readiness for bladder rehabilitation programs; and
- Environmental factors and assistive devices that may restrict or facilitate a resident's ability to access the toilet (e.g., grab bars, raised or low toilet seats, inadequate lighting, distance to toilet or bedside commodes, and availability of urinals, use of bed rails or restraints, or fear of falling).

Types of Urinary Incontinence

Identifying the nature of the incontinence is a key aspect of the assessment and helps identify the appropriate program/interventions to address incontinence. *There are several types of urinary incontinence, and the individual resident may experience more than one type at a time. Some of the more common types include:*

- **Urge Incontinence** *is associated with detrusor muscle over activity (excessive*

contraction of the smooth muscle in the wall of the urinary bladder) resulting in a sudden, strong urge (also known as urgency) to expel moderate to large amounts of urine before the bladder is full). It is characterized by abrupt urgency, frequency, and nocturia (part of the overactive bladder diagnosis). It may be age-related or have neurological causes (e.g., stroke, diabetes mellitus, Parkinson's disease, multiple sclerosis) or other causes such as bladder infection, urethral irritation, etc. The resident can feel the need to void, but is unable to inhibit voiding long enough to reach and sit on the commode. It is the most common cause of urinary incontinence in elderly persons.

- **Stress *Incontinence*** *(outlet incompetence) is associated with impaired urethral closure (malfunction of the urethral sphincter) which allows small amounts of urine leakage when intra-abdominal pressure on the bladder is increased by sneezing, coughing, laughing, lifting, standing from a sitting position, climbing stairs, etc.* . Urine leakage results from an increase in intra-abdominal pressure on a bladder that is not over distended and is not the result of detrusor contractions. It is the second most common type of urinary incontinence in older women.
- **Mixed Incontinence** is the combination of urge incontinence and stress incontinence. Many elderly persons (especially women) will experience symptoms of both urge and stress.
- **Overflow Incontinence** *is associated with leakage of small amounts of urine when the bladder has reached its maximum capacity and has become distended from urine retention.* Symptoms of overflow incontinence may include: weak stream, hesitancy, or intermittency; dysuria; nocturia; frequency; incomplete voiding; frequent or constant dribbling. Urine retention may result from outlet obstruction (e.g., benign prostatic hypertrophy (BPH), prostate cancer, and urethral stricture), hypotonic bladder (detrusor under activity) or both. Hypotonic bladder may be caused by outlet obstruction, impaired or absent contractility of the bladder (neurogenic bladder) or other causes. Neurogenic bladder may also result from neurological conditions such as diabetes mellitus, spinal cord injury, or pelvic nerve damage from surgery or radiation therapy. In overflow incontinence, post void residual (PVR) volume (the amount of urine remaining in the bladder within 5 to 10 minutes following urination) exceeds 200 milliliters (ml). Normal PVR is usually 50 ml. or less. A PVR of 150 to 200 may suggest a need for retesting to determine if this finding is clinically significant. Overflow incontinence may mimic urge or stress incontinence but is less common than either of those.
- **Functional Incontinence** refers to loss of urine that occurs in a resident whose urinary tract function is sufficiently intact that he/she should be able to maintain continence, but who cannot remain continent because of external factors other than inherently abnormal urinary tract function. Examples may include the failure of staff to respond to a request for assistance to the toilet, or the inability to utilize the toilet facilities in time. It may also be related to:
  - Physical weakness or poor mobility/dexterity (e.g., due to poor eyesight, arthritis, deconditioning, stroke, contracture),
  - Cognitive problems (e.g., confusion, dementia, unwillingness to toilet);
  - Medications (e.g., anti-cholinergics, diuretics); or
  - Environmental impediments including excessive distance from the toilet facilities, poor lighting, low chairs that are difficult to get out of, physical restraints and toilets that are difficult to access. Refer to §483.*10*(e) (*3*), *F558, Accommodation of Needs*

for issues regarding unmet environmental needs (e.g., handicap toilet, lighting, assistive devices.

NOTE: Treating the physiological causes of incontinence, without attending to functional components that may have an impact on the resident's continence, may fail to solve the incontinence problem.

- **Transient Incontinence** refers to temporary or occasional incontinence that may be related to a variety of causes, for example: delirium, infection, atrophic urethritis or vaginitis, some pharmaceuticals (such as sedatives/hypnotics, diuretics, anticholinergic agents), increased urine production, restricted mobility or fecal impaction. The incontinence is transient because it is related to a potentially improvable or reversible cause.

Interventions

A number of factors may contribute to the *development of incontinence, or* decline or lack of improvement in urinary continence, such as an underlying medical condition.an inaccurate assessment of the resident's type of incontinence, or lack of knowledge about the resident's voiding patterns. This may contribute to inappropriate interventions or unnecessary use of an indwelling catheter. Facility practices that may promote achieving the highest practicable level of functioning, may prevent *the development of incontinence,* or minimize a decline or lack of improvement in degree of continence include providing treatment and services to address factors that are potentially modifiable, such as:

- Managing pain and/or providing adaptive equipment to improve function for residents suffering from arthritis, contractures, neurological impairments, etc.;
- Removing or improving environmental impediments that affect the resident's level of continence (e.g., improved lighting, use of a bedside commode or reducing the distance to the toilet);
- Treating underlying conditions that have a potentially negative impact on the degree of continence (e.g., delirium causing urinary incontinence related to acute confusion);
- Possibly adjusting medications affecting continence (e.g., medication cessation, dose reduction, selection of an alternate medication, change in time of administration); and
- Implementing a fluid and/or bowel management program to meet the assessed needs.

Options for managing urinary incontinence in nursing home residents include primarily behavioral programs and medication therapy. Other measures and supportive devices used in the management of urinary incontinence and/or urinary retention may include intermittent catheterization; pelvic organ support devices (pessaries); *biofeedback*; the use of incontinence products, garments and an external collection system for men and women; and environmental accommodation and/or modification.

Behavioral Programs

Interventions involving the use of behavioral programs are among the least invasive approaches to address urinary incontinence and have no known adverse complications. Behavior programs involve efforts to modify the resident's behavior and/or environment. Critical aspects of a

successful behavioral program include education of the caregiver and the resident, availability of the staff and the consistent implementation of the interventions.

NOTE: It is important for the comprehensive assessment to identify the essential skills the resident must possess, *such as* the resident's ability to: comprehend and follow instructions; identify urinary urge; control the urge to void until reaching a toilet; and/or respond to prompts to void. Voiding records help detect urinary patterns or intervals between incontinence episodes and facilitate planning care to avoid or reduce the frequency of episodes.

Programs that require the resident's cooperation and motivation in order for learning and practice to occur include the following:

- **"Bladder Rehabilitation/Bladder Retraining**" is a behavioral technique that requires the resident to resist or inhibit the sensation of urgency (the strong desire to urinate), to postpone or delay voiding, and to urinate according to a timetable rather than to the urge to void. Depending upon the resident's successful ability to control the urge to void, the intervals between voiding may be increased progressively. Bladder training generally consists of education, scheduled voiding with systematic delay of voiding, and positive reinforcement. This program is difficult to implement in cognitively impaired residents and may not be successful in frail, elderly, or dependent residents. The resident who may be appropriate for a bladder rehabilitation (retraining) program is usually fairly independent in activities of daily living, has occasional incontinence, is aware of the need to urinate (void), may wear incontinence products for episodic urine leakage, and has a goal to maintain his/her highest level of continence and decrease urine leakage. Successful bladder retraining usually takes at least several weeks. Residents who are assessed with urge or mixed incontinence and are cognitively intact may be candidates for bladder retraining. *This is not to be confused with habit training/scheduled voiding (see below)*; and
- **"Pelvic Floor Muscle Rehabilitation**," also called Kegel and pelvic floor muscle exercise, is performed to strengthen the voluntary periuretheral and perivaginal muscles that contribute to the closing force of the urethra and the support of the pelvic organs. These exercises are helpful in dealing with urge and stress incontinence. Pelvic floor muscle exercises (PFME) strengthen the muscular components of urethral supports and are the cornerstone of noninvasive treatment of stress urinary incontinence. PFME requires residents who are able and willing to participate and the implementation of careful instructions and monitoring provided by the facility. Poor resident adherence to the exercises may occur even with close monitoring.

Programs that are dependent on staff involvement and assistance, as opposed to resident function, include the following:

- **"Prompted Voiding**" is a behavioral technique appropriate for use with dependent or more cognitively impaired residents. Prompted voiding has three components: regular monitoring with encouragement to report continence status; prompting to toilet on a scheduled basis; and praise and positive feedback when the resident is continent and attempts to toilet. These methods require training, motivation and continued effort by the resident and caregivers to ensure continued success. Prompted voiding focuses on

teaching the resident, who is incontinent, to recognize bladder fullness or the need to void, to ask for help, or to respond when prompted to toilet.

Residents who are assessed with urge or mixed incontinence and are cognitively impaired may be candidates for prompted voiding. As the resident's cognition changes, the facility should consider other factors, such as mobility, when deciding to conduct a voiding trial to determine feasibility of an ongoing program *to use the bathroom*; and

- **"Habit Training/Scheduled Voiding**" is a behavioral technique that calls for scheduled *use of the bathroom* at regular intervals on a planned basis to match the resident's voiding habits. Unlike bladder retraining, there is no systematic effort to encourage the resident to delay voiding and resist urges. *This is not considered to be a bladder rehabilitation/retraining program.* Habit training includes timed voiding with the interval based on the resident's usual voiding schedule or pattern. Scheduled voiding is timed voiding, usually every three to four hours while awake. Residents who cannot self-toilet may be candidates for habit training or scheduled voiding programs.

Intermittent Catheterization
Sterile insertion and removal of a catheter through the urethra every 3-6 hours for bladder drainage may be appropriate for the management of acute or chronic urinary retention. See additional discussion below in "Catheterization".

Medication Therapy
Medications are often used to treat specific types of incontinence, including stress incontinence and those categories associated with an overactive bladder, which may involve symptoms including urge incontinence, urinary urgency, frequency and nocturia. The current literature identifies classifications and names of medications used for various types of incontinence. When using medications, potentially problematic anticholinergic and other side effects must be recognized. The use of medication therapy to treat urinary incontinence may not be appropriate for some residents because of potential adverse interactions with their other medications or other co-morbid conditions. The resident/representative must be provided with the risks and benefits of using medications for continence management.

Pessary
A pessary is an intra-vaginal device used to treat pelvic muscle relaxation or prolapse of pelvic organs. Women whose urine retention or urinary incontinence is exacerbated by bladder or uterine prolapse may benefit from placement of a pessary. Female residents may be admitted to the nursing home with a pessary device. The assessment should note whether the resident has a pessary in place or has had a history of successful pessary use. If a pessary is used, the plan of care must address the use, care and ongoing management of the pessary including monitoring for complications.

Absorbent Products, Devices, and External Collection Devices
Absorbent incontinence products include perineal pads or panty liners for slight leakage, undergarments and protective underwear for moderate to heavy leakage, guards and drip collection pouches for men, and products (called adult briefs) for moderate or heavy loss.

Effective November 28, 2017

Absorbent products can be a useful, rational way to manage incontinence; however, every absorbent product has a saturation point. Factors contributing to the selection of the type of product to be used should include the severity of incontinence, gender, fit, and ease of use.

Advantages of using absorbent products to manage urinary incontinence include the ability to contain urine (some may wick the urine away from the skin), provide protection for clothing, and preserve the resident's dignity and comfort.

NOTE: Although many residents have used absorbent products prior to admission to the nursing home and the use of absorbent products may be appropriate, absorbent products should not be used as the primary long term approach to continence management until the resident has been appropriately evaluated and other alternative approaches have been considered.

It is important that residents using various devices, absorbent products, external collection devices, etc., be checked (and changed as needed) on a schedule based upon the resident's voiding pattern, professional standards of practice, and the manufacturer's recommendations.

Skin-Related Complications

Skin problems associated with incontinence and moisture can range from irritation to increased risk of skin breakdown. Moisture may make the skin more susceptible to damage from friction and shear during repositioning. *For a resident with an external catheter, compromise to the skin may also occur.*

One form of early skin breakdown is maceration or the softening of tissue by soaking. Macerated skin has a white appearance and a very soft, sometimes "soggy" texture. The persistent exposure of perineal skin to urine and/or feces can irritate the epidermis and can cause severe dermatitis, skin erosion *and/or ulcerations.* Skin erosion is the loss of some or all of the epidermis (comparable to a deep chemical peel) leaving a slightly depressed area of skin.

Because frequent washing with soap and water can dry the skin, the use of a perineal rinse may be indicated.

CATHETERIZATION

§483.25(e)(2)(i), Incontinence, requires that a resident who enters the facility without an indwelling catheter is not catheterized unless the resident's clinical condition demonstrates that catheterization was necessary; *or that a resident who enters the facility with an indwelling urinary catheter, or subsequently receives one is assessed for removal of the catheter as soon as possible unless the resident's clinical condition demonstrates that catheterization is necessary.* The facility is responsible for the assessment of the resident at risk for urinary catheterization and/or the ongoing assessment for the resident who currently has a catheter, *including the removal of the catheter when the resident's clinical condition demonstrates the catheter is no longer necessary. While the use of a catheter may promote skin integrity and assessment of output, it is also associated with the increase risk of catheter associated urinary tract infections (CAUTI), including the development of sepsis.*

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A catheter that is used for appropriate indications and in a dignified manner may enhance an individual's independence and dignity. Conversely, an improperly or indiscreetly used catheter may negatively impact independence and dignity.

***NOTE**: Also, for concerns related to the care for a resident with a urostomy or nephrostomy, refer to §483.25(f) - Colostomy, urostomy, or ileostomy care at tag F691.*

In addition, according to the Centers for Disease Control and Prevention (CDC), the definition of a suprapubic catheter is one that "is surgically inserted into the bladder through an incision above the pubis. For care of a resident with a suprapubic catheter, refer to current professional guidelines such as the following;
http://c.ymcdn.com/sites/www.wocn.org/resource/resmgr/publications/Care_&_Mgmt_Pts_w_Urinary_Ca.pdf

Assessment
Regardless of the admission status, a comprehensive assessment should address those factors that predispose the resident to the development of urinary incontinence and the use of an indwelling urinary catheter. An admission evaluation of the resident's medical history and a physical examination helps identify the resident at risk for requiring the use of an indwelling urinary catheter. This evaluation is to include detection of reversible causes of incontinence and identification of individuals with incontinence caused by conditions that may not be reversible, such as bladder tumors and spinal cord diseases.

The assessment of continence/incontinence is based upon a comprehensive, interdisciplinary review and assessment. The comprehensive assessment should include *identifying the* underlying factors *which support the clinical indication* for the initiation and continuing need for catheter use, determination of which factors can be modified or reversed (or rationale for why those factors should not be modified), and the development of a plan for removal. The clinician's decision to use an indwelling catheter in the elderly should be based on valid clinical indicators.

For the resident with an indwelling catheter, the facility's documented assessment and staff knowledge of the resident should include information to support the use of an indwelling catheter. Because of the risk of substantial complications with the use of indwelling urinary catheters, they should be reserved primarily for short-term decompression of acute urinary retention. The assessment should include consideration of the risks and benefits of an indwelling (suprapubic or urethral) catheter; the potential for removal of the catheter; and consideration of complications resulting from the use of an indwelling catheter, such as symptoms of blockage of the catheter with associated bypassing of urine, expulsion of the catheter, pain, discomfort and bleeding.

Intermittent Catheterization
Intermittent catheterization can often manage overflow incontinence effectively. Residents who have new onset incontinence from a transient, hypotonic/atonic bladder (usually seen following indwelling catheterization in the hospital) may benefit from intermittent bladder catheterization

until the bladder tone returns (e.g., up to approximately 7 days). A voiding trial and post void residual can help identify when bladder tone has returned.

Indwelling *Urinary* Catheter Use

If the facility provides care for a resident with an indwelling catheter, in collaboration with the medical director and director of nurses, and based upon current professional standards of practice, resident care policies and procedures must be developed and implemented that address catheter care and services, including but not limited to:

- *Documentation of the involvement of the resident/representative in the discussion of the risks and benefits of the use of a catheter, removal of the catheter when criteria or indication for use is no longer present, and the right to decline the use of the catheter;*
- *Timely and appropriate assessments related to the indication for use of an indwelling catheter;*
- *Identification and documentation of clinical indications for the use of a catheter; as well as criteria for the discontinuance of the catheter when the indication for use is no longer present;*
- *Insertion, ongoing care and catheter removal protocols that adhere to professional standards of practice and infection prevention and control procedures;*
- *Response of the resident during the use of the catheter; and*
- *Ongoing monitoring for changes in condition related to potential CAUTI's, recognizing, reporting and addressing such changes.*

(See NOTE below for examples of clinical indications for use.)

The resident's record must include how and when the resident/representative was involved and informed of care and treatment including the potential use and indications for the need for a catheter, how long use is anticipated, and when and why a catheter must be removed. The resident/representative must be included in the development of the care plan including the use of the catheter and associated interventions. In addition, the resident/representative has the right to decline the treatment. Based on current professional standards of practice, information and education of the resident/representative on the identification of risks and benefits for the use of a catheter must be documented.

Anecdotally, it has been reported that residents or their representatives have requested the use of and/or declined to allow the removal of an indwelling urinary catheter. The record must contain documentation as to why a resident/representative chooses to have or chooses to continue to use a catheter in the absence of clinical indications for use. After determining the reasons, staff and the attending practitioner must document the provision of counseling to assist the resident in understanding the clinical implications and risks associated with the use of a catheter without an indication for continued use. The care plan must be revised to address the education being provided, including interventions to restore as much urinary function as possible without the use of catheter.

Documentation in the resident's record must reflect the attending practitioner's valid clinical indication to support the use of an indwelling catheter.

***NOTE**: The following Table from the CDC, includes examples for appropriate indications for indwelling catheter use and includes both acute and long term care. This table has been adapted to include only those examples relevant for a long term care setting. For the full table and for guidance related to indwelling catheter management and care refer to: http://www.cdc.gov/hicpac/cauti/02_cauti2009_abbrev.html*

Table 2.
A. Examples of Appropriate Indications for Indwelling Urethral Catheter Use

- *Resident has acute urinary retention or bladder outlet obstruction;*
- *Need for accurate measurements of urinary output;*
- *To assist in healing of open sacral or perineal wounds in incontinent residents;*
- *Resident requires prolonged immobilization (e.g., potentially unstable thoracic or lumbar spine, multiple traumatic injuries such as pelvic fractures);and*
- *To improve comfort for end of life care, if needed.*

B. Examples of Inappropriate Uses of Indwelling Catheters

- *As a substitute for nursing care of the resident with incontinence; and*
- *As a means of obtaining urine for culture or other diagnostic tests when the resident can voluntarily void.*

***NOTE**: These indications are based on expert consensus.*

Additional care practices related to catheterization include:

- Recognizing and assessing for complications and their causes, and maintaining a record of any catheter-related problems;
- Attempts to remove the catheter as soon as possible when no indications exist for its continuing use;
- Monitoring for excessive post void residual, after removing a catheter that was inserted for obstruction or overflow incontinence;
- Keeping the catheter anchored to prevent excessive tension on the catheter, which can lead to urethral tears or dislodging the catheter; and
- Securing the catheter to facilitate flow of urine, *preventing kinking of the tubing and position below the level of the bladder. (Also refer to F880 – Infection Control for policies and procedures related to care of the catheter and equipment, such as tubing, bags, etc.)*.

***NOTE**: Refer to the CDC site for current information on catheter use, management and care at: http://www.cdc.gov/HAI/ca_uti/uti.html*

Catheter-Related Complications
An indwelling catheter may be associated with significant complications, including bacteremia, febrile episodes, bladder stones, fistula formation, erosion of the urethra, epididymitis, chronic renal inflammation and pyelonephritis *and sepsis related to urinary tract infections*. In addition, indwelling catheters are prone to blockage. Risk factors for catheter blockage include alkaline urine, poor urine flow, proteinuria, and preexisting bladder stones.

Some residents with indwelling catheters experience persistent leakage around the catheter. Examples of factors that may contribute to leakage include irritation by a large balloon or by catheter materials, excessive catheter diameter, fecal impaction, and improper catheter positioning. *Changing indwelling catheters or drainage bags at routine, fixed intervals is not recommended.*
(Refer to: https://www.cdc.gov/hicpac/pdf/CAUTI/CAUTIguideline2009final.pdf)

Catheterization is an important, potentially modifiable, risk factor for UTI. The potential for complications can be reduced by:

- Identifying specific clinical indications for the use of an indwelling catheter;
- Assessing whether other treatments and services would appropriately address those conditions; and
- Assessing whether residents are at risk for other possible complications resulting from the continuing use of the catheter, such as obstruction resulting from catheter encrustation, urethral erosion, bladder spasms, hematuria, and leakage around the catheter.

URINARY TRACT INFECTIONS
Catheter-Related Bacteriuria and UTIs
Bacteriuria *(e.g., pyuria)* alone in a catheterized individual should not be treated with antibiotics. In someone with nonspecific symptoms such as a change in function or mental status, *foul smelling or cloudy urine and/or,* bacteriuria *(e.g. pyuria),* does not necessarily warrant antibiotic treatment. *The decision to treat a UTI is based upon the attending practitioner conducting a thorough evaluation and assessment of the resident and providing documentation of a rationale for the indication of use of an antibiotic.*

NOTE: *For a non-catheterized resident with symptoms associated with a UTI, the attending practitioner should order a urine culture prior to the initiation of antibiotic therapy to help guide treatment. According to current standard of practice, an accurate urine culture for a non-catheterized resident should be obtained by a clean catch or mid-stream specimen for residents who are able to follow instructions. For those unable to provide a clean-catch, a specimen may be obtained preferably by a freshly placed condom catheter for males, or in and out catheterization for females or males unable to provide a specimen by a condom catheter. If the resident has a long-term indwelling urethral catheter, a specimen should be obtained from a freshly placed indwelling catheter. Reference - the IDSA Guidelines for Evaluation of Fever and Infection in Older Adult Residents of Long-Term Care Facilities. (High et al. Clinical Infectious Diseases, 2009:48-149-71).*

The surveyor should determine if facility policy for obtaining urine for cultures is based upon current standards of practice, understanding that these standards may be revised and updated over time. The facility should be able to provide the most current standard that supports the policy that they have developed and implemented. Also refer to F880 Infection Control and F881 for antibiotic stewardship program for infection assessment tools.)

Unnecessary treatment of a UTI with antibiotics may lead to the development of multi drug resistant organisms (e.g., Methicillin-Resistant Staphylococcus Aureus) and other complications

such as the development of clostridium-difficile infection, which may predispose the person to prolonged treatment potential hospitalization and may pose a threat of infection to other residents. (Also refer to F881 for antibiotic stewardship program for infection assessment tools.)

***NOTE**: Standards of practice may be revised and updated over time.*

One current professional standard of practice that addresses critieria for use of antibiotics for UTI's, includes:

"Minimum criteria for initiating antibiotics for an indication of urinary tract infection were considered for residents with no indwelling urinary catheters and for residents with chronic indwelling catheters.

1. *For residents who do not have an indwelling catheter, minimum criteria for initiating antibiotics include: >105 CFU/mL (positive)or pending urine culture and dysuria alone or two or more of the following: fever (>37.9ºC [100ºF] or 1.5ºC [2.4ºF] increase above baseline temperature on two occasions over last 12 hours), new or worsening urgency, frequency, suprapubic pain, gross hematuria, costovertebral angle tenderness (flank pain), urinary incontinence, or shaking chills.*
2. *For residents who have an indwelling catheter or a suprapubic catheter), minimum criteria for initiating antibiotics include the presence of: >105 CFU/mL (positive)or pending urine culture and one or more of the following: fever (>37.9ºC [100ºF] or 1.5ºC [2.4ºF] increase above baseline temperature on two occasions over last 12 hours), new costovertebral tenderness, rigors (shaking chills), or new onset of delirium."*

***NOTE**: Reference - Loeb M, Brazil K, Lohfeld L, et al. Effect of a multifaceted intervention on number of antimicrobial prescriptions for suspected urinary tract infections in residents of nursing homes: cluster randomised controlled trial. BMJ. 2005;331:669. [PMC free article] [PubMed]*

Follow-Up of UTIs

The goal of treating a UTI is to alleviate systemic or local symptoms, not to eradicate all bacteria. Therefore, a post-treatment urine culture is not necessary but may be useful *if UTI signs and symptoms continue or do not respond to antibiotic treatment*. Continued bacteriuria without residual symptoms does not warrant repeat or continued antibiotic therapy. Recurrent UTIs (2 or more in 6 months) in a noncatheterized individual may warrant additional evaluation (such as a determination of an abnormal post void residual (PVR) urine volume or a referral to a urologist) to rule out structural abnormalities such as enlarged prostate, prolapsed bladder, periurethral abscess, strictures, bladder calculi, polyps and tumors.

Recurrent UTIs in a catheterized individual should lead the facility to look for possible impairment of free urine flow through the catheter, to re-evaluate the techniques being used for catheter care and for perineal hygiene including the removal of fecal soiling, and to reconsider the relative risks and benefits of continuing the use of an indwelling catheter.

Effective November 28, 2017

Because the major factors (other than an indwelling catheter) that predispose individuals to bacteriuria, including physiological aging changes and chronic comorbid illnesses, cannot be modified readily, the facility should demonstrate that they:

- Employ infection *prevention and* control practices *(e.g. Standard Precautions)* in managing catheters and associated drainage system;
- Keep the resident and catheter clean of feces to minimize bacterial migration into the urethra and bladder (e.g., cleaning fecal material away from, rather than towards, the urinary meatus)*, however, routine perineal care with an antiseptic is not recommended*;
- Maintain free urine flow through any indwelling catheter; and
- Assess for fluid needs and implement a fluid management program (using alternative approaches as needed) based on those assessed needs.

FECAL INCONTINENCE

Fecal incontinence (FI) involves the unintentional loss of solid or liquid stool. A resident experiencing FI may experience feelings of shame, embarrassment, loss of independence, may tend to isolate himself/herself creating a decrease in social interactions/activities due to fear of "accidents" with associated odors, leakage and soiling of clothing or furnishings. It is important for the facility and the attending practitioner to complete a comprehensive assessment and determine, with the resident/representative, potential treatment and care plan interventions, and to provide ongoing evaluation of the response to those interventions. The resident should be re-evaluated whenever there is a change in bowel function. If the resident has FI that has already been investigated, documented, and determined to be irreversible or not significantly improvable, additional studies may be of limited value, unless there has been advancement in available treatments.

Risk factors for Fecal Incontinence

Risk factors for FI may include, aging and dependency in daily activities, smoking and pulmonary disease, arthritis in adults over 75 years of age, older adults with rectal cancer, comorbidities such as kidney disease, transient ischemic attacks in men, women with arterial hypertension, acute stroke (FI may depend on the severity of a stroke), functional dependency and need for assistance with toilet access 3 months after stroke in men and women, and poor general health and dementia.http://archive.ahrq.gov/downloads/pub/evidence/pdf/fuiad/fuiad.pdf

Assessment:

To ensure that a resident who is incontinent of bowel receives appropriate treatment and services, the facility must conduct an assessment to identify the presenting symptoms and type of FI, including the potential reversible/irreversible causes and risks. Symptoms or types of FI may include (as noted in http://s3.gi.org/physicians/guidelines/FecalIncontinence.pdf):

- *"**Passive incontinence**—which is the involuntary discharge of fecal matter or flatus without any awareness. This suggests a loss of perception and/or impaired rectoanal reflexes either with or without sphincter dysfunction;*
- ***Urge incontinence** — which is the discharge of fecal matter or flatus in spite of active attempts to retain these contents. Here, there is a predominant disruption of the sphincter function or the rectal capacity to retain stool; and/or*
- ***Fecal seepage** — which is the undesired leakage of stool, often after a bowel movement with otherwise normal continence and evacuation. This condition is mostly due to*

incomplete evacuation of stool and/or impaired rectal sensation. The sphincter function and pudendal nerve function are mostly intact".

Causes and Treatment of Fecal Incontinence

For reference, the following potential causes and treatments of FI have been adapted from the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) to address the long term care setting. For the full description of causes and treatment for FI, refer to: http://www.niddk.nih.gov/health-information/health-topics/digestive-diseases/fecal-incontinence/Pages/facts.aspx

Potential causes for FI may include:

- *Diarrhea*
- *Constipation Muscle Damage or Weakness*
- *Trauma, childbirth injuries, cancer surgery, and hemorrhoid surgery*
- *Nerve Damage*
- *Loss of Stretch in the Rectum*
- *Childbirth by Vaginal Delivery*
- *Hemorrhoids and Rectal Prolapse*
- *Rectocele*
- *Inactivity*

Potential treatment/interventions for FI should be based upon the type of FI. Potential treatment options and interventions may include:

- *Eating increased amounts of fiber.*
- *Drinking sufficient liquids.*
- *Use of medications to develop more solid stools that are easier to control.*
- *Pelvic Floor Exercises and Biofeedback that strengthen the pelvic floor muscles may improve bowel control.. Success with pelvic floor exercises depends on the cause of fecal incontinence, its severity, and the person's motivation and ability to follow the health care provider's recommendations.*
- *Surgery may be an option for fecal incontinence that fails to improve with other treatments or for fecal incontinence caused by pelvic floor or anal sphincter muscle injuries.*
- *Electrical Stimulation also called sacral nerve stimulation or neuromodulation, involves placing electrodes in the sacral nerves to the anus and rectum and continuously stimulating the nerves with electrical pulses.*

Care Plan

For the resident with fecal incontinence, the care plan must reflect the results of the resident's assessment and include resident specific interventions for any potential reversible causes and, if irreversible, appropriate interventions for management of fecal incontinence. Interventions and the provision of care should address treating the resident with respect, enhancing dignity and self-worth and reducing embarrassment and shame in relation to FI. Based upon the increased risk for transmission of infection resulting from fecal contamination, the care plan should also identify the PPE appropriate for use during the delivery of care.

Complications Potentially Related to Fecal Incontinence
Complications related to fecal incontinence may include, but are not limited to, emotional distress, loss of self-esteem, social isolation, physical complications such as skin irritation/excoriation, itching, pain, and in addition, frequent loose stool may be an indicator of fecal impaction.

KEY ELEMENTS OF NONCOMPLIANCE
To cite deficient practice at F690, the surveyor's investigation will generally show that the facility failed to do one or more of the following:

- *Provide appropriate and sufficient services and assistance to:*
  - *Maintain bladder continence and/or bowel function in continent residents; or*
  - *Restore bladder continence and/or bowel function as possible, based on a comprehensive assessment and clinical condition; or*
  - *Prevent urinary tract infections to the extent possible;*
- *Ensure that a resident is not catheterized unless required by his/her clinical condition; or*
- *Ensure that a urinary catheter is removed as soon as possible unless the catheter is necessary because of the residents' clinical condition.*

INVESTIGATIVE PROTOCOL
Use
Use the Bladder and Bowel Incontinence Critical Element (CE) Pathway, and/or Urinary Catheter and UTI CE Pathway, for the condition being evaluated, along with the above interpretive guidelines when determining if the facility provides the necessary care and services to meet the resident's needs.

Summary of Procedure
Briefly review the most recent comprehensive assessments, comprehensive care plan and orders to identify whether the facility has assessed and developed an individualized care plan based on professional standards of practice and provided by qualified, competent staff. During this review, identify the extent to which the facility has implemented interventions in accordance with the resident's needs, goals for care and professional standards of practice, consistently across all shifts. This information will guide observations and interviews to be made in order to corroborate concerns identified.

***NOTE**: Always observe for visual cues of psychosocial distress and harm (see Appendix P, Guidance on Severity and Scope Levels and Psychosocial Outcome Severity Guide).*

DEFICIENCY CATEGORIZATION
In addition to actual or potential physical harm, always consider whether psychosocial harm has occurred when determining severity level (See Appendix P, Section IV, E, Psychosocial Outcome Severity Guide).

Examples of Severity Level 4 Noncompliance Immediate Jeopardy to Resident Health or Safety include but are not limited to:

- *The facility failed to ensure that a resident who entered the facility with an indwelling catheter was assessed for removal of the catheter as soon as possible, resulting in the*

resident continuing to have the catheter in place for three weeks and developing a urinary tract infection, leading to sepsis. The facility failed to provide appropriate treatment and services for a resident with fecal incontinence, resulting in the resident having severely excoriated and ulcerated areas of skin around the rectal area, with odor, and purulent exudate. The resident expressed severe pain and refused to leave her room.

Examples of Severity Level 3 Noncompliance Actual Harm that is not Immediate Jeopardy includes but is not limited to:

- *The facility failed to assure that a resident who entered the facility with an indwelling catheter was assessed for removal of the catheter as soon as possible, unless the resident's clinical condition demonstrates that catheterization is necessary. During the survey, a resident was identified as having an indwelling urinary catheter in place for several months. The resident was currently being treated with an antibiotic for a symptomatic urinary tract infection. Staff interviewed were unable to provide the clinical indication for use for the catheter, and the record did not contain documentation for the initial use of the catheter or for the continued use of a urinary catheter. The resident was unable to be interviewed, but his representative was interviewed but did not know why the catheter was in place, except that the resident had a problem with incontinence. Record review indicated that the resident had experienced repeated complications such as recurrent symptomatic UTIs which required treatment with antibiotics.*
- *The facility failed to assure that a resident who was incontinent of bladder received the appropriate treatment and services to restore continence to the extent possible. A resident was identified as incontinent of bladder. Based upon the resident's assessment and identification of the type of urinary incontinence, the facility developed interventions for a restorative program to restore continence. However, based on observations, staff were not implementing the interventions on the care plan, did not respond to the resident's request for assistance with use of the bathroom, and were not monitoring the progress of the interventions. The resident stated that she was frustrated and embarrassed regarding the odors and wetness that occurred as a result of the incontinence episodes. She also stated that she did not attend activities or go for meals as she needed close access to the toilet, and that she didn't want to be around others when she had incontinent episodes. She stated that she felt that she was not improving with her bladder continence, and that it was worse now than when she started the restorative program. Staff interviewed stated that they were aware of the program, but they were not able to implement the program, consistently on all shifts, as they had other resident's and duties assigned during their shifts and were unable to respond. The record reflected a decline in continence since the program began. (Also cited at sufficient staffing at F726)*

Examples of Severity Level 2 Considerations: No Actual Harm with Potential for More Than Minimal Harm that is Not Immediate Jeopardy include but are not limited to:

- *The facility failed to provide appropriate treatment and services for care of a resident with a clinically-justified indwelling catheter. During observations of care for a resident with an indwelling catheter, urine was noted to be leaking. Staff interviewed stated that they were not sure why the catheter leaked, but that they kept the resident as dry as*

possible. In addition, it was observed several times throughout the survey, that the catheter drainage bag and tubing were placed directly on the floor in the resident's room. There were no indications of skin maceration and/or irritation, or symptoms of a UTI symptoms.

- *The facility failed to provide appropriate treatment and services for care of a resident who had intermittent fecal incontinence. During the survey, a resident was observed to stay in her room, did not attend activities and had meals served in her room. The resident was identified as alert and aware of her care needs. She stated that she had problems with intermittent fecal incontinence and was on a bowel management program that included extra fiber and liquids. She stated that recently there were changes in meal service and she was not receiving the extra fiber. She also stated that staff were to assist her with hygiene when incontinence episodes occurred, but they had not consistently provided the care. She stated that when she had the fecal incontinence episodes, she did not attend activities she enjoyed attending, and was irritated that she was unable to attend due to not receiving hygiene when needed.*

Severity Level 1: No actual harm with potential for minimal harm
The failures of the facility to provide appropriate care and services to maintain or improve continence, manage indwelling catheters, and minimize negative outcome places residents at risk for more than minimal harm. Therefore, Severity Level 1 does not apply for this regulatory requirement.

F691
§483.25*(f)* Colostomy, *u*rostomy, or *i*leostomy care.
The facility must ensure that residents who require colostomy, urostomy, or ileostomy services, receive such care consistent with professional standards of practice, the comprehensive person-centered care plan, and the resident's goals and preferences.

INTENT *§483.25(f)*
The intent of this provision is that the resident receives the necessary care and treatment including medical and nursing care and services when they need *colostomy, urostomy, or ileostomy care*.

PROCEDURES AND PROBES *§483.25(f)*
Refer to appropriate sections of the MDS, as applicable.
Identify if *the* resident triggers any *Care Area Assessments* for urinary incontinence, nutritional status, *and/or* pressure injuries (skin care).

- If appropriate, is the resident provided with self-care instructions?
- Does the staff member observe and respond to any signs of the resident's discomfort about the ostomy or its care?
- Is skin surrounding the ostomy free of excoriation (abrasion, breakdown)?
- If excoriation is present, does the clinical record indicate an onset and a plan to treat the excoriation?

Effective November 28, 2017

F692
§483.25(g) ***Assisted nutrition and hydration.***
(Includes naso-gastric and gastrostomy tubes, both percutaneous endoscopic gastrostomy and percutaneous endoscopic jejunostomy, and enteral fluids). **Based on** ***a resident's*** **comprehensive assessment, the facility must ensure that a resident—**

§483.25(g)(1) Maintains acceptable parameters of nutritional status, such as ***usual*** **body weight** ***or desirable body weight range*** **and** ***electrolyte balance*****, unless the resident's clinical condition demonstrates that this is not possible** ***or resident preferences indicate otherwise*****;**

§483.25(g)*(2) Is offered* **sufficient fluid intake to maintain proper hydration and health;**

§483.25(g)(3) ***Is offered*** **a therapeutic diet when there is a nutritional problem** ***and the health care provider orders a therapeutic diet.***

INTENT ***§483.25(g)***
The intent of this requirement is that the resident maintains, to the extent possible, acceptable parameters of nutritional *and hydration* status and that the facility:

- Provides nutritional *and hydration* care and services to each resident, consistent with the resident's comprehensive assessment;
- Recognizes, evaluates, and addresses the needs of every resident, including but not limited to, the resident at risk or already experiencing impaired nutrition *and hydration*; and
- Provides a therapeutic diet that takes into account the resident's clinical condition, and preferences, when there is a nutritional indication.

DEFINITIONS §483.25*(g)*
Definitions are provided to clarify clinical terms related to nutritional status.

"Acceptable parameters of nutritional status" refers to factors that reflect that an individual's nutritional status is adequate, relative to his/her overall condition and prognosis, *such as weight, food/fluid intake, and pertinent laboratory values.*

"Artificial nutrition ***and hydration"*** *are medical treatments and* refer to nutrition that is provided through routes other than the usual oral route, typically by placing a tube directly into the stomach, the intestine or a vein.

"Clinically significant" refers to effects, results, or consequences that materially affect or are likely to affect an individual's physical, mental, or psychosocial well-being either positively by preventing, stabilizing, or improving a condition or reducing a risk, or negatively by exacerbating, causing, or contributing to a symptom, illness, or decline in status.

"Dietary supplements" refers to herbal and alternative products that are not regulated by the Food and Drug Administration and their composition is not standardized. Dietary supplements must be labeled as such and must not be represented for use as a conventional food or as the sole item of a meal or the diet.

Effective November 28, 2017

"Health Care Provider" *includes a physician, physician assistant, nurse practitioner, or clinical nurse specialist, or a qualified dietitian or other qualified nutrition professional acting within their state scope of practice and to whom the attending physician has delegated the task. For issues related to delegation to dietitians, refer to* §483.*60*(e)(2), F808.

"Nutritional status" *includes both nutrition and hydration status.*

"Nutritional Supplements" refers to products that are used to complement a resident's dietary needs (e.g., calorie or nutrient dense drinks, total parenteral products, enteral products, and meal replacement products).

"Therapeutic diet" refers to a diet ordered by a *physician or other delegated provider that is* part of the treatment for a disease or clinical condition, to eliminate, decrease, or increase certain substances in the diet (e.g., sodium or potassium), or to provide mechanically altered food when indicated.

"Tube feeding" *refers to the delivery of nutrients through a feeding tube directly into the stomach, duodenum, or jejunum. It is also referred to as an enteral feeding.*

GUIDANCE §483.25(g)

It is important to maintain adequate nutritional status, to the extent possible, to ensure each resident is able to maintain the highest practicable level of well-being. The early identification of residents with, or at risk for, impaired nutrition *or hydration status* may allow the interdisciplinary team to develop and implement interventions to stabilize or improve nutritional status before complications arise. *Body weight and laboratory results can often be stabilized or improved with time, but may not be correctable in some individuals. Intake alone is not the only factor that can affect nutritional status. Resident conditions and co-morbidities may prevent improved nutritional or hydration status, despite improved intake.*

Many factors can influence weight and nutritional status as one ages. The body may not absorb or use nutrients as effectively, there may be changes in the ability to taste food[2]*, or there may be a decreased sensation for thirst or hunger. The resident's medical condition can also affect how well they maintain weight, such as changes in muscle mass*[3]*, cognitive status*[4]*, nearing end of life, or a disease process, such as kidney disease or congestive heart failure, which may cause the resident to retain fluids in the body. While impaired nutritional status is not necessarily expected as one ages, there could be times where efforts to maintain good nutrition may pose extra challenges.*

Failure to identify residents at risk for compromised nutrition and hydration may be associated with an increased risk of mortality and other negative outcomes, such as impairment of anticipated wound healing, decline in function, fluid and electrolyte imbalance/dehydration, and unplanned weight change.[5]*. While food intake may be considered, ensuring a resident receives the fluids they require can more easily be overlooked. Individuals who do not receive adequate fluids are more susceptible to urinary tract infections, pneumonia, pressure injuries, skin infections, confusion, and disorientation.*

A systematic approach can help staff's efforts to optimize a resident's nutritional status. This process includes identifying and assessing each resident's nutritional status and risk factors, evaluating/analyzing the assessment information, developing and consistently implementing pertinent approaches, and monitoring the effectiveness of interventions and revising them as necessary. *Weight loss, poor nutritional status, or dehydration should be considered avoidable unless the facility can prove it has assessed/reassessed the resident's needs, consistently implemented related care planned interventions, monitored for effectiveness, and ensured coordination of care among the interdisciplinary team.*

ASSESSMENT

*A comprehensive nutritional assessment should be completed on any resident identified as being at risk for unplanned weight loss/gain and/or compromised nutritional status. Through a comprehensive nutritional assessment, t*he interdisciplinary team clarifies nutritional issues, needs, and goals in the context of the resident's overall condition. Completion of the RAI does not remove the facility's responsibility to document a more detailed resident assessment, *when indicated*, *to identify possible effective interventions.* The nutritional assessment may utilize existing information from sources, such as the RAI, assessments from other disciplines, *the existing medical record,* observation, *direct care staff interviews,* and resident and family interviews. *The assessment should identify those factors that place the resident at risk for inadequate nutrition/hydration.* The nutritional assessment may include the following information:

General Appearance: General appearance includes a description of the resident's overall appearance (e.g., robust, thin, obese, or cachectic). *Other findings that may affect or reflect a resident's nutritional status may be included, such as the resident's cognitive status*, affect, oral health and dentition, ability to use the hands and arms, and the condition of hair, nails, and skin.

Height: Measuring a resident's height provides information that is relevant (in conjunction with his or her weight) to his/her nutritional status. There are various ways to estimate height if standing height cannot be readily measured.[6] A protocol for determining height helps to ensure that it will be measured as consistently as possible.

Weight: Weight can be a useful indicator of nutritional status, when evaluated within the context of the individual's personal history and overall condition. *Weight goals should be based on a resident's usual body weight or desired body weight. The facility should have a procedure in place that includes, but is not limited to, establishing a consistent method of weighing a resident (e.g. using the same scale, wearing the same clothes, weighing at the same time of day, adjusting for use of a prosthetic, etc.), verifying the resident's weight upon admission, monitoring a resident's weight over time to identify weight loss/gain, verifying weight measurements when changes in weight occur, and reassessing interventions when appropriate.*

Current professional standards of practice recommend weighing the resident on admission or readmission (to establish a baseline weight), weekly for the first 4 weeks after admission and at least monthly thereafter to help identify and document trends such as *slow and progressive* weight loss. Weighing may also be pertinent if there is a significant change in condition, food

intake has declined and persisted (e.g., for more than a week), or there is other evidence of altered nutritional status or fluid and electrolyte imbalance. In some cases, weight monitoring is not indicated (e.g., the individual is terminally ill and requests only comfort care).

Examples of other factors that may impact weight and the significance of apparent weight changes include the resident's usual weight through adult life, current medical conditions, *diet and supplement orders*, recent changes in dietary intake, and edema.

Suggested parameters for evaluating significance of unplanned and undesired weight loss are:

Interval	Significant Loss	Severe Loss
1 month	5%	Greater than 5%
3 months	7.5%	Greater than 7.5%
6 months	10%	Greater than 10%

The following formula determines percentage of weight loss:
% of body weight loss = (usual weight - actual weight) / (usual weight) x 100

Interviews with key staff members: The facility *may identify* key individuals who should participate in the assessment of nutritional status and related causes and consequences. For example, nursing staff provide details about the resident's nutritional intake. *Physicians and non-physician practitioners* help *identify relevant diagnoses,* identify causes of *weight changes*, tailor interventions to the resident's specific causes and situation, and monitor the continued relevance of those interventions. Qualified dietitians help identify nutritional risk factors and recommend nutritional interventions, based on each resident's medical condition, needs, *preferences*, and goals. Consultant pharmacists can help the staff and practitioners identify medications *and medication interactions* that *may* affect nutrition.

Food and fluid intake: The nutritional assessment includes an estimate of calorie, nutrient and fluid needs, and whether intake is adequate to meet those needs. It also includes information such as the route (oral, enteral or parenteral) of intake, any special food formulation, meal and snack patterns (including the time of supplement or medication consumption in relation to the meals), dislikes, and preferences (including ethnic foods and form of foods such as finger foods); meal/snack patterns, and preferred portion sizes. *While there is no reliable calculation to determine an individual's fluid needs, an assessment should take into account those characteristics pertinent to the resident, such as age, medical diagnoses, activity level, etc.*

Fluid loss or retention: Fluid loss or retention can cause short term weight change. Much of a resident's daily fluid intake comes from meals; therefore, when a resident has decreased appetite, it can result in fluid/electrolyte imbalance. Abrupt weight changes, change in food intake, or altered level of consciousness are some of the clinical manifestations of fluid and electrolyte imbalance. Laboratory tests (e.g., electrolytes, BUN, creatinine and serum osmolality) can help greatly to identify, manage, and monitor fluid and electrolyte status.[7]

Altered Nutrient intake, absorption, and utilization: Poor intake, continuing or unabated hunger, or a change in the resident's usual intake that persists for multiple meals, may indicate an underlying *condition* or illness. Examples of causes include, *but are not limited to*:

- The inability to consume meals provided *as a result of cognitive or functional decline;*
- *Difficulty with chewing or swallowing food;*
- *An inadequate amount of food or fluid, including insufficient tube feedings;*
- *An uncomfortable or disruptive dining environment;*
- *The lack of adequate assistance or supervision;*
- Adverse consequences related to medications; and
- Diseases and conditions such as cancer, diabetes mellitus, advanced or uncontrolled heart or lung disease, infection and fever, liver disease, *kidney disease,* hyperthyroidism, mood disorders, *gastrointestinal disorders, pressure injuries or other wounds,* and repetitive movement disorders (e.g., wandering, pacing, or rocking).

The use of diuretics and other medications may cause weight loss that is not associated with nutritional issues. *This may result in a planned weight loss (e.g. the reduction of edema),* but can also cause fluid and electrolyte imbalance/dehydration that causes a loss of appetite and weight *if unmonitored*.

Early identification of these factors, regardless of the presence of any associated weight changes, can help the facility choose appropriate interventions to minimize any subsequent complications. Often, several of these factors affecting nutrition coexist.

Laboratory/Diagnostic Evaluation: Laboratory tests are sometimes useful to help identify underlying causes of impaired nutrition or when the clinical assessment alone is not enough to define someone's nutritional status. *An additional assessment of other resident risk factors is often needed to confirm if a treatable clinical problem exists*[8]. For example, *low* serum albumin *levels may indicate malnutrition, but may also be the result of an* acute illness for reasons unrelated to nutrition. Therefore, albumin *levels* may not improve, despite consumption of adequate amounts of calories and protein.

The decision to order laboratory tests *by the health care provider* and the interpretation of subsequent results, is best done in light of a resident's overall condition and prognosis.[9] Although laboratory tests such as albumin and pre-albumin may help in some cases in deciding to initiate nutritional interventions, there is no evidence that they are useful for the serial follow-up of undernourished individuals.[9]

NOTE: If laboratory tests were done prior to or after admission to the facility and the test results are abnormal, the physician or other licensed health care practitioner, in collaboration with the interdisciplinary team, reviews the information and determines whether to intervene or order additional diagnostic testing.

CARE PLANNING

Information gathered from the nutritional assessment and current dietary standards of practice are used to develop an individualized care plan to address the resident's specific nutritional concerns and preferences. The care plan *must* address, to the extent possible, identified causes of

impaired nutritional status, reflect the resident's *personal* goals and *preferences*, and identify resident-specific interventions and a time frame and parameters for monitoring. The care plan *should be* updated as needed, *such as when the resident's* condition changes, goals are met, interventions are determined to be ineffective, or as *new* causes of nutrition-related problems are identified. If nutritional goals are not achieved, *the care planned interventions must be reevaluated for effectiveness and modified as appropriate.*

Examples of goals may include, but are not limited to:

- *A target weight range.*
- *Desired fluid intake.*
- *The management of an underlying medical condition (e.g. diabetes, kidney disease, wound healing, heart failure, or infection.)*
- *The prevention of unintended weight loss or gain.*

Weight stability, rather than weight gain, may sometimes be the most pertinent short-term or long-term objective for the nutritionally at-risk or compromised resident. After an acute illness or as part of an advanced or end-stage medical condition, the resident's weight and other nutritional parameters may not return to previous levels and may stabilize at a lower level, sometimes indefinitely.

NOTE: There should be a documented clinical basis for any conclusion that nutritional status or significant weight change are unlikely to stabilize or improve (e.g., physician's documentation as to why weight loss is medically unavoidable).

The resident and/or the resident's representative's involvement in the development of the care plan helps to ensure it is individualized and meets their personal goals and preferences. See F551, Resident Representative; F553, Right to Participate in Care Planning, or §483.21, Comprehensive Resident-Centered Care Plans, for additional guidance.

When preferences are not specified *in an advanced directive*, decisions related to the possible provision of supplemental or artificial nutrition should be made in conjunction with the resident, the resident's family, and/or representative in accordance with state law, taking into account relevant considerations such as condition, prognosis, and the resident's known values and choices.

NOTE: The presence of a "Do Not Resuscitate" (DNR) order does not by itself indicate that the resident is declining other appropriate treatment and services. It only indicates that the resident has chosen not to be resuscitated if cardiopulmonary functions cease.

INTERVENTIONS

Interventions related to a resident's nutritional status must be individualized to address the specific needs of the resident. Examples of care plan development considerations can include, but are not limited to:

Diet Liberalization: *Based on the resident's assessment, it could be* beneficial to minimize restrictions, *such as therapeutic or mechanically altered diets, and provide preferred foods*

before using supplementation. *However, it is the responsibility of the facility to:*

- *Talk with the resident, their family and representative (whenever possible) and provide information pertaining to the risks and benefits of a liberalized diet;*
- *Work with the resident's physician and other nursing home professionals (dietary manager, nurses, speech therapists, etc.), using the care planning process, to determine the best plan for the resident; and*
- *Accommodate the resident's needs, preferences, and goals.*

Weight-Related Interventions: *For at risk residents, the* care plan *should include* nutritional interventions *to* address underlying risks and causes of *unplanned* weight loss or unplanned weight gain, *based on the comprehensive or any subsequent nutritional assessment. The development of these interventions should involve the resident and/or the resident representative to ensure the resident's needs, preferences and goals are accommodated.*

Environmental Factors: Appetite is often enhanced by the appealing aroma, flavor, form, and appearance of food. Resident-specific facility practices that may help improve intake include providing a pleasant dining experience (e.g., flexible dining environments, styles and schedules), providing meals that are palatable, attractive and nutritious (e.g., prepare food with seasonings, serve food at proper temperatures, etc.), and making sure that the environment where residents eat (e.g., dining room and/or resident's room) is conducive to dining.

Disease Processes: *A resident's clinical condition may have a significant impact on the types of interventions considered. The facility is responsible for identifying relevant diagnoses (e.g. wound healing, anorexia, end-of-life, etc.) and appropriate interventions to address specific needs, as applicable.*

Functional Factors: *These include resident conditions that interfere with their ability to physically perform the task of eating or drinking adequately, such as the ability to use one's hands, vision, chewing and swallowing capabilities, or the ability to reposition one's self at the table. The underlying causes should be assessed to identify which interventions may be most effective. For example, a resident may experience a decline in his or her ability to chew food. If the underlying cause is poorly fitting dentures that are causing pain or are loose in the mouth, the intervention of modifying the food texture would not address the primary cause.*

The interventions used to address functional factors will depend on the resident's specific areas of concern and can vary. Some interventions used to address functional factors include using specialized dishes and utensils, having eye glasses or hearing aids in use, ensuring dentures are securely placed, participating in a restorative eating program, or having direct assistance by staff or family. Other interventions may include ensuring food and drinks are readily accessible and in close physical proximity to individuals with mobility impairments.

Modification of food and fluid consistency may be an appropriate intervention, however it may unnecessarily decrease quality of life and impair nutritional status by affecting appetite and reducing intake.[12] Many factors influence whether a swallowing abnormality eventually results in clinically significant complications, such as aspiration pneumonia.[13] Identification of a swallowing abnormality alone does not necessarily warrant dietary restrictions or food texture

modifications. No interventions consistently prevent aspiration and no tests consistently predict who will develop aspiration pneumonia.[14] For example, tube feeding may be associated with aspiration, and is not necessarily a desirable alternative to allowing oral intake, even if some swallowing abnormalities are present.[15,16]

Medications: *Medications may be helpful in improving a resident's nutritional status. Some ways medications may help a resident can be to increase appetite, reduce acid reflux, or reduce nausea. Some medications may have the unintended effect of impairing a resident's nutritional or hydration status and the resident may experience a lack of appetite, nausea, dry mouth, or other unintended effects. Interventions may be required to address these. For example, a resident may require frequent sips of a drink during a meal if they experience dry mouth. It may also be appropriate to consider changing, stopping, or reducing the doses of those medications as appropriate*[17]. For additional guidance related to medications, refer to §483.*45(d), F757,* Unnecessary Drugs, *or §483.45(e), F758, Psychotropic Drugs.*

Food Intake: *Improving intake with* wholesome foods is generally preferable to adding nutritional supplements. However, if the resident is not able to eat recommended portions at meal times, to consume between-meal snacks/nourishments, or if he/she prefers the nutritional supplement, supplements may be tried to increase calorie and nutrient intake. Taking a nutritional supplement during medication administration may also increase caloric intake without reducing the resident's appetite at mealtime.

Examples of *other* interventions to improve food intake include:

- Fortification of foods (e.g., adding protein, fat, and/or carbohydrate to foods such as hot cereal, mashed potatoes, casseroles, and desserts);
- Offering smaller, more frequent meals;
- Providing between-meal snacks or nourishments; or
- Increasing the portion sizes of a resident's favorite foods and meals; and providing nutritional supplements.

To date, the evidence is limited about benefits from appetite stimulants. While their use may be appropriate in specific circumstances, they are not a substitute for appropriate investigation of potentially modifiable risk factors and underlying causes of weight loss.

Maintaining Fluid and Electrolyte Balance: *Poor fluid intake, abnormal lab values for electrolytes, some medications, and resident conditions may all affect a resident's fluid/electrolyte balance. Offering a variety of fluids during and between meals, assisting residents with drinking, keeping beverages available and within reach, and evaluating medications for placing a resident at risk for dehydration are examples of interventions that may be used to improve a resident's fluid balance. Alternate fluids, such as popsicles, gelatin, and ice cream, may also be offered. For some residents, a fluid restriction may be required to address conditions, such as edema or congestive heart failure, and may place them at greater risk for dehydration.*

Feeding Tubes: *Feeding tubes may be used to provide adequate nutrition to a resident who is not able to achieve it with other interventions. The liquid nourishment that is administered*

through a feeding tube is complete nourishment that must be prescribed to meet all the nutritional needs of the resident. Use F692 to guide the investigation into concerns regarding the nutritional adequacy of the prescribed formula. Concerns regarding care of feeding tubes, and/or complications related to their use should be investigated at F693.
NOTE: For residents with *end stage* dementia, *the use of* tube feeding does not *necessarily* extend life, prevent aspiration pneumonia, improve function or limit suffering. *For additional guidance related to feeding tubes, see 42 CFR §483.25(g)(4)-(5), F693, Enteral Nutrition.*

Total Parenteral Nutrition (TPN): *TPN is a method of providing nutrition where a liquid formula is given into a vein through an intravenous catheter (IV) to provide most of the nutrients a resident needs. This method is used when a resident cannot or should not eat or drink by mouth. A resident with TPN may require additional monitoring, such as more frequent weights, to ensure the treatment is effective. For additional guidance, see 42 CFR §483.25(h), F694, Parenteral Fluids.*

NOTE: If the resident and/*or the resident's representative* exercises his/her right to choose and declines *interventions designed to improve or maintain their nutritional or hydration status*, the facility *is responsible for discussing the risks and benefits associated with that decision and offer alternatives, as appropriate. The comprehensive care plan should describe any interventions offered, but declined by the resident or resident's representative. See F656, Comprehensive Care Plans.*

MONITORING
*On-going m*onitoring *of care planned interventions* is necessary for all residents. *On-going m*onitoring *should include, but is not limited to*:

- *Interviewing the resident and/or resident representative to determine if their personal goals and preferences are being met.*
- *Directly observing the resident.*
- *Interviewing direct care staff to gain information about the resident, the interventions currently in place, what their responsibilities are for reporting on these interventions, and possible suggestions for changes, if necessary.*
- Reviewing the resident-specific factors identified as part of the comprehensive resident assessment and any supplemental nutrition assessment, *as needed to determine if they are still relevant or if new concerns have emerged, such as new diagnoses or medications*.
- *Evaluating the care plan to determine if current interventions are being implemented and are effective. This can include reviewing weight records, meal monitors, intake and output logs, nurses' notes, lab values, and physician or dietitian assessments.*

INVESTIGATIVE PROTOCOL
Use the Nutrition and Hydration Critical Element (CE) Pathway, for the concerns being evaluated, along with the above interpretive guidelines when determining if the facility provides the necessary care and services to meet the resident's needs.

Summary of Procedure
Briefly review the most recent comprehensive assessments, comprehensive care plan and orders to determine whether the facility has assessed, identified and addressed as appropriate, the

resident's nutritional and hydration needs. This information will guide observations and interviews to be made in order to corroborate concerns identified.
***NOTE**: Always observe for visual cues of psychosocial distress and harm (see Appendix P, Guidance on Severity and Scope Levels and Psychosocial Outcome Severity Guide).*

KEY ELEMENTS OF NONCOMPLIANCE
To cite deficient practice at F692, the surveyor's investigation will generally show that the facility failed to do one or more of the following:

- Accurately and consistently assess a resident's nutritional status on admission and as needed thereafter;
- Identify a resident at nutritional risk and address risk factors for impaired nutritional status, to the extent possible;
- Identify, implement, monitor, and modify interventions (as appropriate), consistent with the resident's assessed needs, choices, *preferences*, goals, and current professional standards of practice, to maintain acceptable parameters of nutritional status;
- Notify the physician as appropriate in evaluating and managing causes of the resident's nutritional risks and impaired nutritional status;
- Identify and apply relevant approaches to maintain acceptable parameters of residents' nutritional status, *including fluids*;
- Provide a therapeutic diet when *ordered*;
- *Offer sufficient fluid intake to maintain proper hydration and health.*

***NOTE**: Weight loss, abnormal protein and electrolyte lab values, and dehydration are not, by themselves, sufficient to support noncompliance at F692. Additionally, a resident does not need to experience weight loss, abnormal protein levels, D or dehydration to show noncompliance.*

DEFICIENCY CATEGORIZATION
In addition to actual or potential physical harm, always consider whether psychosocial harm has occurred when determining severity level (See Appendix P, Section IV, E, Psychosocial Outcome Severity Guide).

Examples of Severity Level 4 Noncompliance: Immediate Jeopardy to Resident Health or Safety include but are not limited to:

- *Repeated, systemic failure to assess and address a resident's nutritional status and to implement pertinent interventions based on such an assessment resulted in continued significant or severe* weight loss and functional decline;
  Repeated failure to assist a resident who required assistance with meals and drink resulted in or made likely the development of life-threatening symptom(s), or the development or continuation of severely impaired nutritional status;
- *Dietary restrictions or downgraded diet textures, such as mechanical soft or pureed textures, were provided by the facility against the resident's expressed preferences and resulted in substantial* and ongoing decline in food intake resulting in significant *or severe* unplanned weight loss *with accompanying irreversible functional decline to the point where the resident was placed on Hospice*; or

- *The failure to provide an ordered potassium restricted therapeutic diet resulted in* evidence of cardiac dysrhythmias or other changes in medical condition due to hyperkalemia.

Examples of Severity Level 3 Noncompliance: Actual Harm that is not Immediate Jeopardy includes but are not limited to:

- *The failure to revise and/or implement the care plan addressing the resident's impaired ability to feed him/herself resulted in* significant, *not severe,* unplanned weight change and impaired wound healing (not attributable to an underlying medical condition);
- *The failure to identify a decrease in food intake, which resulted in a significant, unintended* weight *loss* from declining food and fluid*s, which resulted in the resident becoming weakened and unable to participate in activities of daily living*;
- *The failure to assess the relative risks and benefits of restricting or downgrading diet and food consistency or to accommodate a resident's choice to accept the related risk resulted in declining food/fluid intake and significant weight loss;*
- *The failure to accommodate documented resident food dislikes and preferences resulted in poor food/fluid intake and a decline* in function; or
- *The failure to provide a gluten-free diet (one free of wheat, barley, and rye products) as ordered for a* resident with known celiac disease (damage to the small intestine related to gluten allergy) *resulted in the resident developing* persistent gastrointestinal symptoms including *significant, not severe,* weight loss, chronic diarrhea, and *occasional* vomiting.

Examples of Severity Level 2 Noncompliance: No Actual Harm with Potential for More Than Minimal Harm that is Not Immediate Jeopardy include but are not limited to:

- Failure to obtain accurate weight(s) and to verify weight(s) as needed;
- The facility's intermittent failure to provide required assistance with eating *resulted in p*oor intake, however, the resident met identified weight goals;
- Failure to provide additional nourishment when ordered for a resident, however, the resident did not experience significant *or severe* weight loss; and
- Failure to provide a prescribed sodium-restricted therapeutic diet (unless declined by the resident or the resident's representative or not followed by the resident); however, the resident did not experience medical complications such as heart failure related to sodium excess.

Severity Level 1: No Actual Harm with Potential for Minimal Harm

- The failure of the facility to provide appropriate care and services to maintain acceptable parameters of nutritional status, which includes hydration, and minimize negative outcomes places residents at risk for more than minimal harm. Therefore, Severity Level 1 does not apply for this regulatory requirement.

POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION

During the investigation of F*692*, the surveyor may have determined that concerns may also be present with related outcome, process and/or structure requirements. The surveyor is cautioned to investigate these related requirements before determining whether non-compliance may be present. Some examples of related requirements that should be considered include *§483.20 Resident Assessment, §483.21 Comprehensive Person-Centered Care Planning, §483.24 Quality*

of Life, §483.30 Physician Services, §483.35 Nursing Services, §483.60 Food and Nutrition Services, §483.70 Administration, and §483.75 QAPI.

F693

§483.25(g) *Assisted nutrition and hydration.*

(Includes naso-gastric and gastrostomy tubes, both percutaneous endoscopic gastrostomy and percutaneous endoscopic jejunostomy, and enteral fluids). **Based on *a resident's* comprehensive assessment, the facility must ensure that a resident—**

§483.25(g)(4)-(5) Enteral Nutrition

§483.25(g)*(4)* A resident who has been able to eat enough alone or with assistance is not fed by *enteral methods* unless the resident's clinical condition demonstrates that *enteral feeding was clinically indicated and consented to by the resident; and*

§483.25(g)*(5)* A resident who is fed by *enteral means* receives the appropriate treatment and services to *restore, if possible, oral eating skills and* to prevent *complications of enteral feeding including but not limited to* aspiration pneumonia, diarrhea, vomiting, dehydration, metabolic abnormalities, and nasal-pharyngeal ulcers.

DEFINITIONS *§483.25(g)(4)-(5)*

"Bolus feeding" is the administration of a limited volume of enteral formula over brief periods of time.

"Continuous feeding" is the uninterrupted administration of enteral formula over extended periods of time.

"Enteral *feeding"* (*also referred to as* "tube feeding") is the delivery of nutrients through a feeding tube directly into the stomach, duodenum, or jejunum.

"Feeding tube" refers to a medical device used to *provide liquid nourishment, fluids, and medications* by bypassing oral intake. *There are two basic categories, naso-grastric and gastrostomy. The type of feeding tube used must be based on clinical assessment and needs of the resident since there are various kinds of feeding tubes within each category.*

"Gastrostomy tube" ("G-tube") is a tube that is placed directly into the stomach through an abdominal wall incision for administration of food, fluids, and medications. The most common type is a percutaneous endoscopic gastrostomy (PEG) tube

"Jejunostomy tube" (a.k.a. "percutaneous endoscopic jejunostomy" (PEJ or "J-tube") is a feeding tube placed directly into the small intestine.

"Naso-gastric feeding tube" ("NG tube") is a tube that is passed through the nose and down through the nasopharynx and esophagus into the stomach.

Effective November 28, 2017

"Transgastric jejunal feeding tube" ("G-J tube") is a feeding tube that is placed through the stomach into the jejunum and that has dual ports to access both the stomach and the small intestine.

GUIDANCE ***§483.25(g)(4)-(5)***
A decision to use a feeding tube has a major impact on a resident and his or her quality of life. It is important that any decision regarding the use of a feeding tube be based on the resident's clinical condition and wishes, as well as applicable federal and state laws and regulations for decision making about life-sustaining treatments

CONSIDERATIONS REGARDING THE USE OF FEEDING TUBES
The regulations at §483.25(g)(4) require that a feeding tube is not used unless there is a valid, clinical rationale, and the resident or if applicable, his/her representative has consented to its use. Consent implies that a discussion has occurred between the resident or representative and the physician, or other member of the treatment team, explaining the process of receiving the tube, and the risks and benefits.

Several factors may be involved in the decision to use a feeding tube including medical conditions that impair the resident's ability to maintain appropriate nutritional parameters (e.g., cerebrovascular accident, esophageal cancer, delirium, reconstructive facial or oral surgery). The need to improve the resident's nutritional status or level of comfort are also factors that may be involved in the decision to use a feeding tube. The duration of use of a feeding tube may vary, depending on the clinical situation *and resident choice*.

The interdisciplinary team, with support and guidance from the physician, is responsible for assuring the ongoing review, evaluation and decision-making regarding the continuation or discontinuation of all treatments, devices or approaches implemented to care for the resident. Involving the resident, family, and/or the resident's representative in discussions about the indications, use, potential benefits and risks of tube feeding, types of approaches, and alternatives helps support the resident's right to make an informed decision to use or not use artificial nutrition and hydration.
A clinically pertinent rationale for using a feeding tube includes, but is not limited to:

- An assessment of the resident's nutritional status, which may include usual food and fluid intake, pertinent laboratory values, appetite, and usual weight and weight changes;
- An assessment of the resident's clinical status, which may include the ability to chew, swallow, and digest food and fluid; underlying conditions affecting those abilities (e.g., coma, stroke, esophageal stricture, potentially correctable malnutrition that cannot be improved sufficiently by oral intake alone); factors affecting appetite and intake (e.g., medications known to affect appetite, taste, or nutrition utilization); and prognosis;
- Relevant functional and psychosocial factors (e.g., inability to sufficiently feed self, stroke or neurological injury that results in loss of appetite, psychosis that prevents eating); and
- Interventions attempted prior to the decision to use a feeding tube and the resident's response to them.

Effective November 28, 2017

The use of a feeding tube may potentially benefit or may adversely affect a resident's clinical condition and/or psychosocial well-being. Examples of some possible benefits of using a feeding tube may include:

- Addressing malnutrition and dehydration;
- Promoting wound healing; and
- Allowing the resident to gain strength, receive appropriate interventions that may help restore the resident's ability to eat and, perhaps, return to oral feeding.

Examples of some possible adverse effects of using a feeding tube may include:

- Diminishing socialization, including, but not limited to, the close human contact associated with being assisted to eat or being with others at mealtimes;
- Not having the opportunity to experience the taste, texture, and chewing of foods;
- Causing tube-associated complications; and
- Reducing the freedom of movement related to efforts to prevent the resident from pulling on the tube or other requirements related to the tube or the tube feeding.

In order to assure that the resident being fed by a feeding tube maintains the highest degree of quality of life possible, it is important to minimize possible social isolation or negative psychosocial impact to the degree possible (e.g., continuing to engage in appropriate activities, socializing in the dining room). Because of the possible side-effects and discomfort associated with the use of nasogastric tubes, there should be clinically pertinent documentation for extended use of nasogastric tubes (e.g., greater than 30 days).
Nutrition and feeding issues and their underlying causes in the resident with advanced dementia or other chronic neurological disorders such as Parkinson's disease present a particular set of issues and considerations that are discussed in F*692*. The extended use of enteral feeding tubes in individuals with advanced dementia *does not necessarily extend life and* remains controversial. The literature regarding enteral feeding of these individuals suggests that there is little evidence that enteral feeding improves clinical outcomes (e.g., prevents aspiration or reduces mortality).

CONSENT
A feeding tube should not be placed unless consented to by the resident or if applicable, appropriately authorized resident representative. The resident has the right to make an informed decision about the treatment they receive. If a resident had a feeding tube placed prior to admission or in another care setting the physician and interdisciplinary care team *must* review the basis (e.g., precipitating illness or condition change) for the initial placement of the feeding tube and the resident's current condition. This is to determine if there is a continued rationale for its use and to ensure that its continued use is consistent with the resident's treatment goals and wishes. Decisions to continue or discontinue the use of a feeding tube are made through collaboration between the resident (or a representative for a resident who lacks capacity to make and communicate such decisions), the physician, and the interdisciplinary care team. This includes a discussion of the relevance of a feeding tube to attaining a resident's goals (e.g., whether the nutritional intervention is likely to have a significant impact on the individual's underlying condition or overall status).

Effective November 28, 2017

TECHNICAL AND NUTRITIONAL ASPECTS OF FEEDING TUBES
It is important that staff providing care and services to the resident who has a feeding tube are aware of, competent in, and utilize facility protocols regarding feeding tube nutrition and care. These protocols are required to be developed with the medical director in order to assure staff implement and provide care and services according to resident needs and professional standards of practice.

Facility *policies and* procedures regarding the technical aspects of feeding tubes *must be developed and implemented, which address*:

Monitoring the feeding tube
How to verify that the tube is functioning before beginning a feeding and before administering medications, *which may include*:

- *Checking gastric residual volume (GRV)*
  - *Not recommended for individuals who are alert and able to report symptoms that indicate a feeding is not well tolerated.*
  - *May be appropriate when initiating tube feedings or for individuals who are unable to report symptoms such as bloating, nausea, or abdominal pain.*
  - *Actions to take based upon the amount of GRV vary depending on the individual and the clinical condition.*
  - *pH of GRV may indicate correct placement i.e. pH < 5 generally indicates gastric contents versus intestinal contents but medications and feeding formulas can alter pH levels.*
  - *Changes in GRV appearance may also be helpful in confirming placement but should not be used in isolation.*
- *Observing changes in external length of tubing may indicate a change in position but can only be used if the exit site was marked upon initial placement; this method does not apply to low profile G tubes (tube that sits at skin level).*

***NOTE**: Auscultation is no longer recommended for checking placement of the feeding tube. Movement of air would likely be heard whether the tube was in the correct or incorrect location. X-ray confirmation is the most accurate method for verification of tube placement when concerns arise regarding dislodgement or placement. Additional information regarding monitoring of feeding tubes may be found at,* https://www.ismp.org/tools/articles/ASPEN.pdf

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Care of the feeding tube

- Securing a feeding tube externally;
- Providing needed personal, skin, oral, and nasal care to the resident;
- Examining and cleaning the insertion site in order to identify, lessen or resolve possible skin irritation and local infection;

- Using infection control precautions and related techniques to minimize the risk of contamination; for example, in connecting the tube and the tube feeding; and
- Defining the frequency of and volume used for flushing, including flushing for medication administration, and when a prescriber's order does not specify.

Feeding tube replacement. Direction for staff regarding the conditions and circumstances under which a tube is to be changed, such as:

- When to replace and/or change a feeding tube (generally replaced either as planned/scheduled or as needed such as when a long-term feeding tube comes out unexpectedly or a tube is worn or clogged);
- How and when to examine a feeding tube and the infusion plug to identify splits or cracks that could produce leakage;
- Instances when a tube can be replaced within the facility and by whom;
- Instances when a tube must be replaced in another setting (e.g., hospital, ambulatory surgery center); and
- Notification of the practitioner when the need for a tube change arises unexpectedly.

Nutritional Aspects of Feeding Tubes

When a resident is receiving nutrition via a feeding tube, the practitioner and the interdisciplinary team identify the resident's nutritional needs and facility procedures that direct staff in providing care and services to the resident. The practitioner's orders related to tube feeding typically include the following components: kind of feeding and its caloric value; volume, duration, and mechanism of administration (e.g., gravity or pump); and frequency of flush.

Facility procedures regarding the nutritional aspects of feeding tubes include, but are not limited to:

Enteral nutrition. Direction to staff regarding the nutritional product and meeting the resident's nutritional needs such as:

- Types of enteral nutrition formulas available for use;
- How to determine whether the tube feedings meet the resident's nutritional needs and when to adjust them accordingly;
- How to balance essential nutritional support with efforts to minimize complications related to the feeding tube;
- Ensuring that the selection and use of enteral nutrition is consistent with manufacturer's recommendations;
- Ensuring that the administration of enteral nutrition is consistent with and follows the practitioner's orders; and
- Ensuring that the product has not exceeded the expiration date;
- *Ensuring that additional water ordered for flushes or for additional hydration is administered per orders.*

Flow of feeding. Direction for staff regarding how to manage and monitor the rate of flow, such as:

- Use of gravity flow;
- Use of a pump;
- Periodic evaluation of the amount of feeding being administered for consistency with practitioner's orders;
- Calibration of enteral feeding pumps to ensure that pump settings accurately provide the rate and volume consistent with the resident's care plan; and
- Periodic maintenance of feeding pumps consistent with manufacturer's instructions to ensure proper mechanical functioning.

Complications Related to the Feeding Tube

An enteral feeding tube may be associated with significant complications, including aspiration, leaking around the insertion site, abdominal wall abscess, or erosion at the insertion site including the nasal areas. Feeding tubes can perforate the stomach or small intestine, with resultant peritonitis. Esophageal complications of feeding tubes may also occur including esophagitis, ulcerations, strictures, and tracheoesophageal fistulas. The use of tubes not designed or intended for enteral feeding may increase the risk of complications.[16, 17]

Tubes may clog for various reasons, including plugging by formula, pill fragments, or the precipitation of medications incompatible with the formula.[18] Flushing feeding tubes regularly and in association with medication administration, as indicated by current professional standards of practice and provided in the resident care policies, can help reduce the risk of clogging.

Complications Related to the Administration of the Enteral Nutrition Product

The administration of an enteral nutrition product may be associated with other complications including, but not limited to, nausea, vomiting, diarrhea, abdominal cramping, inadequate nutrition and aspiration. Additionally, interactions between the formula and various medications can affect the absorption and/or effectiveness of the medication. For example, the effectiveness of phenytoin sodium (Dilantin, Phenytek) may be reduced by the drug binding with the enteral feeding's protein component, leading to less free drug availability and possibly inadequate therapeutic levels.

Metabolic complications related to tube feeding may include inadequate calorie or protein intake, altered hydration, hypo- or hyperglycemia, and altered electrolyte and nutrient levels. These risks may be reduced by calculating the nutritional needs of the resident, taking into account comorbid conditions and medications that affect these balances, monitoring for adequate nutritional status and complications, and adjusting the tube feeding accordingly.

While a feeding tube may be initiated with the intent to address certain medical conditions, the use of a feeding tube does not necessarily decrease the risk of aspiration for individuals with other risk factors, such as moderate or less severe swallowing abnormalities. Aspiration risk may potentially be affected by factors such as diminished level of consciousness, improper positioning of the resident during administration of the feeding, and failure to assure the feeding tube is correctly positioned within the stomach or intestine. The evidence is inconsistent and conflicting regarding any connection between gastric residual volume (GRV) and the risk or occurrence of aspiration.[19]

Risk of aspiration should be assessed individually and appropriate interventions (e.g., proper positioning, rate of flow) implemented accordingly. There may be situations where other coexisting factors influence decisions about elevating the head of the bed; for example, a resident being fed by a tube who may be at risk for shearing by sliding down the sheets when the head of the bed is elevated to a recommended angle.

Complications Management
The facility is expected to identify and address actual or potential complications related to the feeding tube or tube feeding and to notify and involve the practitioner in evaluating and managing care to address these complications and risk factors.

PROCEDURES §483.25(g)(4)-(5)
Use the Tube Feeding Critical Element (CE) Pathway along with the above guidance when determining if the facility utilized a feeding tube only after adequate assessment of the resident's clinical condition to ensure this intervention is medically necessary and with the resident's consent.

The surveyor(s) should *use* the following: observations, interviews and record reviews *to determine if a feeding tube is utilized only if the resident's clinical condition makes this intervention medically necessary and with the resident's consent*. *The surveyor must determine if* a feeding tube is utilized in accordance with current professional standards of practice and if services are provided to prevent complications to the extent possible. *Additionally, for a resident whose goal is to restore normal eating skills to the extent possible, the surveyor must determine if the necessary care and services were provided to reach this goal.* If there are concerns regarding the facility's use and care of feeding tubes, review facility policies and practices with regard to the use and care of feeding tubes.

KEY ELEMENTS OF NONCOMPLIANCE
To cite deficient practice at F693, the surveyor's investigation will generally show that the facility failed to do one or more of the following:

- *Ensure enteral feeding was clinically indicated; or*
- *Ensure enteral feeding was consented to by the resident;* ***or***
- *Ensure a resident receiving enteral feeding received appropriate care and services to restore oral eating skills, if possible,* ***or***
- *Ensure a resident receiving enteral feeding received appropriate care and services to prevent complications of enteral feeding.*

DEFICIENCY CATEGORIZATION
In addition to actual or potential physical harm, always consider whether psychosocial harm has occurred when determining severity level (See Appendix P, Section IV, E, Psychosocial Outcome Severity Guide).

An example of Severity Level 4 Noncompliance : Immediate Jeopardy to Resident Health or Safety, includes but is not limited to:

- *The facility failed to properly set up the tube feeding pump and to monitor a cognitively impaired resident receiving the tube feeding, resulting in the resident receiving too much*

liquid nourishment at a rate too fast to be absorbed. The resident was found to be unresponsive with excess liquid nourishment coming from his or her nose and mouth.

An example of Severity Level 3 Considerations: Actual Harm that is Not Immediate Jeopardy includes, but is not limited to:

- The facility failed to monitor for complications related to a resident's feeding tube and tube feeding. As a result, the resident experienced significant but not serious tube feeding-related complications; or

Examples of Severity Level 2 Noncompliance: No Actual Harm with Potential for More than Minimal Harm that is Not Immediate Jeopardy includes, but is not limited to:

- As a result of staff failure to anchor a feeding tube properly, the resident had leakage and irritation around the tube insertion site that required topical treatment and resolved without complications;
- As a result of staff failure to manage a tube feeding pump properly, the resident did not receive the calculated amount of tube feeding, without resulting in significant weight loss or other GI complications; or
- As a result of staff failure to consistently flush a resident's feeding tube as ordered, the tube clogged and had to be replaced, but there were no other complications.

Severity Level 1: No Actual Harm with Potential for Minimal Harm
The failure of the facility to provide appropriate care and services for feeding tubes, places the resident at risk for more than minimal harm. Therefore, Severity Level 1 does not apply for this regulatory requirement.

POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION
If there are concerns identified regarding the resident receiving adequate nutrition/hydration when receiving tube feeding, review F692, Assisted Nutrition and Hydration, for further investigation.

If there is lack of consent related to the placement of a feeding tube, cite those deficiencies here instead of the Resident Rights since this regulatory language is specific to consent for a feeding tube.

F694
§ 483.25(h) ***Parenteral Fluids.***
Parenteral fluids must be administered consistent with professional standards of practice and in accordance with physician orders, the comprehensive person-centered care plan, and the resident's goals and preferences.

INTENT §483.25 (h)
The intent of this requirement is that the facility assures that each resident receives care and services for the provision of parenteral fluids consistent with professional standards of practice in order to provide:

- *Safe administration of parenteral fluids by qualified, competent and trained staff in accord with State laws/practice acts;*

- *Care consistent with the resident's input, goals and preferences, as delineated in the care plan; and*
- *Ongoing support of the resident, during intravenous fluid (IV) treatments, including monitoring the resident's status, monitoring for complications and assuring the provision of appropriate infection control practices.*

***DEFINITION* §483.25 (h)**
Parenteral fluid *is defined as an IV infusion of various solutions to maintain adequate hydration, restore and/or maintain fluid volume, reestablish lost electrolytes, or provide partial nutrition which includes Total Parenteral Nutrition (TPN). Taken from http://medical-dictionary.thefreedictionary.com/administration+of+parenteral+fluids*

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***GUIDANCE* §483.25 (h)**
There is no requirement that a facility must offer IV treatments/services. If the facility has an arrangement with an outside contractor for the provision of IV services, the facility must inform each resident before or at the time of admission, and periodically during the resident's stay, of IV services, if available in the facility.

Residents of a facility may receive IV services through options such as:

- *The facility provides the IV services either directly or contracting for individuals to provide the services; however, these individuals must be qualified, trained and competent in accordance with professional standards of practice, licensure and State practice acts/laws; or*
- *If a current resident chooses to receive IV services, and the facility does not allow for these onsite services, the facility must assist the resident with the transfer to another facility or in the relocation to a setting (e.g. private home, or residential/assisted living facility) of his/her choice that provides IV services.*

The facility must develop and implement resident care policies, based upon current professional standards of practice for the preparation, insertion, administration, maintenance and discontinuance of the IV as well as prevention of infection at the site to the extent possible. The procedures must include the care and use of all equipment, such as pumps, tubing, syringes, fluids, etc.

The facility minimizes risks to a resident receiving IV therapy by developing and implementing policies that adhere to professional standards of practice, which may include, but are not limited to:

- *Use of appropriate hand hygiene during all aspects of IV services;*
- *Use of aseptic technique when placing a venous access device;*

- *Use of personal protective equipment (PPE) (based on potential for exposure to blood, bodily fluids, and infectious agents);*
- *Competency of staff to:*
  - *Use infusion equipment;*
  - *Accurately perform IV insertion, and maintain vascular access; and*
  - *Assess for complications.*
- *Administration of solutions according to orders [correct solution, administration route (central/peripheral line),duration, frequency, and infusion rate]; and*
- *Labeling and dating, as appropriate, infusion fluids and lines.*

According to the CDC, the following terminology has been used to describe IV catheters: "Terminology and Estimates of Risk - The terminology used to identify different types of catheters is confusing, because many clinicians and researchers use different aspects of the catheter for informal reference. A catheter can be designated by:

- *The type of vessel it occupies (e.g., peripheral venous, central venous, or arterial);*
- *Its intended life span (e.g., temporary or short-term versus permanent or long-term);*
- *Its site of insertion (e.g., subclavian, femoral, internal jugular, peripheral, and peripherally inserted central catheter [PICC]);*
- *Its pathway from skin to vessel (e.g., tunneled versus nontunneled);*
- *Its physical length (e.g., long versus short); or*
- *Some special characteristic of the catheter (e.g., presence or absence of a cuff, impregnation with heparin, antibiotics or antiseptics, and the number of lumens).*
  To accurately define a specific type of catheter, all of these aspects should be described (Table 1)." - https://www.cdc.gov/hicpac/BSI/bsi-table-1-2011.html

Complications/Risks of Intravenous Fluid Administration

Administration of IV fluids may be required to restore or maintain adequate hydration, replace electrolytes, or provide partial nutrition. However, because it is invasive, administration of IV fluids has associated risks such as:

- *Infiltration;*
- *Bruising;*
- *Embolism (Air or Blood);*
- *Phlebitis;*
- *Fluid overload;*
- *Electrolyte imbalance; and*
- *Infections (Cellulitis, Septicemia).*

***NOTE**: Refer to Centers for Disease Control (CDC) guidelines for the prevention of intravascular catheter related infections found at: https://www.cdc.gov/hai/pdfs/bsi-guidelines-2011.pdf*

In addition to adhering to professional standards of practice, facilities are responsible to administer IV therapy according to the resident-centered care plan and in accordance with the resident's goals, preferences, and advance directives, as applicable and according to State law.

INVESTIGATIVE PROCEDURES

Observations: Observe the resident to determine:

- Are there signs of inflammation or infiltration at the insertion site *and has site been changed according to current, professional standards of practice?*
- *If* the rate *of parenteral fluid being administered reflects that which was* ordered by the physician.
- *If* the resident received the amount of fluid during the past 24 hours that he/she should have received according to the physician's orders (allow flexibility up to 150cc unless an exact fluid intake is critical for the resident)?

Observe *staff changing* the IV site, tubing, or bottle/bag, *if possible. Determine* whether *aseptic* technique is maintained *in accordance with current, professional standards of practice*.

Record Review:

Review the medical record and comprehensive care plan (or baseline if the resident's admission was within 14 days of the review) to determine:

- *If the resident has a diagnosis warranting the administration of parenteral fluids;*
- *If the resident has orders for parenteral fluid;*
  - *If yes, note the solution type, administration route, frequency, and infusion rate to compare to observations.*
- *How frequently staff are to change IV tubing.*

Review facility policies and procedures related to parenteral therapy to determine if policies and/or procedures address:

- *Aseptic technique for IV insertion;*
- *Maintenance of IV site;*
- *Frequency of IV site, tubing, and bag changes, and do they reflect current, professional standards of practice?*

Interviews:

Interview the resident or if applicable, the representative to determine:

- *If they understand why the resident is receiving parenteral fluid;*
- *If the resident has had any complications or concerns related to the IV.*

Interview staff to determine if there are specific qualifications and/or competencies required for staff who perform IV insertion, IV maintenance, and parenteral fluid administration.

DEFICIENCY CATEGORIZATION §483.25 (h)

Examples of Severity Level 4 Noncompliance Immediate Jeopardy to Resident Health or Safety include, but are not limited to:

- *Facility's failure to adhere to sterile technique during maintenance of parenteral therapy that lead to sepsis and resulted in the resident's hospitalization or death.*
- *Facility's failure to monitor administration in fluid that resulted in overload of cardiovascular system, resulting in hospitalization or death.*

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Examples of Severity Level 3 Noncompliance Actual Harm that is Not Immediate Jeopardy include, but are not limited to:

- *Facility's failure to monitor for complications related to parenteral therapy, resulting in infiltration of the IV, causing the resident to experience pain and swelling.*
- *Facility's failure to ensure a resident received fluids as ordered, resulting in dehydration, which was later reversed after staff became aware.*

Examples of Severity Level 2 Noncompliance No Actual Harm with Potential for More Than Minimal Harm that is Not Immediate Jeopardy include, but are not limited to:

- *Facility's failure to consistently flush a resident's IV site, resulting in the IV becoming clogged and requiring replacement.*
- *Facility's failure to anchor the IV needle and tubing, resulting in leakage around the IV site that required topical treatment and resolved without complications.*

Severity Level 1 Noncompliance No Actual Harm with Potential for Minimal Harm *The failures of the facility to provide appropriate care and services related to parenteral fluids places the resident at risk for more than minimal harm. Therefore Severity 1 does not apply for this regulatory requirement.*

POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION:

- *If noncompliance with parenteral therapy is related to staff competency issues, also consider F725, §483.35(a)(3), Nursing Services*
- *If noncompliance with parenteral therapy is related to accuracy of fluid type, or amount, also consider F755, §483.45 Pharmacy Services.*
- *If noncompliance with parenteral therapy is related to lack of equipment such as IV tubing, pumps, etc., also consider F907 §483.90(c)(1) Space and equipment.*

If noncompliance with parenteral therapy is related to the provision of adequate nutrition/hydration, also consider F692 §483.25(g), Assisted Nutrition and Hydration.

F695

§483.25(i) **Respiratory care, i*****ncluding tracheostomy care and tracheal suctioning.***

The facility must ensure that a resident who needs respiratory care, including tracheostomy care and tracheal suctioning, is provided such care, consistent with professional standards of practice, the comprehensive person-centered care plan, the residents' goals and preferences, and 483.65 of this subpart.

INTENT

The intent of this provision is that each resident receives necessary respiratory care and services that is in accordance with professional standards of practice, the resident's care plan, and the resident's choice.

DEFINITIONS § 483.25 (i)

"Automatic self-adjusting positive airway pressure *(APAP)". APAP is a non-invasive ventilation machine that automatically adjusts the air pressure according to the patient's requirement at a particular time.*

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"Bi-level positive airway pressure *(BiPAP)". BiPAP is a non-invasive ventilation machine that is capable of generating two adjustable pressure levels - Inspiratory Positive Airway Pressure (IPAP) - high amount of pressure, applied when the patient inhales and a low Expiratory Positive Airway Pressure (EPAP) during exhalation.*

"Continuous positive airway pressure *(CPAP)". CPAP is a non-invasive ventilation machine that involves the administration of air usually through the nose by an external device at a predetermined level of pressure.*

"Hypoxia" *means decreased perfusion of oxygen to the tissues.*

"Hypoxemia" *means decreased oxygen level in arterial blood.*

"Intermittent positive pressure breathing (IPPB)" *is a technique used to provide short term or intermittent mechanical ventilation for the purpose of augmenting lung expansion, delivering aerosol medication, or assisting ventilation and can include pressure- and time-limited as well as pressure, time, and flow-cycled ventilation, and may be delivered to artificial airways and non-intubated patients.*

"Mechanical Ventilation" *may be defined as a life support system designed to replace or support normal ventilatory lung function.*[1]

"Noninvasive ventilation (NIV)" *refers to the administration of ventilatory support without using an invasive artificial airway (endotracheal tube or tracheostomy tube).*[1]

"Obstructive Sleep Apnea (OSA" *refers to apnea syndromes due primarily to collapse of the upper airway during sleep.*

"Oxygen therapy" *is the administration of oxygen at concentrations greater than that in ambient air (20.9%) with the intent of treating or preventing the symptoms and manifestations of hypoxia.*

"Respiratory Therapy Service" *are-services that are provided by a qualified professional (respiratory therapists, respiratory nurse) for the assessment, treatment, and monitoring of residents with deficiencies or abnormalities of pulmonary function (See 483.65, Specialized Rehabilitative Services).*

"Tracheotomy or Tracheostomy" *is an opening surgically created through the neck into the trachea (windpipe) to allow direct access to the breathing tube and is commonly done in an operating room under general anesthesia. A tube is usually placed through this opening to provide an airway and to remove secretions from the lungs. Breathing is done through the tracheostomy tube rather than through the nose and mouth. The term "tracheotomy" refers to the incision into the trachea (windpipe) that forms a temporary or permanent opening, which is called a "tracheostomy," however the terms are sometimes used interchangeably.*

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"Ventilator Assisted Individual (VAI)" *requires mechanical aid for breathing to augment or replace spontaneous ventilatory efforts to achieve medical stability or maintain life.* [2]

GUIDANCE § 483.25(i)

Changes in the respiratory system related to aging may lead to the development of and/or difficulty/challenges in treating diseases in the respiratory system, and may impact treatments/interventions. The Minimum Data Set (MDS) has identified the most frequent respiratory diseases/syndromes that a resident may have been admitted with or required after admission to a nursing home, including but not limited to pneumonia, asthma, chronic obstructive pulmonary disease (COPD), chronic lung disease (chronic bronchitis and restrictive lung diseases such as asbestosis), respiratory failure, shortness of breath (dyspnea) with exertion, or when sitting at rest, lying flat, or during an illness such as influenza. In addition, residents have been admitted with or previously had adult respiratory distress (ARD) syndrome, lung cancer, obstructive sleep apnea or a history of tuberculosis.

Various modalities/treatments for respiratory care identified on the MDS include respiratory treatments/therapy, oxygen therapy, the use of BiPAP/CPAP, tracheostomy and/or suctioning, and some facilities provide chest tube and mechanical ventilation services/care.

Based upon its facility assessment, the resident population, diagnosis, staffing, resources and staff skills/knowledge, the facility must determine whether it has the capability and capacity to provide the needed respiratory care/services for a resident with a respiratory diagnosis or syndrome that requires specialized respiratory care and/or services. This includes at a minimum, sufficient numbers of qualified professional staff, established resident care policies and staff trained and knowledgeable in respiratory care before admitting a resident that requires those services.

Resident Care Policies

The facility, in collaboration with the medical director, director of nurses, and respiratory therapist, as appropriate, must assure that resident care policies and procedures for respiratory care and services, are developed, according to professional standards of practice, prior to admission of a resident requiring specific types of respiratory care and services. (Also refer to F841, §483.70(h) Medical Director) The policies and procedures, based on the type of respiratory care and services provided, may include, but are not limited to:

- *Oxygen services, including the safe handling, humidification, cleaning, storage, and dispensing of oxygen;*
- *Types of respiratory exercises provided such as coughing/deep breathing and if provided therapeutic percussion/vibration and bronchopulmonary drainage;*
- *Aerosol drug delivery systems(nebulizers/metered-dose inhalers) and medications (preparation and/or administration) used for respiratory treatments;*
- *BiPAP/CPAP treatments;*
- *Delineation for all aspects of the provision of mechanical ventilation/tracheostomy care, including monitoring, oversight and supervision of mechanical ventilation, tracheostomy care and suctioning, and how to set, monitor and respond to ventilator alarms;*
- *Emergency care which includes staff training and competency for implementation of emergency interventions for, at a minimum, cardiac/respiratory complications, and*

include provision of appropriate equipment at the resident's bedside for immediate access, such as for unplanned extubation;

- *Procedures to follow in the advent of adverse reactions to respiratory treatments or interventions, including mechanical ventilation, tracheostomy care and provision of oxygen;*
- *Respiratory assessment including who can conduct each aspect of the assessment, what is contained in an assessment, when and how it is conducted, the type of documentation required;*
- *Maintenance of equipment for respiratory care in accordance with the manufacturer specifications and consistent with federal, state, and local laws and regulations, such as oxygen equipment, or equipment for mechanical ventilation if provided, how and by whom the equipment is serviced and how it is maintained;*
- *Emergency power for essential equipment such as mechanical ventilation, if provided;*
- *Infection control measures during implementation of care, handling, cleaning, storage and disposal of equipment, supplies, biohazardous waste and including infection control practices for mechanical ventilation/tracheostomy care including the use of humidifiers; and*
- *Posting of cautionary and safety signs indicating the use of oxygen; and*

Staffing and Qualified Personnel

Refer to §483.65 specialized rehabilitative services, for review of provision of services by qualified personnel. When providing respiratory care, the facility must, based on professional standards of practice:

- *Have sufficient numbers of trained, competent, qualified staff, consistent with State practice acts/laws; and*
- *Identify who is authorized to perform each type of respiratory care service, such as responding to mechanical ventilator alarms, suctioning and tracheostomy care.*

***NOTE**: Surveyors are expected to determine the scope of practice and state laws regarding who may provide mechanical ventilation and/or tracheostomy care in their state.*

Monitoring and Documentation of Respiratory Services/Response

Staff should document, based on current professional standards of practice, the assessment and monitoring of the resident's respiratory condition, including response to therapy provided, and any changes in the respiratory condition. Depending on the type of respiratory services the resident receives, physician orders and the individualized respiratory care plan, documentation should include, as appropriate:

- *Vital signs, including the respiratory rate;*
- *Chest movement and respiratory effort, and the identification of abnormal breath sounds;*
- *Signs of dyspnea, cyanosis, coughing, whether position affects breathing, characteristics of sputum, signs of potential infection, or the presence of behavioral changes that may reflect hypoxia including anxiety, apprehension, level of consciousness; and*
- *Instructions for the resident on how to participate/assist in the respiratory treatments as appropriate.*

Effective November 28, 2017

The attending practitioner must be immediately notified of significant changes in condition, and the medical record must reflect the notification, response and interventions implemented to address the resident's condition. Also, refer to §483.10(g)(14) F580 for notification of physician, family of significant changes.

Modalities/Respiratory Therapy/Care/Services
A variety of respiratory therapy modalities and care may be provided in the nursing home, including coughing/deep breathing, therapeutic percussion/vibration and postural drainage, aerosol/nebulizers, humidification, and therapeutic gas administration, BiPAP or CPAP, tracheostomy care and tracheal suctioning, and mechanical ventilation and oxygenation support.

Coughing/deep breathing, therapeutic percussion/vibration and bronchopulmonary drainage
If a resident has written orders for postural drainage, chest percussion, and vibration to increase the mobility of pulmonary secretions, the care plan must include, based upon the resident's assessments and identified needs, the type of exercise, including when and how often provided. The resident's record should reflect how staff are monitoring the condition of the resident prior to, during and after the treatments, and, as appropriate, vital signs including the respiratory rate, pulse oximetry, presence of dyspnea, and/or signs of infection. The record should reflect the resident's response to the treatment and notification of the practitioner if necessary for a change in the resident's condition or as necessary, the need to revise or alter the respiratory care provided. Refer to §483.10(g)(14) F580 for notification of physician of significant changes.

Respiratory medications via aerosol generators
There are three common types of aerosol generators used for inhaled drug delivery:

- *A small-volume nebulizer (SVN);*
- *A pressurized metered-dose inhaler (pMDI); and*
- *A dry-powder inhaler (DPI).*

***NOTE**: For information related to aerosol delivery devices include, for example, the specific devices' manufacturers guidelines for use; and " Guide to Aerosol Delivery Devices for Physicians, Nurses, Pharmacists and Other Health Care Professionals" American Association for Respiratory Care 2013 http://www.aarc.org//app/uploads/2014/08/aerosol_guide_pro.pdf*

Oxygen (O_2) Therapy
Oxygen therapy may be provided through various types of supply and delivery systems. Equipment may include the provision of oxygen through nasal cannulas, trans-tracheal oxygen catheters, oxygen canisters, cylinders or concentrators.

For a resident receiving oxygen therapy, the resident's record must reflect ongoing assessment of the resident's respiratory status, response to oxygen therapy and include, at a minimum, the attending practitioner's orders and indication for use. In addition, the record should include the type of respiratory equipment to use, baseline SpO_2 levels and to initiate and/or discontinue oxygen therapy. If the resident is ambulatory with his/her oxygen delivery system, the resident must be informed of safety precautions and prohibitions for oxygen, such as where smoking is allowed or other hazardous areas, and staff should monitor to assure the resident adheres to the

safety rules for oxygen. The resident's care plan should identify the interventions for oxygen therapy, based upon the resident's assessment and orders, such as, but not limited to:

- *The type of oxygen delivery system;*
- *When to administer, such as continuous or intermittent and/or when to discontinue;*
- *Equipment settings for the prescribed flow rates;*
- *Monitoring of SpO_2 levels and/or vital signs, as ordered; and*
- *Based upon the individual resident's risks, if applicable, monitoring for complications, such as skin integrity issues related to the use of a nasal cannula.*

***NOTE**: For reference, American Association for Respiratory Care Clinical Practice Guideline - Oxygen Therapy in the Home or Alternate Site Health Care Facility —2007 Revision & Update P1063-1067- http://www.rcjournal.com/cpgs/pdf/08.07.1063.pdf*

Obstructive Sleep Apnea

Obstructive sleep apnea (OSA) refers to apnea syndromes due primarily to collapse of the upper airway during sleep. Nonpharmacologic medical treatments may include weight reduction, tongue-retaining devices, positive airway pressure modalities such as continuous positive airway pressure (CPAP) and bi-level positive airway pressure (BiPAP). CPAP involves the administration of air usually through the nose by an external device at a fixed pressure to maintain the patency of the upper airway. BiPAP is similar to CPAP but the devices are capable of generating two adjustable pressure levels. Other treatment methods for OSA may include the use of medications surgical procedures.

For a resident with OSA, the resident's record must reflect ongoing assessment of the resident's respiratory status, response to therapy and include, at a minimum, the attending practitioner's orders and indication for use. In addition, the record should include the equipment settings, when to use the equipment and humidification as appropriate.

The care plan should identify the interventions for OSA, based upon the resident's assessment and orders, such as, but not limited to:

- *The type of equipment and settings, and*
- *When to administer; and ;*
- *Based upon the individual resident's risks, if applicable, monitoring for complications.*

Respiratory Services for Mechanical Ventilation with Tracheostomy/Tracheotomy Care

Mechanical ventilation is defined as a life support system designed to replace and/or support normal ventilatory lung function. A ventilator-assisted individual (VAI) may require mechanical aid for breathing to augment or replace spontaneous ventilatory efforts to achieve medical stability or maintain life. Persons requiring long term invasive ventilatory support have demonstrated:

- *An inability to become completely weaned from invasive ventilatory support; or*
- *A progression of disease etiology that requires increasing ventilatory support.*

Due to the clinically complex nature of the provision of care for a resident receiving mechanical ventilation, there must be an active, ongoing interdisciplinary approach to the resident's care, including but not limited to participation as needed, by the physician/practitioner,

pulmonologist, registered nurse, pharmacist, dietitian, speech therapist, respiratory therapist, physical and/or occupational therapist, and the resident/representative. The facility, in collaboration with the attending practitioner, must provide a comprehensive assessment of the resident's respiratory needs. The facility must provide an assessment of resident specific communication methodologies, including assessing current visual/hearing needs, cognition, level of consciousness, and identifying potential methods for communication such as writing, communication cards/boards, and/or computer access. The results of the assessment must be used in the development and implementation of a person centered care plan.

A resident receiving mechanical ventilation and/or tracheostomy care is dependent on staff to provide care according to the practitioner's orders, the comprehensive assessment and individualized care plan, including, but not limited to communication, positioning and range of motion, nutrition, hydration, ADL's, bladder and bowel management, monitoring for resident specific risks for possible complications, psychosocial needs, as well as mechanical ventilation and tracheostomy care including suctioning as appropriate. The facility must provide consistent, implementation of all aspects of care related to the provision of mechanical ventilation and tracheostomy care, in accordance with accepted professional standards of practice, including emergency interventions as appropriate.

Staff must be trained and competent in application of life support interventions in case of emergency situations such as cardiac and/or respiratory complications related to mechanical ventilation and environmental emergencies such as power outages.

Care plan for Mechanical Ventilation/Tracheostomy Care

Based upon the resident assessment, attending practitioner's orders, and professional standards of practice, the facility, including the resident/representative, to the extent possible, must develop and implement a care plan that includes appropriate interventions for respiratory care. The facility must develop a care plan based on the resident's individualized assessment that may include:

- *Communication needs and methods;*
- *Positioning, skin Integrity and redistribution of pressure (i.e., use of specialized mattresses/equipment/positioning);*
- *Nutritional support (specialized care such as enteral nutrition);*
- *Bowel and bladder management;*
- *Provision of oral and eye care;*
- *Monitoring for psychosocial needs such as depression or anxiety;*
- *As ordered by the practitioner, and/or as appropriate, monitoring respirations and respiratory rates, heart rates, presence of cyanosis, dusky coloring or other color changes related to respiratory/circulatory conditions, symmetry of chest expansion/movement, diaphoresis, lethargy, vital signs and parameters including pulse oximetry;*
- *Care of a resident who is cognitively impaired and may exhibit restlessness and pulling at tubing;*
- *Adjunctive interventions, as appropriate, such as medications, aerosol (bronchodilators), chest physiotherapy, oxygen therapy, and/or secretion clearance devices; and*
- *Identification of resident specific risks for possible complications, that may include:*

- *Unplanned extubation;*
- *Aspiration and the potential for respiratory infection (tracheal bronchitis, ventilator associated pneumonia (VAP));*
- *Nutritional complications related to tube feedings, gastric distress;*
- *Increased or decreased CO_2 levels;*
- *Development of oral or ocular ulcers,*
- *Barotrauma;*
- *Deep vein thrombosis due to immobility; and/or*
- *Airway complications such as tracheal infections, mucous plugging, tracheal erosion and/or stenosis;*

- *Advance directives, if any;*
- *Type of ventilator equipment, settings, and alarms, (Refer to physicians orders, and manufacturers specifications for use and care); and*
- *Type and size of airway and care of artificial airway.*

PROCEDURE: §483.25 (i)
Use the Respiratory Care Critical Element (CE) Pathway, along with the above interpretive guidelines when determining if the facility provides the necessary care and services to ensure that a resident receives the respiratory care and services as ordered to meet his/her needs.

Surveyors should use the guidance above as general information about the professional standards of practice regarding the provision of care under this tag. It is not intended to prescribe a clinical course for a specific resident.

Summary of Procedure
Briefly review the most recent comprehensive assessments, comprehensive care plan and orders to identify whether the facility has assessed and developed an individualized care plan based on professional standards of practice and provided by qualified, competent staff. During this review, identify the extent to which the facility has implemented interventions in accordance with the resident's needs, goals for care and professional standards of practice, consistently across all shifts. This information will guide observations and interviews to be made in order to corroborate concerns identified.

***NOTE**: Always observe for visual cues of psychosocial distress and harm (see Appendix P, Guidance on Severity and Scope Levels and Psychosocial Outcome Severity Guide).*

***NOTE**: If noncompliance with respiratory care provided by nursing services is related to staff competency issues, also consider F725, §483.35(a)(3), Nursing Services*

KEY ELEMENTS OF NONCOMPLIANCE
To cite deficient practice at F695, the surveyor's investigation will generally show that the facility failed to do one or more of the following:

- *Provide necessary respiratory care and services, such as oxygen therapy, treatments, mechanical ventilation, tracheostomy care, and/or suctioning; or*
- *Provide necessary respiratory care consistent with professional standards of practice, the resident's care plan, goals and preferences.*

Effective November 28, 2017

DEFICIENCY CATEGORIZATION §483.25 (i)

In addition to actual or potential physical harm, always consider whether psychosocial harm has occurred when determining severity level (See Appendix P, Section IV, E, Psychosocial Outcome Severity Guide).

Examples of Severity Level 4 Noncompliance: Immediate Jeopardy to Resident Health or Safety include but are not limited to:

- *The facility failed to assure that staff provided appropriate tracheostomy care including suctioning as ordered by the resident's physician and based on professional standards of practice, to use the appropriate suctioning technique. During observations the resident experienced respiratory distress, and expressed ongoing anxiety and fear related to difficulty breathing. Staff interviewed was not aware of the physician's orders for tracheal suctioning and were not aware of the techniques to use during the suctioning treatment. Staff stated this was the first time they were scheduled to work in this unit, and had no prior experience in providing ventilator or tracheostomy care. This lack of knowledge of how to provide this specialized care including the technique for suctioning increases the likelihood for psychosocial harm, respiratory distress, obstruction of airways, and potentially death.*
- *The facility failed to provide emergency equipment available for accidental extubation for a resident on mechanical ventilation with a tracheostomy. (An extubation creates an emergency situation that requires that an obturator be readily available that can be used by competent staff for reinsertion). Upon interview, staff were not aware of the location of emergency equipment or how to use it in case of accidental extubation. As a result, it is likely any resident who experienced an accidental extubation would suffer serious harm or death.*

Examples of Severity Level 3 Noncompliance, Actual Harm that is not Immediate Jeopardy includes but is not limited to:

- *The facility failed to provide consistent oxygen therapy for a resident who required oxygen during periods of activity. Over a weekend, a resident's oxygen supply was depleted, and staff failed to order replacement oxygen. As a result, the resident experienced dyspnea when dressing, expressed increasing anxiety due to difficulty in "getting his/her breath when ambulating, and refused to go to the dining room for meals, or to take a shower, due to being short of breath.*
- *Facility failed to consistently implement a method for communication that had been established with a resident who was unable to verbally communicate due to being on a mechanical ventilator. The resident had indicated that a clipboard be used for him to write down requests and/or concerns, but night staff cleaning the room, removed it from the resident's bedside and placed it in an area inaccessible by the resident. This had occurred several times, according to the resident who expressed anger to the surveyor when he was interviewed and provided the clipboard. He wrote that staff told him/her to relax and calm down when he could not access the communication board. The resident wrote that he feels isolated, afraid and upset when he cannot use the preferred communication method. He indicated that he did not feel as if staff could be trusted to meet his concerns, and began to cry.*

Examples of Severity Level 2 Noncompliance: No Actual Harm with Potential for More Than Minimal Harm that is Not Immediate Jeopardy include but are not limited to:

- *The facility failed to assure that a resident had a portable supply of oxygen to take along when attending activities as ordered by the attending practitioner. The resident stayed in her room on oxygen and missed the activity programs she usually participated in. The resident stated that she was upset to have to miss the programs because staff failed to order her portable supply of oxygen.*
- *The facility failed to consistently perform coughing/deep breathing exercises as ordered for a resident, however, no increase or exacerbation of respiratory symptoms as a result of the lack of exercises was identified.*

Severity Level 1: No actual harm with potential for minimal harm
The failures of the facility to provide appropriate care and services to provide respiratory care, including oxygen therapy, respiratory treatments and/or mechanical ventilation and tracheostomy care places a resident at risk for more than minimal harm. Therefore, Severity Level 1 does not apply for this regulatory requirement.

F696
§483.25(j) **Prostheses**
The facility must ensure that a resident who has a prosthesis is provided care and assistance, consistent with professional standards of practice, the comprehensive person-centered care plan, the residents' goals and preferences, to wear and be able to use the prosthetic device.

GUIDANCE §483.25(j)
The non-availability of program funding does not relieve a facility of its obligation to ensure that its residents receive all needed services listed in §1819(b)(4)(A) of the Social Security Act for Medicare and §1919(b)(4)(A) of the Act for Medicaid. For services not covered under Medicare or Medicaid, a facility is required to assist the resident in securing any available resources to obtain the needed services.

This requirement does not mean that the facility must purchase or provide funding for the prosthetic.

PROBES *§483.25(j)*
Refer to appropriate sections of the *RAI/*MDS, as applicable.
For residents selected for review, as appropriate:

- Is resident able to *apply* the prosthesis by himself/herself or with some assistance?
- Are residents wearing their prostheses?
- Does the prosthesis fit correctly?
- Is skin/mucous membrane in contact with the prosthesis free of abrasions, wounds, irritation?
- *Is the prosthesis in good condition and functioning as intended?*
- *Is the prosthesis in need of repair?*

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F697

§483.25(k) Pain Management.

The facility must ensure that pain management is provided to residents who require such services, consistent with professional standards of practice, the comprehensive person-centered care plan, and the residents' goals and preferences.

INTENT *§483.25 (k)*

Based on the comprehensive assessment of a resident, the facility must ensure that residents receive the treatment and care in accordance with professional standards of practice, the comprehensive care plan, and the resident's choices, related to pain management.

DEFINITIONS § 483.25 (k)

"Adjuvant *Medication*" describes any medication with a primary indication other than pain management but with analgesic properties in some painful conditions.[2]

"Adverse Consequence" is an unpleasant symptom or event that is due to or associated with a medication, such as impairment or decline in a resident's mental or physical condition or functional or psychosocial status. It may include various types of adverse drug reactions and interactions (e.g., medication-medication, medication-food, and medication-disease).

NOTE: Adverse drug reaction (ADR) is a form of adverse consequences. It may be either a secondary effect of a medication that is usually undesirable and different from the therapeutic effect of the medication or any response to a medication that is noxious and unintended and occurs in doses for prophylaxis, diagnosis, or treatment. The term "side effect" is often used interchangeably with ADR; however, side effects are but one of five ADR categories, the others being hypersensitivity, idiosyncratic response, toxic reactions, and adverse medication interactions. A side effect is an expected, well-known reaction that occurs with a predictable frequency and may or may not constitute an adverse consequence.

GUIDANCE § 483.25 (k)

Recognition and Management of Pain - In order to help a resident attain or maintain his or her highest practicable level of well-being and to prevent or manage pain, the facility, to the extent possible:

- Recognizes when the resident is experiencing pain and identifies circumstances when pain can be anticipated;
- Evaluates the existing pain and the cause(s), and
- Manages or prevents pain, consistent with the comprehensive assessment and plan of care, current professional standards of practice, and the resident's goals and preferences.

Overview of Pain Recognition and Management

Nursing home residents are at high risk for having pain that may affect function, impair mobility, impair mood, or disturb sleep, and diminish quality of life. It is important, therefore, that a resident's reports of pain, or nonverbal signs suggesting pain, be evaluated. The resident's needs and goals as well as the etiology, type, and severity of pain are relevant to developing a plan for pain management. It should be noted that while analgesics can reduce pain and enhance the

quality of life, they do not necessarily address the underlying cause of pain. It is important to consider treating the underlying cause, where possible.

***Strategies for* Pain Management**

Strategies for the prevention and management of pain *may* include *but are not limited to the following:*

- Assessing the potential for pain, recognizing the *onset, presence and duration* of pain, and assessing the *characteristics of the* pain;
- Addressing/treating the underlying causes of the pain, to the extent possible;
- Developing and implementing *both non-pharmacological and pharmacological* interventions/approaches to pain management, depending on factors such as whether the pain is episodic, continuous, or both;
- Identifying and using specific strategies for *preventing or minimizing* different levels or sources of pain or pain-related symptoms based on the resident-specific assessment, *preferences and choices,* a pertinent clinical rationale, and the resident's goals and; using pain medications judiciously to balance the resident's desired level of pain relief with the avoidance of unacceptable adverse consequences;
- Monitoring appropriately for effectiveness and/or adverse consequences (e.g., constipation, sedation) including defining how and when to monitor the resident's symptoms and degree of pain relief; and
- Modifying the approaches, as necessary.

Pain Recognition

Because pain can significantly affect a person's well-being, it is important that the facility recognize and address pain promptly. The facility's evaluation of the resident at admission and during ongoing assessments helps identify the resident who is experiencing pain or for whom pain may be anticipated during specific procedures, care, or treatment. In addition, it is important that a resident be monitored for the presence of pain and be evaluated when there is a change in condition and whenever new pain or an exacerbation of pain is suspected. As with many symptoms, pain in a resident with moderate to severe cognitive impairment may be more difficult to recognize and assess.

Expressions of pain may be verbal or nonverbal *and are subjective.* A resident may avoid the use of the term "pain." Other words used to report or describe pain may differ by culture, language and/or region of the country. Examples of descriptions may include heaviness or pressure, stabbing, throbbing, hurting, aching, gnawing, cramping, burning, numbness, tingling, shooting or radiating, spasms, soreness, tenderness, discomfort, pins and needles, feeling "rough," tearing or ripping. Verbal descriptions of pain can help a practitioner identify the source, nature, and other characteristics of the pain. Nonverbal indicators which may represent pain need to be viewed in the entire clinical context with consideration given to pain as well as other clinically pertinent explanations. Examples of possible indicators of pain include, but are not limited to the following:

- Negative verbalizations and vocalizations (e.g., groaning, crying/whimpering, or screaming);
- Facial expressions (e.g., grimacing, frowning, fright, or clenching of the jaw) ;

- Changes in gait (e.g., limping), skin color, vital signs (e.g., increased heart rate, respirations and/or blood pressure), perspiration;
- Behavior such as resisting care, distressed pacing, irritability, depressed mood, or decreased participation in usual physical and/or social activities;
- Loss of function or inability to perform Activities of Daily Living (ADLs) (*e.g.,* rubbing a specific location of the body, or guarding a limb or other body parts);
- Difficulty eating or loss of appetite; and
- Difficulty sleeping (insomnia).

In addition to the pain item sections of the MDS, many sections such as sleep cycle, change in mood, decline in function, instability of condition, weight loss, and skin conditions can be potential indicators of pain. Any of these findings may indicate the need for additional and more thorough evaluation.

Many residents have more than one active medical condition and may experience pain from several different causes simultaneously. Many medical conditions may be painful such as pressure injuries, diabetes with neuropathic pain, immobility, amputation, post- CVA, venous and arterial ulcers, multiple sclerosis, oral health conditions, and infections. In addition, common procedures, such as moving a resident or performing physical or occupational therapies or changing a wound dressing may be painful. Understanding the underlying causes of pain is an important step in determining optimal approaches to prevent, minimize, or manage pain.

Observations at rest and during movement, particularly during activities that may increase pain (such as dressing changes, exercises, turning and positioning, bathing, rising from a chair, walking) can help to identify whether the resident is having pain. Observations during eating or during the provision of oral hygiene may also indicate dental, mouth and/or facial pain.

Recognizing the presence of pain and identifying those situations where pain may be anticipated involves the participation of health care professionals and direct care and ancillary staff who have contact with the resident. Information may be obtained by talking with the resident, directly examining the resident, and observing the resident's behavior. *Staffing* consistency and familiarity with the residents *has a* significant effect on the staff*'s* ability to identify and differentiate pain-related behavior from other behavior of cognitively impaired residents.

Nursing assistants may be the first to notice a resident's symptoms; therefore, it is important that they are able to recognize a change in the resident and the resident's functioning and to report the changes to a nurse for follow-up. Family members or friends may also recognize and report when the resident experiences pain and may provide information about the resident's pain symptoms, pain history and previously attempted interventions. Other staff, e.g., dietary, activities, therapy, housekeeping, who have direct contact with the resident may also report changes in resident behavior or resident complaints of pain.

Assessment

In addition to the Resident Assessment Instrument (RAI), it is important that the facility identifies how they will consistently assess pain. Some facilities may use assessment tools that are appropriate for use with their resident population. There are many reliable and valid evidenced

based practice tools available to facility staff to assist in the assessment of pain. Pain assessment tools that can be used with cognitively intact and impaired residents can be obtained on the Geriatric Pain website at http://www.geriatricpain.org/Content/Assessment.

An assessment or an evaluation of pain based on *professional* standards of practice may necessitate gathering the following information, as applicable to the resident:

- History of pain and its treatment (including non-pharmacological and pharmacological treatment *and whether or not each treatment has been effective*);
- Characteristics of pain, such as: (intensity, pattern, location, frequency and duration)
- Impact of pain on quality of life (e.g., sleeping, functioning, appetite, and mood);
- Factors such as activities, care, or treatment that precipitate or exacerbate pain *as well as those that reduce or eliminate the pain;*
- Additional symptoms associated with pain (e.g., nausea, anxiety);
- *Physical and psychosocial issues* (physical *examination of the site of the pain, movement, or activity that causes the pain, as well as any discussion with resident about any* psychological *or psychosocial concerns that may be causing or exacerbating the pain*);
- Current medical conditions and medications; *and*
- The resident's goals for pain management and his or her satisfaction with the current level of pain control.

While it may be difficult to conduct a thorough assessment of all of the above factors in a cognitively impaired or non-responsive resident, the facility staff is responsible for obtaining as much information as possible and evaluating the resident's pain through all available means. Observing the resident during care, activities, and treatments helps not only to detect whether pain is present, but also to potentially identify its location and the limitations it places on the resident.

Management of Pain

Based on the evaluation, the facility, in collaboration with the attending physician/prescriber, other health care professionals, and the resident and/or his/her representative, develops, implements, monitors and revises as necessary interventions to prevent or manage each individual resident's pain, beginning at admission. These interventions may be integrated into components of the comprehensive care plan, addressing conditions or situations that may be associated with pain, or may be included as a specific pain management need or goal.

The interdisciplinary team and the resident *and/or representative* collaborate to arrive at pertinent, realistic and measurable goals for treatment, such as reducing pain sufficiently to allow the resident to ambulate comfortably to the dining room for each meal or to participate in 30 minutes of physical therapy. Depending on the situation and the resident's wishes, the target may be to reduce the pain level, but not necessarily to become pain-free. To the extent possible, the interdisciplinary team educates the resident and/or representative about the need to report pain when it occurs and about the various approaches to pain management and the need to monitor the effectiveness of the interventions used.

Effective November 28, 2017

The basis for effective interventions includes several considerations, such as the resident's needs and goals; the source(s), type and severity of pain (recognizing that the resident may experience pain from one or more sources either simultaneously or at different times) and awareness of the available treatment options. Often, sequential trials of various treatment options are needed to develop the most effective approach.

It is important for pain management approaches to follow pertinent professional standards of practice and to identify who is to be involved in managing the pain and implementing the care or supplying the services (e.g., facility staff, such as RN, LPN, CNA; attending physician or other practitioner; certified hospice; or other contractors such as therapists). Pertinent current professional standards of practice may provide recommended approaches to pain management even when the cause cannot be or has not been determined.

Non-pharmacological interventions

Research supports physical activity and exercise as a part of most treatment programs for chronic pain. Activity can be supported by conventional physical therapy and exercise approaches, or by a wide range of movement therapies.

Some non-pharmacologic interventions may need to be ordered by the provider while others can be provided by facility staff during routine care. Examples of non-pharmacological interventions may include, but are not limited to:

- Altering the environment for comfort (such as adjusting room temperature, tightening and smoothing linens, using pressure redistributing mattress and positioning, comfortable seating, and assistive devices);
- Physical modalities, such as ice packs or cold compresses (to reduce swelling and lessen sensation), mid heat (to decrease joint stiffness and increase blood flow to an area), neutral body alignment and repositioning, baths, transcutaneous electrical nerve stimulation (TENS), massage, acupuncture/acupressure, chiropractic, or rehabilitation therapy;
- Exercises to address stiffness and prevent contractures *as well as restorative nursing programs to maintain joint* mobility; and
- Cognitive/Behavioral interventions (e.g., relaxation techniques, reminiscing, diversions, activities, music therapy, *offering spiritual support and comfort, as well as teaching the resident* coping techniques and education about pain).

Pharmacological interventions

The interdisciplinary team (nurses, practitioner, pharmacists, etc.) is responsible for developing a pain management regimen that is specific to each resident who has pain or who has the potential for pain, such as during a treatment. The regimen considers factors such as the causes, location, and severity of the pain, the potential benefits, risks and adverse consequences of medications; and the resident's desired level of relief and tolerance for adverse consequences. The resident may accept partial pain relief in order to experience fewer significant adverse consequences (e.g., desire to stay alert instead of experiencing drowsiness/confusion). The interdisciplinary team works with the resident to identify the most effective and acceptable route for the administration of analgesics, such as orally, *rectally*, topically, by injection, by infusion pump, and/or transdermally.

It is important to follow a systematic approach for selecting medications and doses to treat pain. Developing an effective pain management regimen may require repeated attempts to identify the right interventions. General guidelines for choosing appropriate categories of medications in various situations are widely available *to the provider, pharmacist and nurses*.
Factors influencing the selection and doses of medications include the resident's medical condition, current medication regimen, nature, severity, and cause of the pain and the course of the illness. Analgesics may help manage pain; however, they often do not address the underlying cause of pain. Examples of different approaches may include, but are not limited to: administering lower doses of medication initially and titrating the dose slowly upward, administering medications "around the clock" rather than "on demand" (PRN); or combining longer acting medications with PRN medications for breakthrough pain. Recurrent use of or repeated requests for PRN medications may indicate the need to reevaluate the situation, including the current medication regimen. Some clinical conditions or situations may require using several analgesics and/or adjuvant medications (e.g., antidepressants or anticonvulsants) together. Documentation helps to clarify the rationale for a treatment regimen and to acknowledge associated risks.

Opioids or other potent analgesics have been used for residents who are actively dying, those with complex pain syndromes, and those with more severe acute or chronic pain that has not responded to non-opioid analgesics or other measures. Opioids should be selected and dosed in accordance with current professional standards of practice and manufacturers' guidelines in order to optimize their effectiveness and minimize their adverse consequences. Adverse consequences may be especially problematic when the resident is receiving other medications with significant effects on the cardiovascular and central nervous systems. Therefore, careful titration of dosages based on monitoring/evaluating the effectiveness of the medication and the occurrence of adverse consequences is necessary. The clinical record should reflect the ongoing communication between the prescriber and the staff is necessary for the optimal and judicious use of pain medications.

Other interventions have been used for some residents with more advanced, complex, or poorly controlled pain *such as* radiation therapy, neurostimulation, spinal delivery of analgesics (implanted catheters and pump systems), and neurolytic procedures (chemical or surgical) that are administered under the close supervision of expert practitioners. *Referrals to pain management clinics and pain management specialists may also be appropriate in these situations*.

Monitoring, Reassessment, and Care Plan Revision
Monitoring the resident over time helps identify the extent to which pain is controlled, relative to the individual's goals and the availability of effective treatment. The ongoing evaluation of the status (presence, increase or reduction) of a resident's pain is vital, including the status of underlying causes, the response to interventions to prevent or manage pain, and the possible presence of adverse consequences of treatment. Adverse consequences related to analgesics can often be anticipated and to some extent prevented or reduced. For example, opioids routinely cause constipation, which may be minimized by an appropriate bowel regimen.

Identifying target signs and symptoms (including verbal reports and non-verbal indicators from the resident) and using standardized assessment tools can help the interdisciplinary team evaluate the resident's pain and responses to interventions and determine whether the care plan should be revised, for example:

- If pain has not been adequately controlled, it may be necessary to reconsider the current approaches and revise or supplement them as indicated; or
- If pain has resolved or there is no longer an indication or need for pain medication, the facility works with the practitioner to discontinue or taper (as needed to prevent withdrawal symptoms) analgesics.

KEY ELEMENTS OF NONCOMPLIANCE

To cite deficient practice at F697, the surveyor's investigation will generally show that the facility failed to do one or more of the following:

- *Provide pain management to a resident experiencing pain; or*
- *Provide pain management that met professional standards of practice; or*
- *Provide pain management that was in accordance with the resident's comprehensive care plan, and the resident's goals for care and preferences.*

INVESTIGATIVE SUMMARY

Use the Pain Recognition and Management Critical Element (CE) Pathway, along with the above interpretive guidelines when determining if the facility provides pain management that meets professional standards of practice; and that is in accordance with the resident's comprehensive care plan, goals for care and preferences.

Summary of Procedure

Briefly review the most recent comprehensive assessments, comprehensive care plan and orders to identify whether the facility has assessed and developed an individualized care plan based on professional standards of practice and provided by qualified, competent staff. During this review, identify the extent to which the facility has implemented interventions in accordance with the resident's needs, goals for care and professional standards of practice, consistently across all shifts. This information will guide observations and interviews to be made in order to corroborate concerns identified.

***NOTE**: Always observe for visual cues of psychosocial distress and harm (see Appendix P, Guidance on Severity and Scope Levels and Psychosocial Outcome Severity Guide).*

DEFICIENCY CATEGORIZATION

In addition to actual or potential physical harm, always consider whether psychosocial harm has occurred when determining severity level (See Appendix P, Section IV, E, Psychosocial Outcome Severity Guide).

An example of Severity Level 4 Noncompliance: Immediate Jeopardy to Resident Health or Safety includes, but is not limited to:

- *Facility failed to implement an effective pain management regime for a resident who sustained a fracture of the hip and was determined to not be a surgical candidate. Resident stated that pain medication was not effective, and she was in continuous pain.*

She indicated she had notified staff of the pain, but nothing was done. Interview of staff indicated no one had contacted the practitioner to discuss the ineffective pain relief. The staff stated that they were concerned regarding the amount of pain medication the resident was receiving and that they were concerned that she would become increasingly tolerant and addicted to the medication. They stated they were aware that the resident declined assistance with ADL's due to "pain" and felt that the resident was not having the amount of pain that she stated she had. The resident was observed on multiple occasions to, hold her hip area, moaning and crying out, sweating, and striking out when staff attempted to move her.

An example of Severity Level 3 Noncompliance: Actual Harm that is not Immediate Jeopardy includes, but is not limited to:

- *The facility failed to provide effective pain management to a resident with a diagnosis of bone cancer. Record review revealed the resident only had PRN (as needed) pain medication every six hours. According to the resident this pain regime was not effective resulting in excruciating breakthrough pain multiple times each day. The resident said that staff would tell her she had to wait, and often would not get the PRN medicine promptly when it was due. The surveyor observed the resident to be tearful and unable to participate in activities.*

Examples of Severity Level 2 Noncompliance: No Actual Harm with potential for more than minimal harm that is Not Immediate Jeopardy includes, but is not limited to:

- *Facility failed to provide an effective pain management treatment per the resident's choice and preference. A resident request a hot shower on the evening shift as an effective intervention for back pain. The staff member assigned to her informed her that she would not be able to be showered until later in the evening. A staff member who understood what the resident was experiencing quickly intervened and gave her a hot shower relieving her back pain.*
- *The facility staff failed to consistently evaluate the effectiveness of regularly scheduled pain medication on a resident. The resident was receiving the pain medication on a routine basis, however, the record did not reflect the resident's response to the administration of the pain medication. In interviews, the resident stated that her pain was being managed for the most part, but that staff did not ask her if she received relief from the medication. She stated that occasionally, she would not attend an activity due to discomfort, but this did not routinely occur. When she mentioned it to staff, they would tell her to lie down for a while and would check on her later. However, she stated that they usually did not recheck her. Staff interviewed stated they didn't have the time to go back, check, and record the resident's response, but, if she complained, they would recheck her and see if she needed anything else.*

Severity Level 1 noncompliance: No actual harm with potential for minimal harm includes, *The failure of the facility to provide appropriate care and services related to pain management places the resident at risk for more than minimal harm. Therefore Severity 1 does not apply for this regulatory requirement.*

Effective November 28, 2017

F698

§483.25(l) Dialysis.

The facility must ensure that residents who require dialysis receive such services, consistent with professional standards of practice, the comprehensive person-centered care plan, and the residents' goals and preferences.

INTENT: §483.25(l)

The intent of this requirement is that the facility assures that each resident receives care and services for the provision of hemodialysis and/or peritoneal dialysis consistent with professional standards of practice including the:

- *Ongoing assessment of the resident's condition and monitoring for complications before and after dialysis treatments received at a certified dialysis facility;*
- *Safe administration of hemodialysis at the bedside and/or peritoneal dialysis in the nursing home provided by qualified trained staff/caregivers, in accordance with State and Federal laws and regulations;*
- *Ongoing assessment and oversight of the resident before, during and after dialysis treatments, including monitoring the resident's condition during treatments, monitoring for complications, implementing appropriate interventions, and using appropriate infection control practices; and*
- *Ongoing communication and collaboration with the dialysis facility regarding dialysis care and services.*

DEFINITIONS

"End-Stage Renal Disease (ESRD)" *- The stage of renal impairment that appears irreversible and permanent, and requires a regular course of dialysis or kidney transplantation to maintain life. (42 CFR, Part 405 - §405.2102)*

"Dialysis" - *A process by which dissolved substances are removed from a patient's body by diffusion from one fluid compartment to another across a semipermeable membrane. The two types of dialysis that are currently in common use are hemodialysis (HD) and peritoneal dialysis (PD). (§405.2102)*

"Dialysis facility" - *means an entity that provides outpatient maintenance dialysis services or home dialysis training and support services, or both. (§494.10 Definitions)*

"Home Dialysis" - *Home dialysis means dialysis performed at home by an ESRD patient or caregiver who has completed an appropriate course of training as described in §494.100(a) of this part.*

NOTE*: For the purposes of this guidance the term "nursing home" refers to a long-term care facility and dialysis facility refers to a Medicare certified dialysis facility. Home hemodialysis will be referenced as HHD.*

INTERPRETIVE GUIDANCE: 483.25(l)

There is no requirement that a nursing home must offer dialysis services. If the nursing home has an arrangement with a dialysis facility for the provision of dialysis services, the nursing

home must inform each resident before or at the time of admission, and periodically thereafter during the resident's stay, of dialysis services, if available in the nursing home.

Residents of a nursing home may receive dialysis treatments through two main options:

- ***Medicare Certified Dialysis Facility:*** *This may involve either:*
  - *Transporting to and from an off-site certified dialysis facility for dialysis treatments; or*
  - *Transporting to a location within or proximate to the nursing home building which is dedicated for and separately certified as a dialysis facility providing in-center dialysis; and/or*
- ***Dialysis in a Nursing Home****: Receive home hemodialysis (HHD) or peritoneal dialysis (PD) treatments in the nursing home, by trained and qualified staff who have received training and competency from the dialysis facility.*

If a current resident has been identified as meeting the criteria for HHD/PD by the dialysis facility team, and the nephrologist or the physician prescribing dialysis, and chooses to receive either HHD/PD, and the nursing home does not allow for these onsite services, the nursing home must assist the resident with the transfer to a nursing home or in the relocation to a setting (e.g. private home, or residential/assisted living facility) of his/her choice that provides HHD/PD services.

NOTE*: The long-term care survey team does not have the authority under Federal nursing home regulations to review the care and services provided directly within a Medicare-certified dialysis facility located either on or offsite. If at any time during the survey, a concern or issue arises regarding the dialysis services provided to a sampled resident by the dialysis facility, the survey team should report this as a complaint to the State Agency survey unit responsible for oversight of the Medicare certified ESRD entity. The survey team must identify the specific resident(s) involved and the concerns identified.*

Responsibilities for the Provision of Dialysis Care/Services

If the nursing home has made the decision to provide dialysis care and services according to the options above, there must be, in accordance with current standards of practice, coordination and collaboration between the nursing home and the dialysis facility to assure that:

- *The resident's needs related to dialysis treatments are met;*
- *Only trained and qualified staff/caregivers administer the dialysis treatments;*
- *The provision of the dialysis treatments and care of the resident meets current standards of practice for the safe administration of the dialysis treatments;*
- *Documentation requirements are met to assure that treatments are provided as ordered by the nephrologist, attending practitioner and dialysis team; and*
- *There is ongoing communication and collaboration for the development and implementation of the dialysis care plan by nursing home and dialysis staff.*

The nursing home remains responsible for the overall quality of care the resident receives and must provide the same services to a resident who is receiving dialysis as it furnishes to its residents who are not. This includes the ongoing provision of assessment, care planning and provision of care. There must be a coordinated plan for dialysis treatments developed with input

from both the nursing home and dialysis facility. The resident should not experience any lack of nursing home services or care because of his or her dialysis status. The nursing home staff must be aware and identify changes in resident's behavior, especially for a cognitively impaired resident, that may impact the safe administration of dialysis, including, resistance to care, and pulling on tubes/access sites and inform the attending practitioner and dialysis facility of the changes. This requires more frequent and increased observations and monitoring for this resident before, during (if dialysis is provided by nursing home staff/caregivers or the resident) and after dialysis treatments.

***NOTE**: The nursing home may wish to designate a staff person to coordinate activities and communications with each dialysis facility that they have arrangements with to provide dialysis services.*

The dialysis facility is responsible for the medical management for the end stage renal disease including dialysis treatments, performed offsite or onsite. It is the responsibility of the dialysis facility to provide all necessary equipment and supplies for the provision of the dialysis treatments, including maintenance and repair as needed, testing/monitoring water and dialysate quality for the dialysis treatment, and for the training of individuals providing the HHD/PD.

Shared Communication between the Nursing Home and the Dialysis facility

It is essential that a communication process be established between the nursing home and the dialysis facility to be used 24-hours a day. The care of the resident receiving dialysis services must reflect ongoing communication, coordination and collaboration between the nursing home and the dialysis staff. The communication process should include how the communication will occur, who is responsible for communicating, and where the communication and responses will be documented in the medical record, including but not limited to:

- *Timely medication administration (initiated, administered, held or discontinued) by the nursing home and/or dialysis facility;*
  Physician/treatment orders, laboratory values, and vital signs;
- *Advance Directives and code status; specific directives about treatment choices; and any changes or need for further discussion with the resident/representative, and practitioners;*
- *Nutritional/fluid management including documentation of weights, resident compliance with food/fluid restrictions or the provision of meals before, during and/or after dialysis and monitoring intake and output measurements as ordered;*
- *Dialysis treatment provided and resident's response, including declines in functional status, falls, the identification of symptoms such as anxiety, depression, confusion, and/or behavioral symptoms that interfere with treatments;*
- *Dialysis adverse reactions/complications and/or recommendations for follow up observations and monitoring, and/or concerns related to the vascular access site/PD catheter;*
- *Changes and/or decline in condition unrelated to dialysis. This would include communication related to care concerns such as a resident who is at risk for or who has a pressure ulcer, receiving appropriate interventions; and*
- *The occurrence or risk of falls and any concerns related to transportation to and from the dialysis facility.*

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Coordination of Physician Services between the Nursing Home and Dialysis facility
For a resident receiving dialysis, the nursing home staff must immediately contact and communicate with the attending physician/practitioner, resident/resident representative, and designated dialysis staff (i.e., nephrologist, registered nurse) regarding any significant changes in the resident's status related to clinical complications or emergent situations that may impact the dialysis portion of the care plan. (Refer to F580 – Notification of Changes in condition) These situations may include but are not limited to changes in cognition or sudden unexpected decline in condition, dialysis complications such as bleeding, hypotension, or adverse consequences to a medication or therapy, or other situations.

Any changes in the resident's care initiated by the dialysis facility must be communicated to the resident's nursing home attending physician/practitioner.

Hospital Transfer
The dialysis facility must ensure access to a hospital for emergency services that has the capacity to provide emergency dialysis care (ESRD Conditions for Coverage (CfC) at V770 - §494.180). In order to assure that the dialysis needs of the resident are met in the case of an emergency, the care plan should identify acute care settings that would be able to meet the resident's need for dialysis.

In case of the need to transfer to an acute care facility to manage dialysis complications or other care concerns, the nursing home must have ongoing communication with the dialysis facility and have knowledge of the location and how to access the hospital that has the capacity to provide emergency dialysis care, as identified by the dialysis facility.

***NOTE**: According to the ESRD regulations at V770 - §494.180 - The dialysis facility must have an agreement with a hospital that can provide inpatient care, routine and emergency dialysis and other hospital services, and emergency medical care which is available 24 hours a day, 7 days a week. The agreement must: (i) Ensure that hospital services are available promptly to the dialysis facility's patients when needed. (ii) Include reasonable assurances that patients from the dialysis facility are accepted and treated in emergencies.*

Resident Care Policies and Staffing Specific to Dialysis Care and Services
Some State licensure rules don't allow for the provision of HHD in a nursing home and/or a State's nurse practice act or scope of practice may preclude certain health care workers from performing HHD treatments. Some State licensing rules may have specific regulations related to the provision of HHD/PD in a nursing home, such as specifying patient to staff ratio requirements. The nursing home must identify who is allowed to provide HHD/PD treatments to a resident, such as a licensed nurse or nurse aide. The dialysis facility is responsible for providing training and assuring the competency of staff or individuals that are allowed to initiate, access and discontinue dialysis treatments. The nursing home must maintain documentation of completion of training/competency for staff or other individuals providing the dialysis treatments.

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***NOTE**: Anecdotally, it has been reported that some nursing homes provide dialysis for multiple residents at a time in a single area/den setting. The facility must assure that compliance is maintained for providing dialysis in a location that promotes dignity, individual privacy during treatments, sufficient staff, access to a call system and hand washing facilities, availability of emergency equipment and supplies, secured medication storage and preparation area, including a refrigerator as necessary, soiled utility area, disposal of equipment and supplies, and based upon professional standards of practice, the maintenance of effective infection control practices and measures. This includes ensuring that a resident who is hepatitis B+ is not dialyzed in the same location as resident who is not hepatitis B+. Consideration should be given to implementing appropriate infection control practices related to care of a resident who is hepatitis B+, such as using dedicated staff, a dedicated machine, equipment, instruments, and supplies that will not be used by other resident's including a resident who is not hepatitis B+.*

If PD treatments are provided, the treatments may only be administered by an individual trained by the qualified dialysis trainer from the certified dialysis facility. An LPN/LVN may administer the PD treatment if not in conflict with the States Nurse Practice Act/Scope of practice.

A nursing home, that provides dialysis treatments, in collaboration with the nursing home medical director and the dialysis facility, must develop dialysis specific policies/procedures, based upon current standards of practice. This includes the care of a resident receiving dialysis services whether in the facility or at an offsite location. (Refer to F841 – Responsibilities of Medical Director.) At a minimum, these policies must include, but are not limited to the following:

- *The identification of all staff or contracted individuals who are allowed to provide HHD/PD and the training required. An RN, LPN/LVN, a nurse aide or a trained technician can provide dialysis treatments if not in conflict with the States Nurse Practice Act/Scope of practice and only if the individual has received training from a qualified dialysis trainer from a certified dialysis facility for the individual resident receiving HHD/PD;*
- *The documentation of training and competency requirements for individuals providing dialysis treatments;*
- *If the facility allows a resident/family member or other individual to provide HHD or PD treatments, documentation that training and competency was provided by the certified dialysis facility;*
- *Procedures for the initiation, administration and discontinuation of HHD/PD treatments, type of monitoring required before, during and after the treatments, including documentation requirements;*
- *Procedures for methods of communication between the nursing home and the dialysis facility including how it will occur, with whom, and where the communication and responses will be documented;*
- *The development and implementation of a coordinated comprehensive care plan(s) that identifies nursing home and dialysis responsibilities and provides direction for nursing home staff; and*
- *The development and implementation of interventions, based upon current standards of practice including, but not limited to documentation and monitoring of complications,*

pre-and post-dialysis weights, access sites, nutrition and hydration, lab tests, vital signs including blood pressure and medications;

- *Management of dialysis emergencies including procedures for medical complications, and for equipment and supplies necessary;*
- *The provision of medications on dialysis treatment days;*
- *Procedures for monitoring and documenting nutrition/hydration needs, including the provision of meals on days that dialysis treatments are provided;*
- *Assessing, observing and documenting care of access sites, as applicable, such as:*
  - *Auscultation/palpation of the AV fistula (pulse, bruit and thrill) to assure adequate blood flow;*
  - *Significant changes in the extremity when compared to the opposite extremity (edema, pain, redness);*
  - *Steal Syndrome (pain, numbness, discoloration, or cold to touch in the fingers or hand indicating inadequate arterial flow);*
  - *Skin integrity (waxy skin, ulcerations, drainage from incisions);*
  - *Bruising/hematoma;*
  - *Collateral vein distension (veins in access arm close to AV fistula becoming larger);*
  - *Complaints of pain or numbness; or*
  - *Evidence of infection at the surgical site, such as drainage, redness, tenderness at incision site, fever.*
- *Safe and sanitary care and storage of dialysis equipment and supplies;*
- *Responsibility for reporting adverse events, including who to report to, investigating the event and correcting identified problems;*
- *Response and management of technical problems related to HHD and/or PD treatments, such as power outages or:*
  - *For PD, how to recognize impaired flow and drainage or failure of the PD cycler;*
  - *For failure of HHD machines: clotting of the hemodialysis circuit, dialyzer blood leak, or line disconnection; and*
  - *For HHD/PD: how and when to stop dialysis and/or seek help when there are significant issues.*

***NOTE**: The dialysis facility is responsible for the overall provision and maintenance of the dialysis equipment and monitoring source water. The nursing home staff should be aware of any issues with the source water, and the care plan should address these issues. The nursing home trained and qualified staff responsible for providing the dialysis treatment, must know how to use the dialysis equipment and identify if there are issues in order to provide safe treatments.*

- *Dialysis specific infection control policies, including but not limited to:*
  - *Transmission based precautions including blood borne precautions, placement/location (cohorting), staff/visitor personal protection equipment (PPE) requirements, indications for the use of gloves, masks, and hand hygiene;*
  - *Potential health care associated infections (HAI) including Hepatitis B and tuberculosis;*
  - *Restrictions for visitors/roommate, if any, during provision of HHD/PD;*

- *Handling, using, and disposing of equipment/supplies, medications or other products in accordance with manufacturer's instructions, and in accordance with all applicable Federal, State and local laws and regulations;*

***NOTE**: Nursing home staff who have been trained to provide dialysis treatments for a resident, must understand how to properly dispose of needles, effluents, disposable items, blood tubing and dialyzers to minimize risks of infection or injury to self and others and to prevent environmental contamination (e.g. using impervious puncture resistant containers for disposal of sharps, placing empty dialysate bags and dialysis tubing and other contaminated items in specific biohazard container(s) or bag(s) before discarding.*

- *Obtaining and reviewing dialysis facility monitoring for the dialysis water and dialysate quality, including total chlorine testing and at least quarterly testing of water and dialysate bacterial and endotoxin as applicable to the HHD equipment in use;*
- *Types of furnishings allowed (such as a recliner used during the dialysis treatment), based on infection control standards and the cleaning/sanitizing of these furnishings that have the potential to become contaminated with blood/blood products;*
- *Access to clean sink for hand washing, in addition, disposal needs to be addressed for dialysis by-products from the dialysis treatment;*
- *Housekeeping/laundry policies for cleaning/sanitizing the location(s) where treatments are provided, including linen handling and waste disposal;*
- *Vascular access or peritoneal catheter care and dressing changes; and*
- *Cleaning and disinfecting dialysis equipment, including procedures for spills and splashes of blood or effluent on furnishings, equipment, floors and supplies.*

***NOTE**: For information regarding home dialysis guidance see ESRD CfC 494.100 – V580 Care at Home. This condition also provides information regarding the provision of home dialysis including water treatment and quality testing and other requirements of the ANSI/AAMI RD52:2004. For information related more specifically to water testing and treatment refer to:*

- *V-253 -ANSI/AAMI RD52:2004 Requirements as Adopted by Reference 42 CFR 494.40 (a)7.2 Microbial monitoring methods: 7.2.1 General: Dialysate: monthly dialysate sample/collection/frequency. Culture …dialysate fluid weekly for new systems until a pattern has been established. For established systems, culture monthly unless a greater frequency is dictated by historical data at a given institution; and*
- *V 278 - In-center preconfigured HD: quarterly cultures/LALs Moreover, the facility must perform bacteriological and endotoxin testing on a quarterly, or more frequent basis, as needed, to ensure that the water and dialysate are within AAMI limits.*

Some portable dialysis machines may have a self-check system and more stringent requirements may need to be followed as recommended by the manufacturer.

Dialysis Provided at a Medicare Certified Dialysis Facility Located Offsite or Onsite

A resident may choose to receive dialysis at a dialysis facility located off site or in a separately certified dialysis unit located within the facility. The choice of the dialysis provider is made by the resident/resident representative. The nursing home must assist the resident to assure that

arrangements are provided for safe transportation to and from the dialysis facility. (See F745 – Social Services).

The nursing home staff must provide immediate monitoring and documentation of the status of the resident's access site(s) upon return from the dialysis treatment to observe for bleeding or other complications. The nursing home and dialysis facility dietitians should coordinate the nutritional care including monitoring, documenting, and deciding how and when to address weight changes and nutrition issues. This includes identifying weight fluctuations due to fluid retention between dialysis sessions, possible fluid volume depletion in the immediate post-dialysis period or associated with anorexia which may be due to renal failure. Staff must weigh the resident and document the findings based on orders. If weight loss occurs, the facility must notify the attending practitioner and dialysis facility practitioner regarding the management for causes of anorexia and weight loss other than fluid loss that might present.

Home Hemodialysis provided by Nursing Home Staff
The nursing home must continue to meet the nursing home requirements found throughout 42 CFR Part 483 to assure the residents health, safety and well-being. The facility must be able to demonstrate in collaboration with the dialysis facility, the arrangements in place in order to provide safe HHD/HPD through qualified trained staff/caregivers and assure that the resident receives the dialysis treatments as ordered. The nursing home is responsible for the ongoing coordination of dialysis care in collaboration with the Medicare certified ESRD entity. The nursing home resident who receives dialysis is entitled to the same rights, services, and efforts to achieve expected outcomes as a person receiving dialysis at a dialysis facility.

***NOTE**: According to 42 CFR §494.100 - V581, a dialysis facility that is certified to provide services to home patients must ensure through its interdisciplinary team, that home dialysis services are at least equivalent to those provided to in-facility patients and meet all applicable conditions part 494. This does not imply that the nursing home surveyor surveys to or applies ESRD regulations.*

- *Provision of HHD Treatments*

The nursing home and the dialysis facility must have ongoing communication to coordinate the care and manage any changes/issues that arise. The nursing home staff must use appropriate infection precautions, including blood-borne precautions, for all aspects of dialysis care. In addition, if the HHD is provided in a semi-private resident room, adherence to the right of privacy during treatment is required. The nursing home staff must have specific written guidance for identifying and handling complications and emergencies before, during and after the provision of HHD.

The nursing home must have a system in place for staff to contact the dialysis facility immediately with any concerns/issues regarding dialysis. This includes who to communicate with, such as the dialysis staff, attending practitioner, or nephrologist regarding HHD. The nursing home must have dialysis facility contact numbers readily accessible to licensed nursing home staff that assures the on-call dialysis qualified licensed professional staff is available by phone 24 hours a day 7 days a week.

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HHD may be performed by either the resident (if physically and cognitively capable) or an individual, such as a family member (if allowed by the nursing home), nursing home staff or a contracted individual, such as a licensed nurse or dialysis technician, who has completed training/competency by a qualified trainer from a Medicare certified dialysis facility in accordance with State licensure, Scope of Practice for Nursing. The required training for staff providing HHD (and PD) treatments in nursing homes must be individualized and ***resident specific*** *and provided directly by the Medicare certified dialysis facility that is responsible for the provision of the resident's overall dialysis care. This training cannot be provided by nursing home staff even if they have previously received the training for dialysis by this or another dialysis facility for another resident. The nursing home must have documentation of the completion of resident specific dialysis training by the dialysis facility for each nursing home staff member providing dialysis treatments for the resident. While a nursing home may allow a resident and/or a dialysis trained caregiver to provide the dialysis treatment, the nursing home nonetheless remains responsible for the resident's care and services.*

The facility must maintain documentation of the required ongoing dialysis training in order to assure qualified staff/caregivers are capable of providing the HHD treatments. (Refer to F658) Training based upon current standards of practice must include, but not be limited to, the following:

- *Specific (step-by step) instructions on how to use the resident's prescribed dialysis equipment (e.g. hemodialysis machine and water treatment components);*
- *Specific (step-by step) instructions in home dialysis procedures to facilitate adequate dialysis as prescribed by the physician;*
- *Training in proper storage and administration of Erythropoiesis-Stimulating Agents (ESAs), if applicable and in accordance with State laws and State scope of practice. ESAs are medications that may be used to treat anemia in a resident with a diagnosis of ESRD;*
- *How to identify/recognize medical emergencies, implement immediate responses/actions and methods for contacting emergency medical systems. Medical emergencies may include, but are not limited to, cardiac arrest, air embolism, drug reactions, suspected pyrogen reactions, profound hypotension or hypertension and significant blood loss;*
- *How to recognize, manage and report such potential complications as vascular access problems such as difficulty with cannulation, a change in bruit or thrill, or bleeding, and infections, hypertension or hypotension, hyperkalemia, etc;*
- *Infection control practices, including indications for the use of gloves, masks, and other personal protective equipment, methods for hand hygiene, vascular access and dressing changes, cleaning and disinfecting dialysis equipment, cleaning and disinfection procedures for spills and splashes of blood or effluent;*
- *Identifying symptoms associated with water and dialysate contamination that cannot be readily attributed to other causes. Clinical symptoms may include, but are not limited to, chills, shaking, fever, vomiting, headache, dizziness, muscle weakness, skin flushing, itching, diarrhea, hyper/hypotension, hemolysis and anemia. If such symptoms are present, the facility must notify the attending practitioner and dialysis team to determine appropriate action; and*
- *Recognizing, managing and reporting power outages, failure of the HD machine, failure of water treatment components (e.g., chlorine/chloramine breakthrough), clotting of the*

hemodialysis circuit, dialyzer blood leaks, line disconnection, water supply problems or leaks, and problems with supply delivery.

The nursing home must have orders for the provision of the dialysis treatments, including individualized dialysis prescription such as, at a minimum, the number of treatments per week, length of treatment time, the type of dialyzer, and specific parameters of the dialysis delivery system (e.g., electrolyte composition of the dialysate, blood flow rate, and dialysate flow rate), anticoagulation, and the resident's target weight.

The resident's care plan must, based on standards of practice, identify the resident specific parameters for blood pressure, weights and other vital signs. The resident's blood pressures must be monitored pre, during, and post treatment and abnormal values must be addressed. Excessively high or low blood pressure measurements during treatment without evidence of assessment and action to address those values would indicate the care plan for this parameter was either not developed or not implemented. The nursing home staff must provide ongoing assessment of the resident during dialysis, including vital signs, level of consciousness, muscle cramping, itching and comfort or distress; and must report identified or suspected complications to the attending practitioner and identified dialysis staff to enable timely interventions. In addition, staff must ensure that a resident who is hepatitis B+ is not dialyzed in the same location as resident who is not hepatitis B+. Consideration should be given to implementing appropriate infection control practices related to care of a resident who is hepatitis B+, such as using dedicated staff, a dedicated machine, equipment, instruments, and supplies that will not be used by other resident's including a resident who is not hepatitis B+.

***NOTE**: According to the interpretive guidelines at ESRD regulation V581 - CFR 494.100 Condition: Care at Home – "Home dialysis patients are considered part of the census of the ESRD facility and are entitled to the same rights, services, and efforts to achieve expected patient outcomes as the in-center dialysis patients of the facility."*

After receiving dialysis, staff must obtain vital signs, assess the resident's stability and monitor for post-dialysis complications and symptoms such as but not limited to dizziness, nausea, vomiting, fatigue or hypotension.

The resident receiving HHD must be under direct observation of the trained caregiver who must be physically present in the room with the resident throughout the entire HHD treatment in the immediate location where the HHD is being provided.

***NOTE**: Nursing home staff assigned to provide an HHD treatment, must not have assignments for additional residents throughout the duration of the HHD treatment and after completed until the resident is determined stable according to accepted standards of practice.*

The resident's vascular access site and bloodline connections must be able to be seen by the trained caregiver throughout the dialysis treatment. Allowing a resident to cover access sites and line connections provides an opportunity for accidental needle dislodgement or a line disconnection to go undetected. This dislodgement or disconnection could result in exsanguination and death in minutes. The medical record should reflect the care and monitoring

of the access site, including but not limited to examining the arteriovenous fistula (AV fistula) and/or surgical incisions to detect problems that require immediate notification of the attending practitioner.

Peritoneal Dialysis (PD) Provided by Nursing Home Staff

If the nursing home provides PD on site, it is responsible for the ongoing coordination of dialysis care in collaboration with the Medicare certified dialysis facility. The nursing home staff must have specific written guidance for the provision of treatments, and handling complications and emergencies during the provision of PD. The nursing home must have contact information available for staff to assure that dialysis qualified licensed professional staff is available by phone 24 hours a day 7 days a week, including who to communicate with regarding PD related issues.

PD may be performed by either the resident (if physically and cognitively capable) or an individual, such as a family member (if allowed by the nursing home), nursing home staff or a contracted caregiver who has completed training/competency by a qualified trainer from a Medicare certified dialysis facility. While a nursing home may allow a resident and/or a dialysis trained caregiver to provide the dialysis treatment, the nursing home nonetheless remains responsible for the resident's care and services.

The facility must maintain documentation of the required ongoing dialysis training in order to assure qualified staff/caregivers are capable of providing the PD treatments. (Refer to F658 – Meeting professional standards) Training based upon current standards of practice must include, but not be limited to, the following:

- *Specific (step-by step) instructions on how to use the resident's prescribed dialysis equipment (e.g. peritoneal dialysis cycler) and instructions in home dialysis procedures for PD to facilitate adequate dialysis as prescribed by the practitioner;*
- *Training in proper storage and administration of Erythropoiesis-Stimulating Agents (ESAs), if applicable;*
- *How to identify/recognize medical emergencies, implement immediate responses/actions and methods for contacting emergency medical systems. Medical emergencies may include, but are not limited to, cardiac arrest, drug reactions, suspected pyrogen reactions, profound hypotension or hypertension and significant blood loss;*
- *How to recognize, manage and report dialysis complications, including catheter, tunnel or exit site infection; peritonitis; catheter dislodgement; hypotension; hypokalemia; failure of sufficient dialysate to drain from the peritoneal space; protein malnutrition;*
- *Indications for the use of gloves, masks, and other personal protective equipment, methods for hand hygiene, peritoneal catheter care and dressing changes, cleaning and disinfecting dialysis equipment, cleaning and disinfection procedures for spills and splashes of effluent;*
- *How to properly dispose of needles, effluents, disposable items, and tubing and to minimize risks of infection or injury to self and others and to prevent environmental contamination (e.g. using impervious puncture resistant containers for disposal of sharps, placing empty dialysate bags and tubing in intact plastic bags before discarding.); and*
- *Recognizing, managing and reporting power outages, failure of the PD cycler.*

Provision of PD Treatment

PD may be provided via the following modalities:

- ***Continuous ambulatory peritoneal dialysis (CAPD) is a treatment in which*** *dialysis solution is introduced through a catheter into the abdomen via gravity and the bag is disconnected. After a specified period of time, the catheter is reconnected and drains the solution containing wastes back into the bag. CAPD does not require a machine; the process uses gravity to fill and empty the abdomen. CAPD may be provided during three or four exchanges during the day and one overnight. A mini-cycler machine may be used to exchange the dialysis solution overnight as the resident sleeps; or*
- ***Continuous cycler-assisted peritoneal dialysis (CCPD)*** *uses a machine to fill and empty the abdomen three to five times during the night. In the morning, the last fill remains in the abdomen with a dwell time that is individualized according to the resident's needs. In some cases, an additional exchange is done in the mid-afternoon to increase the amount of waste removed and to prevent excess fluid absorption.*

For a resident receiving PD, the practitioner orders for the individualized prescription must include at least the number of exchanges or cycles to be done during each dialysis session, the volume of fluid with each exchange, duration of fluid in the peritoneal cavity, the concentration of glucose or other osmotic agent to be used for fluid removal, and the use of an automated, manual, or combined techniques.

Before, during and after receiving the PD, nursing home staff must, based on practitioner's orders and professional standards of practice, obtain vital signs, weights, assess the resident's stability level of consciousness, and comfort or distress; and monitor for post-dialysis complications and symptoms such as but not limited to dizziness, nausea, fatigue or hypotension. The staff must report identified or suspected complications immediately to the attending practitioner and dialysis staff to enable timely interventions. The resident's record must include documentation of ongoing evaluation of the peritoneal catheter, including assessment of catheter related infections (For example, exit site acute and chronic infections) and tunnel for condition, monitoring for patency, leaks, infection, and bleeding at the site. In addition, staff should be monitoring for complications such as peritonitis (For example, abdominal pain/tenderness/distention, cloudy PD fluid, fever, nausea and vomiting).

NOTE*: For more information related to PD related infections, refer to* *https://www.cdc.gov/disasters/icfordialysis.html*

Interim and Emergency Medications for Residents Receiving Dialysis

Nursing homes must have access to medications and treatments such as antibiotics and intravenous fluids to treat common complications of dialysis. The nursing home staff must collaborate with the medical director, consultant pharmacist and dialysis facility to develop policies and procedures to address common complications and to ensure access to needed medications.

The attending practitioner and dialysis team may have prescribed Erythropoiesis-Stimulating Agents (ESAs), which are medications that may be used to treat anemia in a resident with a

diagnosis of ESRD. These medications act similarly to erythropoietin to stimulate the production of red blood cells and are administered either intravenously or subcutaneously. Commonly used ESAs include Epogen (epoetin alfa) 2 and Aranesp (darbepoetin alfa). Other causes of anemia unrelated to kidney disease (e.g., hemolytic anemia and blood loss anemia) may also occur in individuals with ESRD. Additionally, many anemic individuals with ESRD are also treated with iron supplements because iron is necessary for the production of red blood cells. These include iron supplements such as Venofer (iron sucrose) and Ferrlecit (sodium ferric gluconate complex) to treat iron-deficiency anemia.

***NOTE**: ESAs were approved by the FDA starting with Epogen for the treatment of anemia in 1989 and Aranesp in 2001. Since the approval, the product labeling for this class of medications has been updated several times to incorporate new safety information. The FDA approved-new labeling for both drugs in March 2007 that included a warning that ESAs can increase the risk for death and serious cardiovascular events (including myocardial infarction, stroke, heart failure) when they are dosed to achieve a target hemoglobin of greater than 12 g/dL. For individuals with chronic kidney disease on dialysis, FDA approved labels for ESAs now recommend that health care professionals initiate ESA treatment when the hemoglobin level is less than 10 g/dL and that the dose be reduced or interrupted if the hemoglobin approaches or exceeds 11 g/dL,. Ongoing monitoring is mandated to ensure efficacy as well as safety and reimbursement of the medication(s).*
http://www.fda.gov/drugs/drugsafety/postmarketdrugsafetyinformationforpatientsandproviders/ucm109375.htm

Depending on the dialysis method and the resident's comorbidities, medication administration may need to be modified. The attending practitioner and nephrologist determine which medications are to be administered during dialysis, which are to be held prior to dialysis (e.g., because of excessive hypotension during dialysis), whether any specific medications are to be given prior to dialysis and any medications (such as antibiotics or ESA's) that are to be given by dialysis staff. All such medication administration must be coordinated, communicated and documented between dialysis staff, nursing home staff, and practitioners. (For issues related to medications and or pharmacy review, refer to F757 Unnecessary Medications, and/or F755 Pharmacy Services and/or F756 – Pharmacy Review.)

Canceling or Postponing Dialysis (Either HD, HHD and/or PD)
The nephrologist/dialysis team, the resident's attending practitioner must be notified of the canceled or postponed dialysis treatment and responses to the change in treatment must be documented in the resident's medical record. If dialysis is canceled or postponed, the nursing home and dialysis staff should provide or obtain ongoing monitoring and medical management for changes such as fluid gain, respiratory issues, review of relevant lab results, and any other complications that occur until dialysis can be rescheduled based on resident assessment, stability and need.

- ***Lack of sufficient trained and qualified staff to provide treatments***
  In the event circumstance do not allow dialysis to be provided by the designated trained and qualified individual, the nursing home must immediately notify the dialysis facility in order to make arrangements to assure that no dialysis treatments are missed.
- ***Equipment Failure for HHD/PD***

Dialysis may be stopped, postponed, or delayed due to dialysis equipment failure. If this happens during dialysis, the staff and practitioner must assess the resident immediately to assure that urgent medical needs are met, identify and manage any consequences, contact the dialysis facility and reschedule the dialysis as appropriate and/or transport the resident to the off-site certified dialysis facility to receive the required dialysis treatments. The staff must check the equipment and supplies to identify what happened, and why, and arrange with the dialysis facility for the repair/replace the equipment and supplies as necessary.

- ***Resident Declines or Acute Illness, Or Resident Complications***

  Dialysis may be stopped, postponed or delayed due to a resident's declines of the dialysis treatment or the presence of acute illness or complications to the resident before, during, after, and in between dialysis sessions. As part of care coordination between the nursing home and the dialysis facility, there must be a systematic approach to handling situations where the resident has a condition change and/or becomes ill or unstable during dialysis. This approach includes knowing who is to be contacted, who decides whether to stop dialysis, who documents the situation, under what circumstances dialysis may be terminated and when the dialysis treatment may be restarted or the next treatment scheduled. The record must reflect the how the missed treatments will be addressed in order to prevent an avoidable decline and/or potential complications. If a resident wants to decline the dialysis treatment(s), the nursing home and dialysis facility social workers, should coordinate services to assess psychosocial concerns related to the resident's desire to discontinue dialysis treatments.

The nursing home and dialysis staff must coordinate their approaches in order to provide immediate care for possible emergencies and complications, such as cardiac arrest during dialysis. Any orders related to cardio-pulmonary resuscitation (CPR) and any documents that might be needed (e.g., practitioner orders for life-sustaining treatment, advance directives including code status) must be available for both the nursing home and the dialysis staff. Knowledge of existing advance directives, including specific directives about treatment choices and code status, must be communicated between dialysis and nursing home staff to ensure that there is a uniform approach, consistent with State laws and regulations. (Refer to F678 – Advance Directives)

ADMINISTRATIVE REVIEW OF NURSING HOME PRACTICES

As appropriate, the administrator, nursing director, medical director, and pharmacist, and the QAA committee should review the nursing home's dialysis care and services on an ongoing basis including:

- *The communication, training, supervision and care coordination between the nursing home and the participating dialysis facility;*
- *Whether policies and procedures for the types of dialysis that are provided in the nursing home are consistent with current standards of practice and are being followed consistently;*
- *Any complications associated with dialysis provision, such as those associated with potential breeches in infection control, those resulting in hospitalization and those due to equipment, technique, process failures, or supplies;*

- *Provision of ongoing staff training which is individualized to meet the needs of each HHD/PD resident. Staff training must be provided by qualified dialysis facility instructors and include how to address emergencies; and*
- *Communication and coordination between the nursing home and the dialysis facility in sharing data about outcomes and processes and reviewing quality indicators and care issues.*

Investigative Summary for Dialysis Care and Services
Use
Use the Dialysis Critical Element (CE) Pathway, along with the interpretive guidelines when determining if the facility meets the requirements for providing care and services for a resident receiving dialysis services, in accordance with professional standards of practice, and the comprehensive person-centered care plan,

Summary of Investigative Procedure
Briefly review the most recent comprehensive assessments, comprehensive care plan and orders to identify whether the facility has recognized, assessed, provided interventions and implemented care and services according to professional standards of practice in order to meet the resident's dialysis care needs under investigation. This information will guide observations and interviews to be made in order to corroborate concerns identified. In addition, investigate to assure that there are sufficient numbers of trained, qualified and competent staff to provide the interventions identified for a resident receiving dialysis care and services.

If the resident has been in the facility for less than 14 days (before completion of all the Resident Assessment Instrument (RAI) is required), review the baseline care plan which must be completed within 48 hours to determine if the facility is providing appropriate care and services based on information available at the time of admission. In addition, review to determine whether the comprehensive care plan is evaluated and revised based on the resident's response to interventions.

***NOTE**: Always observe for visual cues of psychosocial distress and harm (see Appendix P, Guidance on Severity and Scope Levels and Psychosocial Outcome Severity Guide). In addition, if noncompliance at this tag demonstrates a pervasive disregard for the resident's quality of life, consider investigating concerns at F675 – Quality of Life.*

OTHER TAGS, CARE AREAS (CA) AND TASKS TO CONSIDER:
Dignity CA (F550); Right to be informed and make treatment decisions (F552); Right to refuse (F578); Advance Directives CA (F561); Notification of change (F580); Accommodation of needs, call system (Environment task & F558); Be provided by qualified persons (F659); Pressure ulcer CA (F686); Nutrition CA(F692); Hydration CA (F692); Sufficient and Competent Staffing (Task & F725); Unnecessary Medications CA (F757); Infection Control (Task & F880); Medical director (F841); Resident Records (F842); and QA&A QAPI (Task F868);

V. DEFICIENCY CATEGORIZATION (Part IV, Appendix P)
***NOTE**: The death or transfer of a resident, who was harmed as a result of nursing home practices, does not remove a finding of immediate jeopardy. The nursing home is required to*

implement specific actions to correct the deficient practices which allowed or caused the immediate jeopardy.

Examples that demonstrate severity at Level 4 include, but are not limited to:

- *The nursing home failed to ensure that the nursing home staff provided adequate monitoring for a resident after returning from receiving an offsite HHD treatment at an ERSD unit. The resident was found to have pulled out the hemodialysis catheter and was found by staff over an hour later to be profusely bleeding which led to death.*
- *The nursing home failed to ensure that nursing home staff providing the HHD monitored and identified complications during a dialysis treatment. The resident's vital signs were not monitored during the dialysis treatment and as a result, the resident experienced serious hypotensive complications resulting in an emergency transfer and admission to the hospital.*
- *The nursing home failed to ensure that the nursing home staff monitored the PD catheter site for complications. The nursing home staff providing the PD treatments, failed to monitor the condition of the PD catheter site and identify signs of infection. As a result of the infection at the catheter site, the resident required medical intervention for removal of the catheter and initiation of hemodialysis.*

Examples that demonstrate severity at Level 3 may include, but are not limited to:

- *The nursing home failed to notify the attending practitioner and dialysis team of changes in a resident's behavior and failed to assure the treatments were provided according to the orders. A cognitively impaired resident was observed during a HHD treatment to exhibit combative and resistive behaviors, such as pulling at the tubing and access site. The resident had a history of previously dislodging the catheter, causing bleeding. The resident was observed trying to remove his/her shoes and trying to stand up from the dialysis chair and requires constant supervision during the treatment. The staff attributed the behavioral symptoms to dementia and administered a benzodiazepine to try to sedate the resident. Due to the behavioral symptoms, the HHD treatment had to be discontinued but the practitioner wasn't contacted regarding discontinuing the treatment. This had occurred several times, however the nursing home staff failed to contact the practitioner, identify underlying causes, such as delirium or medication side effects and did not attempt to consider environmental or other non-pharmacological measures to try to reduce the restlessness during dialysis. As a result of the treatments being discontinued early, the resident had electrolyte imbalance and fluid retention.*

Examples that demonstrate Severity Level 2 include, but are not limited to:

- *The nursing home failed to ensure that the nursing home staff provided PD treatments as ordered. The nursing home staff providing the PD failed to follow the orders for the duration of fluid in the peritoneal cavity however, the resident's status was stable.*
- *The nursing home failed to ensure that the nursing home staff provided PD treatments as ordered. The nursing home staff failed to identify a recent change in a resident's dialysis order for an increase in the number of daily PD treatments; however, the resident's status was stable.*

Effective November 28, 2017

Severity Level 1: No actual harm with potential for minimal harm
The failure of the nursing home to provide appropriate care and services to a resident who is receiving dialysis care and services is more than minimal harm. Therefore, Severity Level 1 does not apply for this regulatory requirement.

F699
§483.25(m) Trauma-informed care.
The facility must ensure that residents who are trauma survivors receive culturally competent, trauma-informed care in accordance with professional standards of practice and accounting for residents' experiences and preferences in order to eliminate or mitigate triggers that may cause re-traumatization of the resident.
[§483.25(m) will be implemented beginning November 28, 2019 (Phase 3)]

F700
§483.25(n) Bed Rails.
The facility must attempt to use appropriate alternatives prior to installing a side or bed rail. If a bed or side rail is used, the facility must ensure correct installation, use, and maintenance of bed rails, including but not limited to the following elements.

§483.25(n)(1) Assess the resident for risk of entrapment from bed rails prior to installation.

§483.25(n)(2) Review the risks and benefits of bed rails with the resident or resident representative and obtain informed consent prior to installation.

§483.25(n)(3) Ensure that the bed's dimensions are appropriate for the resident's size and weight.

§483.25(n)(4) Follow the manufacturers' recommendations and specifications for installing and maintaining bed rails.

INTENT 483.25(n)
The intent of this requirement is to ensure that prior to the installation of bed rails, the facility has attempted to use alternatives; if the alternatives that were attempted were not adequate to meet the resident's needs, the resident is assessed for the use of bed rails, which includes a review of risks including entrapment; and informed consent is obtained from the resident or if applicable, the resident representative. The facility must ensure the bed is appropriate for the resident and that bed rails are properly installed and maintained.

DEFINITIONS §483.25(n)
"Entrapment" *is an event in which a resident is caught, trapped, or entangled in the space in or about the bed rail.*

"Bed rails" *are adjustable metal or rigid plastic bars that attach to the bed. They are available in a variety of types, shapes, and sizes ranging from full to one-half, one-quarter, or one-eighth lengths. Also, some bed rails are not designed as part of the bed by the manufacturer and may be installed on or used along the side of a bed.*

Examples of bed rails include, but are not limited to:

- *Side rails, bed side rails, and safety rails; and*
- *Grab bars and assist bars.*

GUIDANCE §483.25(n)

Even when bed rails are properly designed to reduce the risk of entrapment or falls, are compatible with the bed and mattress, and are used appropriately, they can present a hazard to certain individuals, particularly to people with physical limitations or altered mental status, such as dementia or delirium.

Resident Assessment

After a facility has attempted alternatives to bed rails and determined that these alternatives do not meet the resident's needs, the facility must assess the resident for the risks of entrapment and possible benefits of bed rails. In determining whether to use bed rails to meet the needs of a resident, the following components of the resident assessment should be considered including, but not limited to:

- *Medical diagnosis, conditions, symptoms, and/or behavioral symptoms;*
- *Size and weight*
- *Sleep habits*
- *Medication(s)*
- *Acute medical or surgical interventions*
- *Underlying medical conditions*
- *Existence of delirium*
- *Ability to toilet self safely*
- *Cognition*
- *Communication*
- *Mobility (in and out of bed)*
- *Risk of falling.*

In addition, the resident assessment must include an evaluation of the alternatives to the use of a bed rail that were attempted and how these alternatives failed to meet the resident's assessed needs.

The facility must also assess the resident's risk from using bed rails. The following includes potential risks regarding the use of bed rails as identified by the Food and Drug Administration's Hospital Bed Safety Workgroup Clinical Guidance For the Assessment and Implementation of Bed Rails In Hospitals, Long Term Care Facilities, and Home Care Settings (April 2003) and have been adapted for surveyor guidance:

- *Accident hazards*
  - *The resident could attempt to climb over, around, between, or through the rails, or over the foot board,*
  - *A resident or part of his/her body could be caught between rails, the openings of the rails, or between the bed rails and mattress.*
- *Barrier to residents from safely getting out of bed*

  - *A resident could crawl over rails and fall from greater heights increasing the risk for serious injury*
  - *A resident could attempt to get out of bed over the foot board*
- *Physical restraint*
  - *Hinders residents from independently getting out of bed thereby confining them to their beds*
  - *Creates a barrier to performing routine activities such as going to the bathroom or retrieving items in his/her room*
- *Other potential negative physical outcomes*
  - *Decline in resident function, such as muscle functioning/balance*
  - *Skin integrity issues*
  - *Decline in other areas of activities of daily living such as using the bathroom, continence, eating, hydration, walking, and mobility*
- *Other potential negative psychosocial outcomes*
  - *Creates an undignified self-image and alter the resident's self-esteem*
  - *Contributes to feelings of isolation*
  - *Induces agitation or anxiety*

These potential risks can be exacerbated by improper match of the bed rail to bed frame, improper installation and maintenance, and use with other devices or supports that remain when the bed rail is removed.

Entrapment may occur when a resident is caught between the mattress and bed rail or in the bed rail itself. Although, not all bed rails create a risk for entrapment, injury may still occur. It varies depending on the resident. Residents most at risk for entrapment are those who are frail or elderly or those who have conditions such as agitation, delirium, confusion, pain, uncontrolled body movement, hypoxia, fecal impaction, acute urinary retention, etc. that may cause them to move about the bed or try to exit from the bed. The untimeliness of assistance using the bathroom and inappropriate positioning or other care-related activities can contribute to the risk of entrapment.

Informed Consent

After alternatives have been attempted and prior to installation, the facility must obtain informed consent from the resident or if applicable, the resident representative for the use of bed rails. The facility should maintain evidence that it has provided sufficient information so that the resident or resident representative could make an informed decision. Information that the facility must provide to the resident, or resident representative include, but are not limited to:

- *What assessed medical needs would be addressed by the use of bed rails;*
- *The resident's benefits from the use of bed rails and the likelihood of these benefits;*
- *The resident's risks from the use of bed rails and how these risks will be mitigated; and*
- *Alternatives attempted that failed to meet the resident's needs and alternatives considered but not attempted because they were considered to be inappropriate.*

The information should be presented to the resident, or if applicable, the resident representative, so that it could be understood and that consent can be given voluntarily, free from coercion.

Effective November 28, 2017

Installation and Maintenance of Bed Rails

Assuring the correct installation and maintenance of bed rails is an essential component in reducing the risk of injury resulting from entrapment or falls. The FDA and the United States Consumer Product Safety Commission (CPSC) has recommended the following initial and ongoing actions to prevent deaths and injuries from entrapment and/or falls from bed rails:

- *Before bed rails are installed, the facility should:*
  - *Check with the manufacturer(s) to make sure the bed rails, mattress, and bed frame are compatible, since most bed rails and mattresses are purchased separately from the bed frame.*

    ***NOTE**: The FDA has published (1) the Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment as a resource to reduce entrapments resulting from hospital beds and (2) Practice Hospital Bed Safety as to the proper dimensions and distance of various parts of the beds (i.e.; distance between bed frames and mattresses, bed rails and mattresses, etc.)*

  - *Rails should be selected and placed to discourage climbing over rails to get in and out of bed, which could lead to falling over bed rails.*
- *When installing and using bed rails, the facility should:*
  - *Ensure that the bed's dimensions are appropriate for the resident.*
  - *Confirm that the bed rails to be installed are appropriate for the size and weight of the resident using the bed.*
  - *Install bed rails using the manufacturer's instructions to ensure a proper fit.*
  - *Inspect and regularly check the mattress and bed rails for areas of possible entrapment.*
  - *Regardless of mattress width, length, and/or depth, the bed frame, bed rail and mattress should leave no gap wide enough to entrap a resident's head or body. Gaps can be created by movement or compression of the mattress which may be caused by resident weight, resident movement or bed position, or by using a specialty mattress, such as an air mattress, mattress pad or water bed.*
  - *Check bed rails regularly to make sure they are still installed correctly as rails may shift or loosen over time.*

In addition, ongoing precautions may include following manufacturer equipment alerts and recalls and increasing resident supervision.

The use of a specialty air-filled mattress or a therapeutic air-filled bed may also present an entrapment risk that is different from rail entrapment with a regular mattress. The high compressibility of an air-filled mattress compared to a regular conventional mattress requires appropriate precautions when used for a resident at risk for entrapment. An air-filled mattress compresses on the side to which a person moves, thus raising the center of the mattress and lowering the side. This may make it easier for a resident to slide off the mattress or against the rail. Mattress compression widens the space between the mattress and rail. When a resident is between the mattress and rail, the mattress can re-expand and press the chest, neck, or head against the rail. While using air therapy to prevent and treat pressure injuries, facilities should

also take precautions to reduce the risk of entrapment. Precautions may include following manufacturer equipment alerts and increasing supervision.

Facilities must also conduct routine preventive maintenance of beds and bed rails to ensure they meet current safety standards and are not in need of repair. For concerns regarding installation and maintenance of the beds or bed rails, see guidance for 42 CFR 483.90(d)(3), F909.

Ongoing Monitoring and Supervision

Assuring the correct use of an installed bed rail, and maintenance of bed rails is an essential component in reducing the risk of injury. After the installation of bed rails, it is expected that the facility will continue to provide necessary treatment and care, in accordance with professional standards of practice and the resident's choices. This should be evidenced in the resident's record, and include the following components, but are not limited to:

- *The type of specific direct monitoring and supervision provided during the use of the bed rails, including documentation of the monitoring;*
- *The identification of how needs will be met during use of the bed rails, such as for re-positioning, hydration, meals, use of the bathroom and hygiene;*
- *Ongoing assessment to assure that the bed rail is used to meet the resident's needs;*
- *Ongoing evaluation of risks;*
- *The identification of who may determine when the bed rail will be discontinued; and*
- *The identification and interventions to address any residual effects of the bed rail (e.g., generalized weakness, skin breakdown).*

KEY ELEMENTS OF NONCOMPLIANCE

To cite deficient practice at F700, the surveyor's investigation will generally show that the facility failed to do one or more of the following:

- *Identify and use appropriate alternative(s) prior to installing a bed rail;*
- *Assess the resident for risk of entrapment prior to installing a bed rail;*
- *Assess the risk versus benefits of using a bed rail and review them with the resident or if applicable, the resident's representative;*
- *Obtain informed consent for the installation and use of bed rails prior to the installation.*
- *Ensure appropriate dimensions of the bed, based on the resident's size and weight;*
- *Ensure correct installation of bed rails, including adherence to manufacturer's recommendations and/or specifications;*
- *Ensure correct use of an installed bed or side rail; and/or*
- *Ensure scheduled maintenance of any bed rail in use according to manufacturer's recommendations and specifications.*

INVESTIGATIVE PROTOCOL

Use this protocol for:

- *A sampled resident who has MDS data that indicates a bed/side rail is used;*
- *Surveyor observation of the use of a bed/side rail for a resident; and/or*
- *An allegation of inappropriate use of a bed/side rail received by the State Survey Agency.*

Effective November 28, 2017

PROCEDURES

Briefly review the assessment, care plan, and orders of the resident to identify facility interventions and to guide observations to be made. Corroborate observations by interview and record review.

Observation- Resident

During observations of a resident who has bed/side rails, determine:

- *What type of bed rail is installed and for how long the bed rail has been in use;*
- *If the bed rail in good working order;*
- *Frequency of use of the bed rail;*
- *Any physical or psychosocial reaction to the bed rail, such as attempts to release/remove the bed rail, verbalizing anger/anxiety;*
- *Who applies the bed rail and how often monitoring is provided;*
- *How the resident is positioned in the bed relative to the bed rails and how the resident moves in bed;*
- *How the resident requests staff assistance (e.g., access to the call light);*
- *Whether the resident is toileted, ambulated or provided exercises or range of motion when the bed rails are released, who released the bed rails and for how long;*

  NOTE*: A resident may have a device in place that the facility has stated can be removed by the resident. For safety reasons, do not request that the resident remove the bed rails, but rather request that staff ask the resident to demonstrate how he/she releases the bed rails.*

Interview-Resident or Resident Representative

Interview the resident, or if applicable, the resident representative, to the degree possible to identify:

- *Who requested the bed rail to be installed,*
- *Prior to the use of the bed rail, whether staff provided information regarding how the bed rail would address a resident need, the risks and/or benefits, and alternatives to bed rails, when and how long the bed rails were going to be used;*
- *Whether the interdisciplinary team provided interventions for monitoring and release of the bed rails for activities, such as use of the bathroom, walking and range of motion;*
- *Whether staff discussed mobility issues with the resident, or resident's representative, when the bed rail is in use and/or other impacts on activities of daily living and involvement in activities; and*
- *How the resident can request staff assistance when the bed rail is in use.*

Interviews-Staff

Interview direct care and licensed nursing staff on various shifts who provide care to the resident to determine:

- *Knowledge of specific interventions related to the use of the bed rails for the resident, including:*
  - *When use of the bed rail was initiated;*
  - *The rationale for selecting the bed rail for use;*
  - *Identifying the benefits and risks of using the bed rail;*

- *What is the resident's functional ability, such as bed mobility and ability to transfer between positions, to and from bed or chair, to toilet and to ability to stand.;*
- *Whether there have been any physical and/or psychosocial changes related to the use of the bed rail, such as increased incontinence, decline in ADLs or ROM, increased confusion, agitation, and depression;*
- *Whether other interventions have been attempted to minimize or eliminate the use of the bed rails; and*
- *Whether there are facility guidelines/protocols for the use of bed rails.*

Interview the charge nurse, to gather the following additional information:

- *How the implementation of the use of bed rails is monitored and who is responsible for the monitoring;*
- *Who evaluates and assesses the resident to determine the ongoing need for bed rails;*
- *Whether bed rail use should be gradually decreased; and*
- *How the modifications for the interventions are evaluated for effectiveness in discontinuing the use of the bed rails.*

Record Review

Review the MDS, assessments, physician orders, therapy and nursing notes and other progress notes that may have assessment information related to use of the bed rail. Determine whether identified decline can be attributed to a disease progression or use of bed rails. Determine whether the assessment information accurately and comprehensively reflects the status of the resident for:

- *The identification of specific medical symptom(s) for which the bed rail is used;*
- *Functional ability, including strength and balance (such as bed mobility and ability to transfer between positions, to and from bed or chair, and to stand and the ability to toilet);*
- *Identification of the resident's risks such as physical/functional decline and psychosocial changes, and benefits, if any, due to the use of the bed rails;*
- *Attempts at using alternatives to bed rails, including how the alternatives did not meet the resident's medical or safety need or were inappropriate;*
- *Identification of any injuries, or potential injuries, that occurred during the use of bed rails.*

When the interdisciplinary team has determined that a resident may benefit from the use of a device for mobility or transfer, whether the assessment includes a review of the resident's:

- *Bed mobility; and*
- *Ability to transfer between positions, to and from bed or chair, to stand and the ability to toilet.*

Review the resident's care plan to determine if it is consistent with the resident's specific conditions, risks, needs, behaviors, preferences, current professional standards of practice, and included measurable objectives and timetables, with specific interventions/services for use of the bed rail. The care plan may include:

- *Which medical need would be met through the use of bed rails;*

- *How often the bed rail is applied, duration of use, and the circumstances for when it is to be used;*
- *How monitoring is provided, and when and how often the bed rail is to be released and assistance provided for use of the bathroom, walking and range of motion;*
- *What the resident's functional ability is, such as bed mobility and ability to transfer between positions, to and from bed or chair, and to stand and toilet and staff required for each function that requires assistance;*
- *Identification of interventions to address any potential complications such as physical and/or psychosocial changes related to the use of the bed rails, such as increased incontinence, decline in ADLs or ROM, increased confusion, agitation, and depression;*
- *Identification of interventions to minimize or eliminate the use of the bed rails; and*
- *Who monitors for the implementation of the use of the bed rails, and who evaluates and assesses the resident to determine the ongoing need for bed rails, whether the bed rail use should be gradually decreased, and how the modifications for the interventions are evaluated for effectiveness in discontinuing the use of the bed rail.*

DEFICIENCY CATEGORIZATION

Examples of Severity Level 4 Noncompliance Immediate Jeopardy to Resident Health or Safety include, but are not limited to:

- *A facility failed to attempt to use alternatives to bed rails and assess a resident for risk of entrapment. The resident was assessed to be at risk of falls when she made repeated attempts to self-transfer off of her bed. All of the falls occurred when a half side rail was in use. According to a facility accident report, the resident was found on the floor with her back against the bed, holding onto one of the half side rails with both hands, with her neck wedged between the half side rails. The resident was able to remove herself from between the mattress and the bed rail, and did not sustain any injuries from the fall. After this incident, the facility performed a bed rail assessment, which did not indicate the risks/benefits of using bed rails. However, no changes were made to the resident's care plan, nor was there any documentation that the facility considered discontinuing use of the bed rails. Nine months later, the resident was found dead on the floor next to her bed, with her head wedged between the half side rail and the mattress. The resident's death certificate listed the cause to be asphyxiation-positional, extrinsic compression of the neck, and neck trapped under the bed rail.*
- *The facility failed to assess the resident for use of a bed rail, and failed to ensure that the bed rails did not pose a risk of entrapment or injury from falls. A moderately cognitively impaired resident was admitted to the facility who required extensive assistance with bed mobility and transfer, and was not ambulatory. The nursing assessment completed on admission indicated that the resident was at high risk for falls and full bed rails were used on all open sides of the bed. No assessment related to the use of bed rails was completed. A facility investigation report revealed that the resident crawled to the foot of his bed with the full bed rails in a raised position, tried to stand and ambulate, and fell off the right side of the bed. The resident sustained a femoral neck fracture and was hospitalized.*
- *A facility failed to attempt to use alternatives to bed rails and assess a resident for risk of entrapment. A bed rail assessment indicated that two half side rails would be used for the resident to promote independence. There was no evidence that the facility*

evaluated risks associated with bed rail use when the facility changed the bed mattress to an air mattress. A facility accident report indicated that a nurse aide discovered the resident on the floor, with his/her head positioned between the side rail and the air mattress. The resident had visible bruising to the neck, had no pulse, or blood pressure.

Examples of Severity Level 3 Noncompliance Actual Harm that is Not Immediate Jeopardy include, but are not limited to:
An example of noncompliance that demonstrates severity at level three includes, but is not limited to:

- *A facility failed to ensure the resident's bed dimensions were appropriate for the resident's size and weight. An extremely obese resident fell out of bed and sustained an injury while using the bed rail as an enabler to turn on his side. The bed was narrow and the bed rail could not sustain his weight and broke. The bed was meant to sustain the size and weight of a smaller person per manufacturer's directions.*

Examples of Severity Level 2 Noncompliance No Actual Harm with Potential for More Than Minimal Harm that is Not Immediate Jeopardy include, but are not limited to:
An example of noncompliance that demonstrates severity at level two includes, but is not limited to:

- *The facility failed to inform a resident/representative of the risks and benefits of using side rails, prior to installing them on the resident's bed. The resident was cognitively impaired and was unable to comprehend, however, the staff did not contact the resident's representative to provide the information.*

Severity Level 1 Noncompliance No Actual Harm with Potential for Minimal Harm *Facility failed to have a schedule for routine maintenance of its four beds with bed rails, which were newly installed two years ago. There is no evidence of incidents or injuries in those two years, the relevant resident care plans appear appropriate regarding bedrail usage, and the facility provides evidence of checks by staff on the impacted residents and appropriate use and installation of bed rails.*

NOTE: References to non-CMS/HHS sources or sites on the Internet included above or later in this document are provided as a service and do not constitute or imply endorsement of these organizations or their programs by CMS or the U.S. Department of Health and Human Services. CMS is not responsible for the content of pages found at these sites. URL addresses were current as of the date of this publication.

Other resources which may be useful :
Falls
National Council on Aging National Falls Prevention Resource Center at
http://www.ncoa.org/center-for-healthy-aging/falls-resource-center

Centers for Disease Control and Prevention at
http://www.cdc.gov/homeandrecreationalsafety/falls/

Effective November 28, 2017

World Health Organization Fall Prevention in Older Age at http://www.who.int/ageing/projects/falls_prevention_older_age/en/

National Institute of Health- Senior Health at http://nihseniorhealth.gov/falls/aboutfalls/01.html

Wandering and Elopement Resources

National Council of Certified Dementia Practitioners at http://www.nccdp.org

Resources
Research into appropriate practices to prevent, manage, and treat urinary incontinence, urinary catheterization, and UTI continues to evolve. Many recognized clinical resources on the prevention and management of urinary incontinence, infection, and urinary catheterization exist. Some of these resources include:

- The American Medical Directors Association (AMDA) - Clinical Practice Guidelines: Clinical Practice Guidelines, 1996 - *http://www.amda.com/tools/guidelines.cfm*
- *http://www.mc.vanderbilt.edu/documents/cqa/files/Incontinence%20Management/Vanderbilt%20Incontinence%20Management%20Module.pdf*
- Association for Professionals in Infection Control and Epidemiology (APIC) at www.apic.org;
- Centers for Disease Control at www.cdc.gov;
- The Annals of Long Term Care publications: *http://www.annalsoflongtermcare.com/search?keywords=urinary%20catheters*
- Urology Care Foundation – The Official Foundation of the American Urological Association - *http://www.urologyhealth.org/*
- The American Geriatrics Society at www.americangeriatrics.org
- *http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3538836/*
  Surveillance Definitions of Infections in Long-Term Care Facilities: Revisiting the McGeer Criteria

Resources for Fecal Incontinence:

- *https://www.fascrs.org/sites/default/files/downloads/publication/clinical_practice_guideline_for_the_treatment_of_fecal_incontinence.pdf*
- *http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2614622/*

F710
§483.*30* Physician Services
A physician must personally approve in writing a recommendation that an individual be admitted to a facility. Each resident must remain under the care of a physician. *A physician, physician assistant, nurse practitioner, or clinical nurse specialist must provide orders for the resident's immediate care and needs.*

§483.*30*(a) Physician Supervision.
The facility must ensure that—

Effective November 28, 2017

§483.*30*(a)(1) The medical care of each resident is supervised by a physician;

§483.*30*(a)(2) Another physician supervises the medical care of residents when their attending physician is unavailable.

INTENT §483.*30(a)*
The intent of this regulation is to ensure the medical supervision of the care *of each resident by a physician and that orders for the resident's immediate care and needs are provided throughout the resident's stay.*

DEFINITIONS §483.30(a)
"Attending physician" *refers* to the primary physician *who* is responsible for managing the resident's medical care. This does not include other physicians whom the resident may see periodically, such as specialists.

"Non-physician practitioner (NPP)" *is a nurse practitioner (NP), clinical nurse specialist (CNS), or physician assistant (PA).*

"Nurse practitioner" *is a registered professional nurse currently licensed to practice in the State and who meets the State's requirements governing the qualification of nurse practitioners.*

"Clinical nurse specialist" *is a registered professional nurse currently licensed to practice in the State and who meets the State's requirements governing the qualifications of clinical nurse specialists.*

"Physician assistant" *is a person who meets the applicable State requirements governing the qualifications for assistants to primary care physicians.*

GUIDANCE* §483.*30(a)
A physician's personal approval of an admission recommendation must be in written form. *The written recommendation for admission to the facility must be provided by a physician and cannot be provided by a NPP. This may be accomplished through a hospital transfer summary written by a physician, paperwork completed by the resident's physician in the community, or other written form by a physician. If a physician does not provide a written recommendation that the individual be admitted to the facility prior to the resident's admission,* the physician's admission orders for the resident's immediate care as required in §483.20(a) will be accepted as "personal approval" of the admission ***if*** *the orders are provided by a physician. Admission orders in lieu of a physician's written recommendation for admission to the facility cannot be provided by a NPP.*

Generally, the term "attending physician" or "physician" may also include a NPP involved in the management of the resident's care, to the extent permitted by State law. However, when the regulation specifies a task to be completed "personally" by the physician, that task may not be delegated to a NPP.

Effective November 28, 2017

Supervising the medical care of residents means participating in the resident's assessment and care planning, monitoring changes in resident's medical status, and providing consultation or treatment when *contacted* by the facility. It also includes, but is not limited to, prescribing *medications and* therapy, ordering a resident's transfer to the hospital, conducting required routine visits or delegating to and supervising follow-up visits *by NPPs*.

It is the responsibility of the facility to ensure that another physician supervises the care of residents when the attending physician is unavailable. The attending physician may designate another physician to act on his/her behalf when unavailable. If the attending physician is unavailable and does not designate another physician to act on his/her behalf, or the designated physician is unavailable, the facility must have a physician available who will supervise the care of the attending physician's residents.

There may be examples of physician orders in the medical record that would not impact a resident's medical care, such as instructions to contact a family member or providing date/time of an order; concerns related to these types of orders do not fall under the category of a physician's supervision of medical care and would not be cited here.

PROBES §483.30(a)

- *Is there evidence that the attending physician supervises the resident's medical care? If not, what did the facility do?*
- *If the physician makes a change to the residents' plan of care, e.g. orders a new medication or changes a medication, is there evidence that the physician re-evaluated the effectiveness of the intervention and the resident's response?* ***NOTE****: the timing of the re-evaluation may vary depending upon the type of change, type of medication.*
- If staff reported a change in medical status to the physician, *how* did the physician respond?
- If the *attending* physician was unavailable and could not respond, did the facility have a physician available to supervise the medical care of the resident? *How d*id this physician respond?
- When a NPP performs a delegate physician visit, and determines that the resident's condition warrants direct contact between the physician and the resident, does the physician follow-up promptly with a personal visit?

POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION

The facility must ensure each resident *has the right* to designate *an attending* physician For potential concerns related to the resident having the choice of attending physician who is able and willing to meet the physician services requirements, see §483.10(*d*), *F555, for additional guidance.*

For concerns related to admission orders, see §483.20(a), F635. At the time each resident is admitted, the facility must have physician's orders for the resident's immediate care.

For concerns related to physician availability for emergencies 24 hours a day, see §483.30(d), F713.

Effective November 28, 2017

DEFICIENCY CATEGORIZATION

Examples of Level 4, immediate jeopardy to resident health and safety include, but are not limited to:

- *The facility failed to ensure the physician conducted a medical evaluation of a resident with a new onset of seizures. As a result, anticonvulsant medications were prescribed, but the primary cause of the seizures was not evaluated to determine if it was neurological or secondary to another condition, such as infection or drug interaction. This placed the resident at risk for serious harm or death.*
- *The physician failed to provide laboratory orders for routine monitoring for a resident receiving anticoagulant medication, placing the resident at risk for significant adverse side effects including the risk for serious injury or death, such as gastrointestinal bleeding or stroke. The facility failed to follow up with the physician regarding the absence of laboratory orders and administered the anticoagulant medication as ordered.*

An example of level 3, actual harm that is not immediate jeopardy includes, but is not limited to:

- *The facility failed to ensure the physician supervised the resident's medical care, when the physician did not evaluate the effectiveness of treatments ordered for a skin condition, resulting in the development of a localized skin infection causing significant pain for the resident.*

An example of Level 2, no actual harm, with potential for no more than minimal harm, that is not immediate jeopardy includes, but is not limited to:

- *The facility failed to follow-up on recommendations from the dietitian for diet liberalization for a resident whose attending physician did not respond to phone calls. The facility then failed to contact another physician to assist with providing care for the resident when the facility was unable to reach the attending physician.*

An example of Level 1, no actual harm with potential for no more than a minor negative impact on the resident includes, but is not limited to:

- *The failure of the facility to ensure a resident's medical care is supervised by a physician or to ensure that the resident has orders for immediate care and needs always places the resident at risk for more than minimal harm. Therefore, Severity Level 1 does not apply for this regulatory requirement.*

F711
§483.*30*(b) Physician Visits
The physician must—

§483.*30*(b)(1) Review the resident's total program of care, including medications and treatments, at each visit required by paragraph (c) of this section;

§483.*30*(b)(2) Write, sign, and date progress notes at each visit; and

Effective November 28, 2017

§483.*30*(b)(3) Sign and date all orders with the exception of influenza and pneumococcal vaccines, which may be administered per physician-approved facility policy after an assessment for contraindications.

INTENT §483.*30*(b)
The intent of this regulation is to have the physician take an active role in supervising the care of the residents. *Physician visits* should not be superficial visits, but *must* include an evaluation of the resident's condition *and total program of care, including medications and treatments,* and a decision about the continued appropriateness of the resident's current medical regimen.

***GUIDANCE* §483.*30*(b)**
Except where the regulation specifies the task must be completed ***personally*** *by the physician, the term "attending physician" or "physician" also includes a non-physician practitioner (NPP) involved in the management of the resident's care, to the extent permitted by State law.*

Total program of care includes all care the facility provides residents to maintain or improve their highest practicable *physical,* mental *and psychosocial well-being*, as defined by the comprehensive assessment and plan of care. Care includes medical services and medication management, physical, occupational, and speech/language therapy, nursing care, nutritional interventions, social work and activity services that maintain or improve psychosocial functioning.

*During required visits, t*he physician *must document a review of the* resident's *total program of care, including the resident's current condition,* progress and problems in maintaining or improving their *physical*, mental *and psychosocial well-being and decisions about the continued appropriateness of the resident's current medical regimen.* The physician need not review the total plan of care at each visit, but must review the total plan of care at visits required by §483.*30*(c), *F712*.

Progress notes must be written, signed and dated at each physician visit, which may be done in a physical chart or electronic record, in keeping with facility practices.

During visits, the physician must also sign and date all orders, with the exception of influenza and pneumococcal vaccinations, which may be administered per physician-approved facility policy after an assessment for contraindications. This includes co-signing orders written by NPPs, qualified dietitians, other clinically qualified nutrition professionals and qualified therapists, as required by state law.

In cases where facilities have created the option for a resident's record to be maintained by computer, rather than hard copy, electronic signatures are acceptable. See Guidelines for §483.*70(i)(1), F842,* for information on facility safeguards concerning electronic signatures.

Physician orders may be transmitted by facsimile machine if the following conditions are met:

- The physician should have signed and retained the original order from which the facsimile was transmitted and be able to provide it upon request. Alternatively, the original may be sent to the facility at a later time and substituted for the facsimile.

- The facility should photocopy the faxed order, *if the faxed order is subject to fading over time*. The facsimile copy can be discarded after facility photocopies it.
- It is not necessary for a physician to re-sign the facsimile order when he/she visits the facility.

When rubber stamp signatures are authorized by the facility's *management*, the individual whose signature the stamp represents shall place in the administrative offices of the facility a signed statement to the effect that he/she is the only one who has the stamp and uses it. A list of computer codes*, identification numbers* and/or written signatures must be readily available and maintained under adequate safeguards. *Adequate safeguards may include, but are not limited to, locked in a drawer; locked in a location that is accessible only by appropriate staff as defined by the facility; or available on a protected electronic site accessible by appropriate staff as defined by the facility.*

PROBES §483.*30*(b)

- *Are physician progress notes written, signed and dated during each physician visit?*
- *For visits required by §483.30(c), do physician progress notes reflect a review of the resident's total program of care and current condition, including medications and treatments?*
- *Do physician progress notes reflect the physician's decisions about the continued appropriateness of the resident's current medical regimen?*
- *Does the physician sign and date all physician orders, during visits, with the exception of influenza and pneumococcal vaccines as outlined above?*
- *If the physician has not met the requirements of physician visits, how has the facility worked with the physician or sought alternate physician participation to assure that the resident receives appropriate care and treatment?*
- *If facility management allows for the use of rubber stamp signatures, are adequate safeguards in place to ensure the security of the stamps?*

POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION

If concerns regarding physician supervision of the resident's care are identified, investigate §483.30(a), F710.

For concerns related to admission orders, see §483.20(a), F635.

For concerns related to the frequency of physician visits, see §483.30(c), F712.

For concerns related to the medical director's follow-up on clinical issues or physician activities, see §483.70(h), F841.

Deficiency Categorization

Examples of Level 4, immediate jeopardy to resident health and safety, include, but are not limited to:

- *After a recent hospitalization, the facility failed to ensure the attending physician reviewed the hospital discharge summary or hospital progress notes. This lack of review of the resident's total program of care, including medications and treatments, resulted in the resident not receiving orders for new medications essential to the resident's medical*

treatment. As a result of the lack of essential medications, serious harm or death occurred or was likely to occur.

- *Facility staff contacted the physician on multiple occasions regarding the resident's elevated blood sugar levels. During a visit, the physician did not review the resident's recorded blood sugar values, or talk to the nurse regarding the resident's status or order changes to the resident's treatment regimen. The facility's failure to intervene when the physician was onsite or to seek alternate intervention resulted in the resident experiencing diabetic ketoacidosis which required hospitalization for management.*

Example of level 3, actual harm that is not immediate jeopardy, includes, but is not limited to:

- *The facility failed to ensure the physician completed a medical evaluation of a resident's condition and review the appropriateness of the resident's medical regimen. Specifically, a resident who had executed a Living Will at a time when he had capacity, indicated that it was his desire to refuse any treatment, other than comfort measures, in the event of an irreversible terminal illness from which there was no hope of recovery. Despite documentation from the pulmonologist that there was no expectation that the resident could survive without artificial means and contrary to the resident's wishes, the attending physician ordered, and the facility provided, aggressive, life-sustaining treatment including artificial ventilation and feeding. As a result, the resident received unwanted treatment in the facility.*

Examples of Level 2, no actual harm, with potential for than more than minimal harm, that is not immediate jeopardy, include, but are not limited to:

- *While the physician reviewed areas identified as high priority for the physician to address in the resident's program of care, the facility failed to ensure the physician reviewed the resident's total program of care or wrote, signed and dated progress notes with each visit.*
- *The facility failed to ensure physician progress notes that documented the physician's involvement in the assessment and care of residents were completed as required.*

Example of Level 1, no actual harm with potential for no more than a minor negative impact on the resident, includes, but is not limited to:

- *During a physician visit, the physician failed to sign and date new orders, however the orders were followed as intended and no adverse outcome was experienced by the resident.*

F712
§483.*30*(c) Frequency of physician visits
§483.*30*(c)(1) The residents must be seen by a physician at least once every 30 days for the first 90 days after admission, and at least once every 60 thereafter.

§483.*30*(c)(2) A physician visit is considered timely if it occurs not later than 10 days after the date the visit was required.

§483.*30*(c)(3) Except as provided in paragraphs (c)(4) and (f) of this section, all required physician visits must be made by the physician personally.

Effective November 28, 2017

§483.*30*(c)(4) At the option of the physician, required visits in SNFs, after the initial visit, may alternate between personal visits by the physician and visits by a physician assistant, nurse practitioner or clinical nurse specialist in accordance with paragraph (e) of this section.

DEFINITIONS §483.*30*(c)
Must be seen, *for purposes of the visits required by §483.30(c)(1), means that the physician or NPP must make actual face-to-face contact with the resident, and at the same physical location, not via a telehealth arrangement.* There is no requirement for this type of contact at the time of admission, since the decision to admit an individual to a nursing facility (whether from a hospital or from the individual's own residence) generally involves physician contact during the period immediately preceding the admission.

"Non-physician practitioner (NPP)" means a nurse practitioner (NP), clinical nurse specialist (CNS) or physician assistant (PA).

***GUIDANCE* §483.*30*(c)**
The timing of physician visits is based on the admission date of the resident.

In a SNF, the first physician visit (this includes the initial comprehensive visit) must be conducted within the first 30 days *after admission*, and then at 30 day intervals up until 90 days after the admission date. After the first 90 days, visits must be conducted at least once every 60 days thereafter.

Permitting up to 10 days' slippage of a due date will not affect the next due date. However, do not specifically look at the timetables for physician visits unless there is indication of inadequate medical care. The regulation states that the physician (or his/her delegate) must visit the resident **at least** every 30 or 60 days. There is no provision for physicians to use discretion in visiting at intervals longer than those specified at §483.*30*(c), *F712*. Although the physician may not delegate the responsibility for conducting the initial visit in a SNF, NPPs may perform other medically necessary visits prior to and after the physician's initial visit, as allowed by State law.

After the initial physician visit in SNFs, where States allow their use, *a NPP may* make every other required visit. (See §483.*30*(*e*), *F714* Physician delegation of tasks in SNFs.) These alternate visits, as well as medically necessary visits, may be performed and signed by the NPP. (Physician co-signature is not required, unless required by State law).

In a NF, the physician visit requirement may be satisfied in accordance with State law by *a NPP* who is not an employee of the facility but who is working in collaboration with a physician and who is licensed by the State and performing within the state's scope of practice. (See §483.*30*(*f*)).

In a NF, medically necessary visits performed by NPPs employed by the facility, may not take the place of physician required visits, nor may the visit count towards meeting the physician visit schedule prescribed at §483.20(c)(1).

Effective November 28, 2017

In SNFs and NFs, facility policy *that* allows *NPPs* to *conduct required visits*, and/*or* allows a 10-day slippage in the time of the *required* visit, does not relieve the physician of the obligation to visit a resident *personally* when the resident's medical condition makes that visit necessary.

Table 1: Authority for *Non-physician Practitioners* to Perform Visits, Sign Orders *and Sign Medicare Part A Certifications/Re-certifications* when Permitted by the State

	Initial Comprehensive Visit /Orders	Other Required Visits^	Other Medically Necessary Visits & Orders+	*Certification/ Recertification* ±
SNFs				
PA, NP & CNS employed by the facility	May not perform/ May not sign	May perform alternate visits	May perform and sign	*May not sign*
PA, NP & CNS not a facility employee	May not perform/ May not sign	May perform alternate visits	May perform and sign	*May sign subject to State Requirements*
NFs				
PA, NP, & CNS employed by the facility	May not perform/ May not sign	May not perform	May perform and sign	*Not applicable*
PA, NP, & CNS not a facility employee	May perform/ May sign*	May perform	May perform and sign	*Not applicable*

**A NPP may provide admission orders if a physician personally approved in writing a recommendation for admission to the facility prior to admission. For additional requirements on physician recommendation for admission and admission orders, see §483.30(a), F710.*
^Other required visits are the physician visits required by 483.30(c)(1) other than the initial comprehensive visit.
+Medically necessary visits are independent of required visits and may be performed prior to the initial comprehensive visit.
±Though not part of a compliance determination for this section, this requirement is provided for clarification and relates specifically to coverage of a Part A Medicare stay, which can take place only in a Medicare-certified SNF.

In a facility where beds are dually-certified under Medicare and Medicaid, the facility must determine how the particular resident stay is being paid in order to identify whether physician delegation of tasks is *permissible* and if a NPP may perform the tasks. For example:

- For residents in a Part A Medicare stay, the NPP must follow the requirements for physician services in a SNF. This includes, at the option of a physician, required

physician visits alternated between personal visits by the physician and visits by a NPP after the physician makes the initial *comprehensive* visit; and

- For residents in a Medicaid stay, the NPP must follow the requirements for physician services in a NF. *A NPP who is not employed by the facility and is working in collaboration with a physician* may perform any required physician task for a resident in a Medicaid-stay, at the option of the State. *(NPPs employed by the facility may not perform required physician visits but may perform other medically necessary visits)*

It is expected that visits will occur at the facility rather than the doctor's office unless office equipment is needed or a resident specifically requests an office visit. If the facility has established policy that residents leave the grounds for medical care, the resident does not object, and this policy does not infringe on his/her rights including the right to privacy, there is no prohibition to this practice. The facility should inform the resident of this practice, in accordance with §483.*10(g)(16), F581, Notice of rights and services.*

Certifications/Re-certifications in SNFs: Under 42 C.F.R. §424.20, certifications and re-certifications are required to verify that a resident requires daily skilled nursing care or rehabilitation services. NPs, CNSs, and PAs who are not employed by the facility and who are working in collaboration with a physician may sign the required initial certification and re-certifications when permitted under the scope of practice for the State. 42 C.F.R. §424.20(e)(2).

PROBES §483.*30*(c)

- *D*oes the scheduling and frequency of physician visits relate to any identified quality of care problems?
- *If the resident is admitted under a SNF stay, did the physician conduct the initial comprehensive visit, in-person, within the first 30 days?*
- *If the resident is admitted under a NF stay, did the physician or a NPP who is not employed by the facility but who is working in collaboration with a physician conduct the initial comprehensive visit, in-person, within the first 30 days?*
- *Are physician visits conducted at the required intervals, with no more than 10 days slippage from the due date?*
- *In a SNF, if the physician delegates required visits to a NPP, does the physician personally conduct alternate visits with the NPP as required?*
- *Does the resident or resident representative report meeting with the physician? If so, how often?*

POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION

*If the failure of the physician to visit the resident at the required intervals resulted in a negative outcome to the resident, also investigate compliance with §483.30(a)**,** F710, Resident's care supervised by a physician.*

DEFICIENCY CATEGORIZATION

Example of Level 4, immediate jeopardy to resident health and safety, includes, but is not limited to:

- *The facility failed to ensure the attending physician conducted required visits for several consecutive months in the facility. The physician responded to phone calls and provided*

verbal orders during this time-frame, however did not visit and make face-to-face contact with the resident, who experienced a significant negative change in status. No other physicians or NPPs visited the resident. This placed the resident at risk for serious harm or death.

Example of level 3, actual harm that is not immediate jeopardy, includes, but is not limited to:

- *A resident newly admitted to the facility and determined to be at high risk of developing a pressure ulcer/injury, developed an unstageable pressure ulcer during the first 30 days. While the physician was consulted by telephone, the facility failed to ensure the physician conducted an initial comprehensive visit for over 40 days, contributing to the decline in the resident's skin status.*

Examples of Level 2, no actual harm, with potential for than more than minimal harm, that is not immediate jeopardy, includes, but is not limited to:

- *The facility failed to ensure the physician conducted an initial comprehensive visit within the first 30 days after admission, for a resident under a Medicare Part A stay.*

Example of Level 1, no actual harm with potential for no more than a minor negative impact on the resident, includes, but is not limited to:

- *The facility failed to ensure that the attending physician alternated required monthly visits with the Nurse Practitioner as required for a resident under a SNF stay. A review of the Progress Notes revealed that notes were written, signed and dated by the NP for several consecutive visits, and all of the resident's needs were met. No documentation was found to indicate that the attending physician had visited and examined the resident at least once every 30 days for the first 90 days after admission or at least once every 60 days thereafter during this time.*

F713
§483.*30(*d) Availability of physicians for emergency care
The facility must provide or arrange for the provision of physician services 24 hours a day, in case of emergency.

***GUIDANCE* §483.*30*(d)**
If a resident's *attending* physician is unavailable, the facility should attempt to contact *the* physician *covering for the attending physician* before assuming the responsibility of *contacting another physician.*

Arranging for physician services may include assuring resident transportation to a hospital emergency room or other medical facility if the facility is unable to *meet the particular* medical *need* at the facility. *The provision of transportation does not remove the facility's responsibility to have a physician available, 24 hours a day, to respond to emergencies that do not require medical care in an alternative setting.*

PROBES §483.*30*(d)

- Does the facility have a physician on-call for medical emergencies? Does this physician respond?

- *In emergency situations, are residents unnecessarily sent to hospital emergency rooms due to the lack of physician availability or inability to contact a physician? Consider whether the resident's needs could have been met in the facility had the facility had a physician available.*
- *If the facility did not arrange for the provision of physician services 24 hours a day, for emergencies, what was the impact on residents?*

DEFICIENCY CATEGORIZATION

Example of Level 4, immediate jeopardy to resident health and safety, includes, but is not limited to:

- *The attending physician, who was the only physician of the facility and the medical director, failed to have an alternate physician or non-physician practitioner available for the residents in case of an emergency, when he left the country. The facility did not have an agreement with another physician to provide physician services in the absence of the attending physician. When a resident with a known history of congestive heart failure developed edema in the lower extremities, the facility did not have a physician to contact for consultation and new orders for interventions, resulting in hospitalization of the resident.*

Example of level 3, actual harm that is not immediate jeopardy includes, but is not limited to:

- *The facility received laboratory results indicating that a resident had a urinary tract infection (UTI). Attempts to contact the attending physician were unsuccessful, and the facility did not have an alternate physician on-call for emergencies. The facility did not secure timely medical treatment at the local hospital or alternate medical facility for the resident resulting in progression of the infection before interventions were implemented.*

Example of Level 2, no actual harm, with potential for than more than minimal harm, that is not immediate jeopardy, includes, but is not limited to:

- *The facility failed to ensure the physician responded promptly to notification of a resident's fall. Phone calls from the licensed nurses about the fall and the swelling of the left ankle were not returned for 24-hours and the facility did not secure alternate medical intervention for the resident during this time.*

Example of Level 1, no actual harm with potential for no more than a minor negative impact on the resident, includes, but is not limited to:

- *The failure of the facility to provide physician services 24-hours a day, in case of an emergency, places the resident at risk for more than minimal harm. Therefore, Severity Level 1 does not apply for this regulatory requirement.*

F714

§483.*30*(e) Physician delegation of tasks in SNFs.

§483.*30*(e)(1) Except as specified in paragraph (e)(4) of this section, a physician may delegate tasks to a physician assistant, nurse practitioner, or clinical nurse specialist who—

(i) Meets the applicable definition in §491.2 of this chapter or, in the case of a clinical nurse specialist, is licensed as such by the State;

Effective November 28, 2017

(ii) Is acting within the scope of practice as defined by State law; and
(iii) Is under the supervision of the physician.

***

§483.*30*(e)(4) A physician may not delegate a task when the regulations specify that the physician must perform it personally, or when the delegation is prohibited under State law or by the facility's own policies.

§483.*30*(f) Performance of physician tasks in NFs.
At the option of State, any required physician task in a NF (including tasks which the regulations specify must be performed personally by the physician) may also be satisfied when performed by a nurse practitioner, clinical nurse specialist, or physician assistant who is not an employee of the facility but who is working in collaboration with a physician.

INTENT §483.30(e)(1)&(4)
To allow the physician, under certain conditions, to delegate tasks to a nurse practitioner, clinical nurse specialist or physician assistant, working under the physician's supervision.

DEFINITIONS *§483.30(e)(1)&(4)*
"Clinical nurse specialist" is a registered professional nurse currently *licensed to* practice in the State and who meets the State's requirements governing the qualifications of clinical nurse specialists.

"Nurse practitioner" is a registered professional nurse *who is currently* licensed to practice in the State, who meets the State's requirements governing the qualification of nurse practitioners *and who meets one of the following conditions:*

(1) is currently certified as a primary care nurse practitioner by the American Nurses' Association or by the National Board of Pediatric Nurse Practitioners and Associates; or
(2) has satisfactorily completed a formal 1 academic year educational program that (i) prepares registered nurses to perform an expanded role in the delivery of primary care; (ii) includes at least 4 months (in the aggregate) of classroom instruction and a component of supervised clinical practice; and (iii) awards a degree, diploma or certificate to persons who successfully complete the program; or
(3) has successfully completed a formal educational program (for preparing registered nurses to perform an expanded role in the delivery of primary care) that does not meet the requirements above and has been performing an expanded role in the delivery of primary care for a total of 12 months during the 18-month period immediately preceding September 22, 2006.

"Physician assistant" is a person who meets the applicable State requirements governing the qualifications for assistants to *primary* care *physicians, and who meets at least one of the following conditions:*

(1) is currently certified by the National Commission on Certification of Physician Assistants to assist primary care physicians; or

(2) has satisfactorily completed a program for preparing physician's assistants that (i) was at least 1 academic year in length; (ii) consisted of supervised clinical practice and at least 4 months (in the aggregate) of classroom instruction directed toward preparing students to deliver health care; and (iii) was accredited by the American Medical Association's Committee on Allied Health Education and Accreditation; or

(3) Has satisfactorily completed a formal educational program (for preparing physician assistants) that does not meet the requirements above and has been assisting physicians for a total of 12 months during the 18-month period that ended on December 31, 1986.

"Non-physician practitioner (NPP)" *is a nurse practitioner (NP), clinical nurse specialist (CNS), or physician assistant (PA) as defined above.*

GUIDANCE* §483.*30(e)(1)&(4)

The extent to which physician services *may be* delegated to *NPPs* in SNFs *is governed* by the provisions of §483.30(e), while the extent to which these services may be performed by *NPPs* in NFs *is governed by the provisions of* §483.30(f). (Refer to table in *F712).*

In SNFs, when **personal** performance of a particular task by a physician is specified in the regulations, performance of that task cannot be delegated to anyone else. The tasks of examining the resident, reviewing the resident's total program of care, writing progress notes, and signing orders may be delegated *unless prohibited by* State law *or facility policies*.

PROBES §483.*30*(*e*)*(1)&(4)*

- Do the attending physicians delegate *tasks* to NPPs?
- *If the physician delegates tasks to NPs or PAs, does the NP or PA meet the requirements in §491.2?*
- *If the physician delegates tasks to CNSs, is the CNS licensed as such by the State?*
- Do *NPPs* follow the scope of practice allowed by State law *in conducting examinations, evaluations, writing progress notes and orders*?
- *Does the physician supervise the NPP in the SNF? Examples of supervision may include face-to-face encounters, clinical record reviews, telephone consults, e-mail, telehealth, and electronic health records.*

DEFINITIONS §483.30(f)

"Collaboration" *is a process often governed by the laws of a given State in which a non-physician practitioner (NPP) works with one or more physicians to deliver health care services within the scope of the NPP's expertise, with medical direction and appropriate supervision as provided for in jointly developed guidelines or other mechanisms.*

In the absence of State law governing collaboration, such collaboration is to be evidenced by NPPs documenting the NPP's scope of practice and indicating the relationships that they have with physicians to deal with issues outside their scope of practice.

The collaborating physician does not need to be present with the NPP when the services are furnished or to make an independent evaluation of each resident who is seen by the NPP.

Effective November 28, 2017

***GUIDANCE* §483.*30*(*f*)**
At the option of the State, NPPs in a NF, *who are not employees of the facility, may perform physician tasks* includ*ing* performing *examinations, evaluations,* required visits *and writing orders*.

If the physician delegates the task of performing visits to the NPP, the NPP must meet all of the requirements for

- *§483.30(a), F710, physician supervision*
- *§483.30(b), F711, physician visits*
- *§483.30(c), F712, physician frequency and timeliness of visits*

NOTE: If concerns are identified regarding the NPP meeting the requirements for physician supervision, physician visits or frequency and timeliness of visits, investigate under the corresponding regulation.

Orders written by a NPP who is employed by the NF and are written during visits that are not required visits, and are therefore "other medically necessary visits," do not require physician co-signature except as mandated by State law.

PROBES: §483.*30*(*f*)

- *If the physician delegates the performance of required physician tasks to the NPP in the NF, is the delegation allowed by the State?*
- *When performing physician tasks in the NF, is the NPP functioning within their scope of practice as permitted in their State?*
- If a *NPP* is performing required physician *visits in the NF, is the NPP* an employee of the facility? (Facility employees are prohibited from serving in this capacity.)
- *How does the facility ensure the NPP is* working in collaboration with the physician?

F715
§483.30(e)(2) A resident's attending physician may delegate the task of writing dietary orders, consistent with §483.60, to a qualified dietitian or other clinically qualified nutrition professional who—

(i) Is acting within the scope of practice as defined by State law; and
(ii) Is under the supervision of the physician.

§483.30(e)(3) A resident's attending physician may delegate the task of writing therapy orders, consistent with §483.65, to a qualified therapist who—

(i) Is acting within the scope of practice as defined by State law; and
(ii) Is under the supervision of the physician

INTENT §483.30(e)(2)-(3)
To provide physicians with the flexibility to delegate to a qualified dietitian/other clinically qualified nutrition professional the task of writing dietary orders, and to delegate to a qualified therapist the task of writing therapy orders. This flexibility is beneficial to the physician and the resident, allowing the physician to determine how to best use his or her time and allowing the

resident to have more frequent adjustments to nutritional needs and therapy as his or her condition or abilities change.

DEFINITIONS §483.30(e)(2)-(3)

"Qualified dietitian" *– is defined in §483.60 as follows: §483.60(a)(1) A qualified dietitian or other clinically qualified nutrition professional either full-time, part-time, or on a consultant basis. A qualified dietitian or other clinically qualified nutrition professional is one who—*

(i) Holds a bachelor's or higher degree granted by a regionally accredited college or university in the United States (or an equivalent foreign degree) with completion of the academic requirements of a program in nutrition or dietetics accredited by an appropriate national accreditation organization recognized for this purpose.

(ii) Has completed at least 900 hours of supervised dietetics practice under the supervision of a registered dietitian or nutrition professional.

(iii) Is licensed or certified as a dietitian or nutrition professional by the State in which the services are performed. In a State that does not provide for licensure or certification, the individual will be deemed to have met this requirement if he or she is recognized as a "registered dietitian" by the Commission on Dietetic Registration or its successor organization, or meets the requirements of paragraphs (a)(1)(i) and (ii) of this section.

(iv) For dietitians hired or contracted with prior to November 28, 2016, meets these requirements no later than 5 years after November 28, 2016 or as required by state law.

"Qualified therapist" *– professional staff, licensed, certified or registered to provide specialized therapy/rehabilitative services in accordance with State laws. Includes: Physical, Occupational, and Respiratory therapists and Speech-Language Pathologists.*

GUIDANCE §483.30(e)(2)-(3)

Physicians and NPPs may delegate the task of writing orders to qualified dietitians or clinically qualified nutrition professionals and qualified therapists if the State practice act allows the delegation of the task, and the State practice act for the qualified individual being delegated the task of writing orders permits such performance. Delegation of this task does not relieve the physician of the obligation to supervise the medical care of his/her residents. Physician responsibilities related to physician supervision of resident care are located in §483.30(a), F710, and physician obligations for conducting resident visits are located at §483.30(b), F711.

Dietary orders written by a qualified dietitian/clinically qualified nutritional professional, or therapy orders written by therapists, do not require physician co-signature, except as required by State law.

PROBES 483.30(e)(2)-(3)

- *If the dietitian/other clinically qualified nutrition professional is writing dietary orders, or a qualified therapist is writing therapy orders, did the attending physician delegate this task?*
- *If State law allows dietitians or other clinically qualified nutrition professionals to write dietary orders, are they functioning within the scope of practice defined by State law?*
- *If State law allows therapists to write therapy orders, are they functioning within the scope of practice defined by State law?*

- *Do physicians cosign dietitian/other clinically qualified nutrition professional orders and/or therapists orders, if required by State law?*
- *Is there evidence of physician supervision of dietitians/other clinically qualified nutritional professionals and/or qualified therapists who write orders? Examples of supervision may include face-to-face encounters, clinical record reviews, telephone consults, e-mail, telehealth, and electronic health records.*
- *When facility policy and State law allows physicians to delegate the task of writing orders to qualified dietitians, other clinically qualified nutrition professionals and qualified therapists, how does the facility ensure the physician supervision of individuals performing these tasks?*

§483.*35* Nursing Services
The facility must have sufficient nursing staff *with the appropriate competencies and skills sets* to provide nursing and related services *to assure resident safety and* attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident, as determined by resident assessments and individual plans of care *and considering the number, acuity and diagnoses of the facility's resident population in accordance with the facility assessment required at §483.70(e).*

Always, review nursing services requirements under §483.35 during a standard or extended survey, when a waiver of RN and/or licensed nurse (RN/LPN) staffing has been requested or granted, *or if a complaint has been received regarding nursing services.*

If the survey investigation reveals that there are not sufficient or competent staff refer to:
- *F725 or 726, §§483.35(a),(c) for any nursing services not related to behavioral health care or dementia care;*
- *F741, §483.40(a) for any staff caring for residents with dementia or a history of trauma and/or post-traumatic stress disorder;*
- *F801, §483.60(a) for Food and Nutrition staff;*
- *F826, §483.65(b), Specialized rehabilitative services;*
- *F839, §483.70(f), Administration for any other staff not referenced above.*

Potential Requirements for Additional Investigation
If noncompliance with §483.35 has been identified, the surveyor may have identified concerns with related structure, process, and/or outcome requirements. If any additional concerns have been identified, the surveyor must investigate the identified concern. Do not cite any related or associated requirements before first investigating to determine compliance or noncompliance with the related or associated requirement. Examples include, but are not limited to, the following:
- *Freedom from abuse, neglect, and exploitation, §483.12;*
- *Quality of Life, §483.24;*
- *Quality of Care, §483.25;*
- *Behavioral Health Services, §483.40;*
- *Administration §483.70(e) Facility Assessment, (f) Staff Qualifications, or (g) Use of Outside Resources;*

- *Quality Assurance and Performance Improvement §483.75;*
- *Training, §483.95.*

F725
§483.35 Nursing Services
The facility must have sufficient nursing staff *with the appropriate competencies and skills sets* to provide nursing and related services to *assure resident safety and* attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident, as determined by resident assessments and individual plans of care *and considering the number, acuity and diagnoses of the facility's resident population in accordance with the facility assessment required at §483.70(e).*

§483.35(a) Sufficient Staff.
§483.*35*(a)(1) The facility must provide services by sufficient numbers of each of the following types of personnel on a 24-hour basis to provide nursing care to all residents in accordance with resident care plans:
(i) Except when waived under paragraph (*e*) of this section, licensed nurses; and
(ii) Other nursing personnel, *including but not limited to nurse aides.*

§483.*35*(a)(2) Except when waived under paragraph (*e*) of this section, the facility must designate a licensed nurse to serve as a charge nurse on each tour of duty.

***INTENT* §§483.3*5*(a)(1)-(2)**
To assure that there is sufficient qualified nursing staff available *at all times to provide nursing and related services* to meet the residents' needs *safely and in a* manner that promotes each resident's *rights,* physical, mental and psychosocial well-being.

***DEFINITIONS* §§483.3*5*(a)(1)-(2)**
"Nurse Aide" *as defined in §483.5, is any individual providing nursing or nursing-related services to residents in a facility. This term may also include an individual who provides these services through an agency or under a contract with the facility, but is not a licensed health professional, a registered dietitian, or someone who volunteers to provide such services without pay. Nurse aides do not include those individuals who furnish services to residents only as paid feeding assistants as defined in §488.301.*

***GUIDANCE* §§483.3*5*(a)(1)-(2)**
Note: *Cite this Tag only if there are deficiencies related to the* ***sufficiency*** *of nursing staff.*

If the survey investigation reveals that there are not sufficient staff in areas other than Nursing Services refer to;
- *F741, §483.40(a) for any staff caring for residents with dementia or a history of trauma and/or post-traumatic stress disorder;*
- *F801, §483.60(a) for Food and Nutrition staff;*
- *F826, §483.65(b), Specialized rehabilitative services;*
- *F839, §483.70(f), Administration for any other staff not referenced above.*

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NOTE: The actual or potential physical, mental, or psychosocial resident outcomes related to noncompliance cited at F725, should be investigated at the relevant tags, such as Abuse, Quality of Life, and/or Quality of Care.

Many factors must be considered when determining whether or not a facility has sufficient nursing staff to care for residents' needs, as identified through the facility assessment, resident assessments, and as described in their plan of care. A staffing deficiency under this requirement may or may not be directly related to an adverse outcome to a resident's care or services. It may also include the ***potential*** *for physical or psychosocial harm.*

As required under Administration at F838, §483.70(e) an assessment of the resident population is the foundation of the facility assessment and determination of the level of sufficient staff needed. It must include an evaluation of diseases, conditions, physical, functional or cognitive limitations of the resident population's, acuity (the level of severity of residents' illnesses, physical, mental and cognitive limitations and conditions) and any other pertinent information about the residents that may affect the services the facility must provide. The assessment of the resident population should drive staffing decisions and inform the facility about what skills and competencies staff must possess in order to deliver the necessary care required by the residents being served.

PROCEDURES AND PROBES: **§§483.35(a)(1)-(2)**
Although federal regulations do not define minimum nursing staff ratios, many States do. If a facility does not meet State regulations for staffing, do NOT cite that as a deficiency here, refer to Administration, F836, §483.70(b). In addition, if a facility meets the State's staffing regulations that is not, by itself, sufficient to demonstrate that the facility has sufficient staff to care for its residents.

Surveyors must determine through information obtained by observations, interviews and verified by record reviews, whether the facility employed sufficient staff to provide care and services in assisting residents to attain or maintain their highest practicable level of physical, mental, functional and psycho-social well-being. Refer to ***the Critical Element Pathway on Sufficient and Competent Staffing*** *for additional information.*

- *When interviewing staff, residents and others, are concerns raised with the amount of time staff are available to provide care and services, such that there is not sufficient time allowed to provide the necessary care and services to a resident. If so, verify these concerns through observations and record review if necessary.*
- *Does the facility assessment describe the type and level of staff required to meet each resident's needs as required under 483.70(e). Does the type and level of the staff onsite reflect the expectations described in the facility assessment?*
- *Does the workload or assignments of the nursing staff allow them time to participate in team meetings, care planning meetings, attend training, spend time caring for residents and take time for breaks including meal breaks?*
- *Are there enough licensed staff to provide services to residents, and assist and monitor aides?*

- *Do residents and families report that* nursing staff *are* responsive to residents' *request for* assistance, *such as* call bells *typically* answered *promptly*? *Do they feel that they can have a conversation with a direct caregiver and not feel rushed?*
- *Are there any indications of delays in responsiveness for staff such as pungent odors, residents calling out, or residents wandering with inadequate supervision?*
- *Are there any indications of the use of devices or practices to manage residents' behaviors or activities such as the use of position-change alarms, positioning residents in chairs that limit their movement, or residents who are subdued or sedated?*
- *Are* residents who are unable to *use* call *bells or otherwise communicate their needs* checked frequently (e.g., each half hour) for safety, comfort, *bathroom needs* positioning, and offer*ed* fluids and *other* provision*s* of care? *Have* care problems associated with a specific unit*, day or* tour of duty *been identified by the facility? For example, does documentation show that skin integrity issues are identified more on days following a long weekend?*
- *Has the use of overtime hours increased? (If overtime hours have increased substantially, it can indicate that there is not sufficient staff or a back-up plan when staff call-out).*
- *When there are staff call-outs, did the facility fill those positions in a timely manner (e.g. within 1 hour after the start of the shift)?*

Concerns such as falls, weight loss, dehydration, pressure ulcers, as well as the incidence of elopement and resident altercations can also offer insight into the sufficiency of the numbers of staff. Surveyors must investigate if these adverse outcomes related to sufficient staffing.

KEY ELEMENTS OF NONCOMPLIANCE

To cite deficient practice at F725, the surveyor's investigation will generally show that the facility failed to do any one of the following:

- *Ensure there are a sufficient number of skilled licensed nurses, nurse aides, and other nursing personnel to provide care and respond to each resident's need;* ***or***
- *Ensure licensed nurse coverage 24 hours a day, except when waived;* ***or***
- *Ensure a licensed nurse is designated to serve as a charge nurse on each tour of duty, except when waived.*

DEFICIENCY CATEGORIZATION

Once the survey team has completed its investigation, analyzed the data, reviewed the regulatory requirements, and determined that noncompliance exists, the team must determine the severity of each deficiency, based on the harm or potential for harm to the resident.

An example of Level 4, immediate jeopardy to resident health and safety includes, but is not limited to:

- *A resident with a Stage 4 pressure injury, did not receive skin assessments and treatments for two weeks due to the absence of the only trained wound nurse on the resident's scheduled skin assessment days. No accommodations were made for coverage in the absence of this wound nurse and no other nursing staff were trained to provide this care. The pressure injury became infected during this timeframe and resulted in the resident being hospitalized requiring IV antibiotics for sepsis. Failure to provide sufficient staff*

with the necessary skill set to provide skin assessments and treatments led to serious injury with the potential for death for this resident.

Examples of Level 3, actual harm (physical or psychosocial) that is not immediate jeopardy includes, but are not limited to:

- *A resident's room has a strong smell of urine. Upon further investigation, the surveyor discovers the resident is incontinent and has soiled undergarments. Upon interview, the resident stated he called for help about an hour ago and was told by staff that they were short-staffed today and would get to him as soon as they could. He also mentioned that this happens almost every day and he is embarrassed to ask staff for help to clean himself up, so he remains withdrawn in his room until a staff member can assist him. Refer to the Psychosocial Outcome Guide in Appendix P for additional direction.*
- *A resident's care plan documented that the resident was at a risk for falling and required frequent monitoring. During an interview with the resident, she stated that she fell between her and her roommate's bed. Both residents were unable to reach the call light so both yelled for help for about 10 minutes before someone came to check on the fallen resident. After the fall, the resident was extremely sore and unable to perform activities of daily living independently as usual.*
- *Interviews with facility staff, resident family members and verified through record review demonstrated that a resident routinely expressed suicidal ideation which resulted in admission to a psychiatric unit for a month. Upon readmission to the nursing home the resident did not express a desire to harm himself but still expressed feelings of distress and loneliness. Upon interview with this resident he stated that he still contemplates suicide and feels hopeless because he can't talk to staff "because they are so busy." Interviews with staff, revealed that while they would like to spend time with this resident, they are not able, because they are busy providing direct care to other residents that needs to be completed in a shift. Failure of the facility to provide adequate staffing to address each resident's needs resulted in negative outcome for this resident with the potential for recurrence. Refer to the Psychosocial Outcome Guide in Appendix P for additional direction.*

Examples of Level 2, no actual harm, with potential for no more than minimal harm, that is not immediate jeopardy includes, but are not limited to:

- *A resident's family complained that their loved one's personal hygiene was never completed in a timely manner, due to lack of staff. When interviewed, staff stated that they typically assist this resident once the care is completed for all other residents in their assignment since it takes longer to provide care for him. This results in the resident occasionally missing occupational therapy. There has been no decline in ADL function but there is a potential for decline.*
- *Residents complain that they are not allowed choices such as receiving showers consistently on the days or at times they prefer due to inadequate staffing. Refer to the Psychosocial Outcome Guide in Appendix P for additional direction.*

Level 1 - Severity 1 does not apply for this regulatory requirement.

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F726
§483.35 Nursing Services
The facility must have sufficient nursing staff *with the appropriate competencies and skills sets* to provide nursing and related services to *assure resident safety and* attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident, as determined by resident assessments and individual plans of care *and considering the number, acuity and diagnoses of the facility's resident population in accordance with the facility assessment required at §483.70(e).*

§483.*35*(a)*(3) The facility must ensure that licensed nurses have the specific competencies and skill sets necessary to care for residents' needs, as identified through resident assessments, and described in the plan of care.*

§483.*35(*a)*(4) Providing care includes but is not limited to assessing, evaluating, planning and implementing resident care plans and responding to resident's needs.*

§483.*3*5*(c)* Proficiency of nurse aides.
The facility must ensure that nurse aides are able to demonstrate competency in skills and techniques necessary to care for residents' needs, as identified through resident assessments, and described in the plan of care.

INTENT §483.3*5(a)(3)-(4),*(c)
To assure that *all* nursing staff possess *the competencies and skill sets necessary to provide nursing and related services* to meet the residents' needs *safely and in a* manner that promotes each resident's *rights,* physical, mental and psychosocial well-being.

DEFINITIONS* §483.3*5
***"Competency"** is a measurable pattern of knowledge, skills, abilities, behaviors, and other characteristics that an individual needs to perform work roles or occupational functions successfully.*

***GUIDANCE* §483.3*5(a)(3)-(4),*(c)**
*Cite this Tag only if there are deficiencies related to the **competency** of nursing staff.*

If the survey investigation reveals that there are concerns with the competency of staff in areas other than Nursing Services refer to;

- *F741, §483.40(a) for any staff caring for residents with dementia or a history of trauma and/or post-traumatic stress disorder;*
- *F801, §483.60(a) for Food and Nutrition staff;*
- *F826, §483.65(b), Specialized rehabilitative services;*
- *F839, §483.70(f), Administration for any other staff not referenced above.*

NOTE: The actual or potential physical, mental, or psychosocial resident outcomes related to noncompliance cited at F726, should be investigated at the relevant tags, such as Abuse, Quality of Life, and/or Quality of Care.

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All nursing staff must also meet the specific competency requirements as part of their license and certification requirements defined under State law or regulations.

Many factors must be considered when determining whether or not facility staff have the specific competencies and skill sets necessary to care for residents' needs, as identified through the facility assessment, resident-specific assessments, and described in their plan of care. A staff competency deficiency under this requirement may or may not be directly related to an adverse outcome to a resident's care or services. It may also include the ***potential*** *for physical and psychosocial harm.*

As required under F838, §483.70(e), the facility's assessment must address/include an evaluation of staff competencies that are necessary to provide the level and types of care needed for the resident population. Additionally, staff are expected to demonstrate competency with the activities listed in the training requirements per §483.95, such as preventing and reporting abuse, neglect, and exploitation, dementia management, and infection control. Also, nurse aides are expected to demonstrate competency with the activities and components that are required to be part of an approved nurse aide training and competency evaluation program, per §483.152.

Competency in skills and techniques necessary to care for residents' needs includes but is not limited to competencies in areas such as;

- *Resident Rights;*
- *Person centered care;*
- Communication;
- Basic nursing skills;
- Basic restorative services;
- *Skin and wound care;*
- *Medication management;*
- *Pain management;*
- Infection control;
- *Identification of changes in condition;*
- *Cultural competency.*

Staff Competencies in Identifying Changes in Condition

A key component of competency is a nurse's (CNA, LPN, RN) ability to identify and address a resident's change in condition. Facility staff should be aware of each resident's current health status and regular activity, and be able to promptly identify changes that may indicate a change in health status. Once identified, staff should demonstrate effective actions to address a change in condition, which may vary depending on the staff who is involved. For example, a CNA who identifies a change in condition may document the change on a short form and report it to the RN manager. Whereas an RN who is informed of a change in condition may conduct an in-depth assessment, and then call the attending practitioner.

These competencies are critical in order to identify potential issues early, so interventions can be applied to prevent a condition from worsening or becoming acute. Without these competencies, residents may experience a decline in health status, function, or need to be transferred to a hospital. Not all conditions, declines of health status, or hospitalizations are preventable.

However, through the facility assessment (483.70(e)), facilities are required to address the staff competencies that are necessary to provide the level and types of care needed for the resident population considering the types of diseases, conditions, physical and cognitive disabilities, overall acuity, and other pertinent facts that are present within that population. Furthermore, per §483.95, facilities must determine the amount and types of training based on the facility assessment. We also note that the curriculum of a nurse aide training program must include training on recognizing abnormal changes in body functioning and the importance of reporting such changes to a supervisor (§483.152(b)(2)(iv)).Therefore, facility staff are expected to know how to identify residents' changes in conditions, and what to do once one is identified.

Facilities may adopt certain tools to aid staff with these competencies, as these tools have proven to be effective. For example, the Agency for Healthcare Research and Quality (AHRQ) has training modules for detecting and communicating resident changes in condition https://www.ahrq.gov/professionals/systems/long-term-care/resources/facilities/ptsafety/ltcmodule1.html. Also, Interventions to Reduce Acute Care Transfers (INTERACT) is a program with several resources aimed at improving staff competencies in this area https://interact2.net/tools_v4.html. Staff may inform surveyors of the tools they use to help show evidence of the required competencies. However, merely stating or referencing the tools is not enough on its own to verify compliance. Staff must also demonstrate that they possess the competency to use the tools in a manner that accomplishes their purpose, of aiding to effectively identify and address resident changes in condition.

Cultural Competencies

Cultural competencies help staff communicate effectively with residents and their families and help provide care that is appropriate to the culture and the individual. The term cultural competence (also known as cultural responsiveness, cultural awareness, and cultural sensitivity) refers to a person's ability to interact effectively with persons of cultures different from his/her own. With regard to health care, cultural competence is a set of behaviors and attitudes held by clinicians that allows them to communicate effectively with individuals of various cultural backgrounds and to plan for and provide care that is appropriate to the culture and to the individual.

The following resources are intended for informational purposes only:

- *The National Center for Cultural Competency https://nccc.georgetown.edu/index.html*
- *The National Standards for Culturally and Linguistically appropriate Services in Health and Health Care (developed by the Office of Minority Health in HHS) https://www.thinkculturalhealth.hhs.gov/pdfs/EnhancedCLASStandardsBlueprint.pdf*

NOTE: References to non-CMS sources do not constitute or imply endorsement of these organizations or their programs by CMS or the U.S. Department of Health and Human Services and were current as of the date of this publication.

Demonstration of Competency

Competency may not be demonstrated simply by documenting that staff attended a training, listened to a lecture, or watched a video. A staff's ability to use and integrate the knowledge and

skills that were the subject of the training, lecture or video must be assessed and evaluated by staff already determined to be competent in these skill areas.

Examples for evaluating competencies may include but are not limited to:

- *Lecture with return demonstration for physical activities;*
- *A pre- and post-test for documentation issues;*
- *Demonstrated ability to use tools, devices, or equipment that were the subject of training and used to care for residents;*
- *Reviewing adverse events that occurred as an indication of gaps in competency; or*
- *Demonstrated ability to perform activities that is in the scope of practice an individual is licensed or certified to perform.*

Nursing leadership with input from the Medical Director should delineate the competencies required for all nursing staff to deliver, individualize, and provide safe care for the facility's residents. There should also be a process to evaluate staff skill levels, and to develop individualized competency-based training, that ensure resident safety and quality of care and service being delivered. A competency-based program might include the following elements:

a. Evaluates current staff training programming to ensure nursing competencies (e.g. skills fairs, training topics, return demonstration).

b. Identifies gaps in education that is contributing to poor outcomes (e.g. potentially preventable re-hospitalization) and recommends educational programing to address these gaps.

c. Outlines what education is needed based on the resident population (e.g. geriatric assessment, mental health needs) with delineation of licensed nursing staff verses non-licensed nursing and other staff member of the facility.

d. Delineates what specific training is needed based on the facility assessment (e.g. ventilator, IV's, trachs).

e. Details the tracking system or mechanism in place to ensure that the competency-based staffing model is assessing, planning, implementing, and evaluating effectiveness of training.

f. Ensures that competency-based training is not limited to online computer based but should also test for critical thinking skills as well as the ability to manage care in complex environments with multiple interruptions.

***PROCEDURES AND PROBES* §483.3*5(a)(3)-(4),*(c)**

For specific survey procedures see the Sufficient and Competent Staffing Critical Element Pathway.

Surveyors must determine through information obtained by observations, interviews and verified by record reviews, whether the facility employs competent nursing staff to provide care and services in assisting residents to attain or maintain their highest practicable level of physical, mental, functional and psychosocial well-being.

- *How are staff competencies and skill sets evaluated upon their initial hire and routinely thereafter and when new technologies/equipment are put into use?*

- *Does the facility assessment describe the type of competencies required to meet each resident's needs as required under §483.70(e). Do the competencies of the staff reflect the expectations described in the facility assessment?*
- *Is there evidence that staff are able to identify and address resident changes in condition? What are the practices or tools used that demonstrate this ability? Is there evidence of a lack of competency, such as:*
  - *Adverse events that could have been prevented;*
  - *Conditions that occurred that could have been identified and addressed earlier to prevent them from worsening; or*
  - *Hospital transfers that could have been potentially avoided if the reason for the transfer had been identified and addressed earlier.*
- *How are staff evaluated to determine that they demonstrate knowledge of individual residents and how to support resident preferences?*
- *When observing the provision of care, does the nursing staff demonstrate:*
  - *Necessary competencies and skill sets in accordance with current standards of practice? For example, if the resident requires a manual lift for transferring, do staff demonstrate knowledge and skill in the proper use of the lift and perform the activity in a safe manner?*
  - *The use of techniques and skills that maintain or improve the resident's physical, mental or psychosocial functioning as identified through required assessments and the care plan such as, but not limited to, the following:*
    1. *Providing mobility assistance, such as assistance with walking and transferring.*
    2. *Assisting with Activities of Daily Living: eating, bathroom needs, bed mobility, bathing, oral care, incontinence care, dressing, etc.*
    3. *Providing care to residents with communication needs and ensuring that devices are utilized per the care plan.*
    4. *Demonstrating knowledge about residents' condition and behavior and when to report changes to the licensed or registered nurse.*
- *Determine how agency/contract staff have been evaluated to ensure their competencies and skills to care for the facility's resident population.*

POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION **§483.3***5(a)(3)-(4),***(c)**

If there are concerns with staff skills and competencies it may be necessary to review the facility's assessment as required at F838, §483.70(e) to determine how competencies are evaluated. Also, review the facility's process for assessing these competencies and skills and addressing staff performance for the effective application of knowledge and skill in the practice setting. It may also be necessary to review the Training requirements at §483.95.

KEY ELEMENTS OF NONCOMPLIANCE

To cite deficient practice at F726, the surveyor's investigation will generally show that the facility failed to do the following:

- *Ensure the licensed nurses and other nursing personnel have the knowledge, competencies and skill sets to provide care and respond to each resident's individualized needs as identified in his/her assessment and care plan.*

Effective November 28, 2017

DEFICIENCY CATEGORIZATION

Once the survey team has completed its investigation, analyzed the data, reviewed the regulatory requirements, and determined that noncompliance exists, the team must determine the severity of each deficiency, based on the harm or potential for harm to the resident.

Examples of Level 4, immediate jeopardy to resident health and safety includes, but are not limited to:

- *A resident sustained a serious injury that required hospitalization and surgery resulting from a fall from a mechanical lift due to an unsafe transfer by one staff member. When interviewed, this staff member stated that she was not familiar with how to use the mechanical lift. The facility failed to ensure the staff was competent to operate the equipment.*
- *Staff did not demonstrate competency in maintaining the airway of a resident with a tracheostomy when it became obstructed by a mucous plug. Staff were unable to act immediately to the situation resulting in the resident experiencing a respiratory arrest. Staff did not have the necessary skills to adequately meet the needs of the resident resulting in a life-threatening situation for the resident.*
- *A new resident was recently admitted to the nursing home with a diagnosis of diabetes. Upon interview several staff stated that they were not familiar with using this new blood sugar monitor. As a result the resident's blood sugar levels were inaccurate and not reliable. The levels continued to fluctuate from very high to very low and in each case the amount of insulin administered to the resident was adjusted based on these results. As a result after 3 days the resident went into diabetic shock and was hospitalized.*
- *The facility failed to ensure that licensed nurses had the skills and knowledge to detect changes in a resident's condition. After the nurse's aide notified the nurse on duty that the resident has swelling in her feet, the nurse determined that the resident has 2+ pitting edema and documented the finding in the medical record. No further action was taken. The nurse did not review the medical record which identified the resident's history of congestive heart failure (CHF). The next day the resident's edema increased, the nurse notified the attending physician but did not inform the physician of the resident's history of CHF. The nurse did not conduct any further assessment of the resident, secure orders from the physician, or document a request for intervention from the physician. On day three the resident experienced respiratory distress and was admitted to the hospital with CHF exacerbation. The inability of the nursing staff to conduct a thorough assessment and to recognize the signs and symptoms of CHF resulted in heart failure and placed the resident at risk for serious harm or death.*

Examples of Level 3 actual harm that is not immediate jeopardy includes but are not limited to:

- *An increase in facility acquired Stage 2 pressure injuries was noted over the past two months for residents with darker pigmentation. When interviewed, several nursing staff, including the Director of Nursing, stated that in residents with darker pigmentation, staff cannot identify pressure injuries until the skin is no longer intact. The facility failed to provide staff with the necessary skill set to identify and prevent pressure injuries and meet the residents' needs.*

- *A resident who usually gets up at 6am and eats breakfast in the dining room every day has been getting up at 8am for the past few days. When interviewed he says he doesn't want to eat breakfast and just wants to sleep. Staff have been letting him continue to sleep throughout the day. When interviewed they said they think he is just tired and this went on for several days. The resident then began to decline to eat dinner and seems confused about his whereabouts. The nurse stated she thinks he is just tired and continues to let him sleep. In the morning, the resident is falling in and out of sleep, is incoherent and has a fever. The facility orders a hospital transfer where the resident is admitted with a high fever and a positive lab result for a Urinary Tract Infection.*
- *A 78 year old with a diagnosis of hypertension, Peripheral Vascular Disease, Diabetes and CVA (cerebrovascular accident) receives anticoagulant therapy. The resident developed a nose bleed. Since the resident is on anticoagulant therapy the MD was notified and an order for PT/INR was ordered and obtained. The INR was noted to be elevated requiring the resident to receive an injection of Vitamin K. When staff were interviewed CNA #1 stated that two days prior she had noted the resident's gums were bleeding during oral care and thought that maybe he just needed his teeth cleaned but she did mention it to the nurse. CNA #2 reports that the resident had a medium black tarry stool the night before but she became busy and forgot to report it to the Charge Nurse. The facility failed to provide staff with the necessary skill set to identify residents at risk for bleeding related to anticoagulant therapy so therefore the facility staff did not meet the needs of the resident.*

An example of Level 2 no actual harm with a potential for more than minimal harm that is not immediate jeopardy includes but is not limited to:

- *Resident did not have pacemaker check performed via telephone due to lack of knowledge by staff on procedure.*

Level 1 - Severity 1 does not apply for this regulatory requirement.

F727
§483.3*5*(b) Registered nurse
§483.3*5*(b)(1) Except when waived under paragraph (*e*) or (*f*) of this section, the facility must use the services of a registered nurse for at least 8 consecutive hours a day, 7 days a week.

§483.3*5*(b)(2) Except when waived under paragraph (*e*) or (*f*) of this section, the facility must designate a registered nurse to serve as the director of nursing on a full time basis.

§483.3*5*(b)(3) The director of nursing may serve as a charge nurse only when the facility has an average daily occupancy of 60 or fewer residents.

***DEFINITIONS* §483.3*5*(b)**
"Full-time" is defined as working 35 or more hours a week.

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***GUIDANCE* §483.3*5*(b)**
The facility *must* designate a registered nurse (RN) to serve as the DON on a full-time basis. The facility can only be waived from this requirement if it has a waiver under subsection *§§483.35* (*e*) or (*f*). This requirement can be met when *two or more* RNs share the *DON* position. *The roles and responsibilities for each individual serving as the DON must be clearly defined and all f*acility staff must understand *how these responsibilities are* shared *among the individuals functioning as the DON*.

F728
§483.35(d) Requirement for facility hiring and use of nurse aides-
§483.*3*5(*d*)(*1)* General rule.
A facility must not use any individual working in the facility as a nurse aide for more than 4 months, on a full-time basis, unless—

- **(i) That individual is competent to provide nursing and nursing related services; and**
- **(ii)(A) That individual has completed a training and competency evaluation program, or a competency evaluation program approved by the State as meeting the requirements of §483.151 through §483.154; or**
  - **(B) That individual has been deemed or determined competent as provided in §483.150(a) and (b).**

§483.*35(d)(2)* Non-permanent employees.
A facility must not use on a temporary, per diem, leased, or any basis other than a permanent employee any individual who does not meet the requirements in paragraphs (d)(1)(i) and (ii) of this section.

§483.*3*5(*d*)(*3*) *Minimum* Competency
A facility must not use any individual who has worked less than 4 months as a nurse aide in that facility unless the individual—

- **(i) Is a full-time employee in a State-approved training and competency evaluation program;**
- **(ii) Has demonstrated competence through satisfactory participation in a State-approved nurse aide training and competency evaluation program or competency evaluation program; or**
- **(iii) Has been deemed or determined competent as provided in §483.150(a) and (b).**

***DEFINITIONS* §483.3*5(d)*(1-3)**
A "**permanent employee**" is defined as any employee the facility expects to continue working on an ongoing basis.

***GUIDANCE* §483.3*5(d)*(1-3)**
*A*ny individual who successfully completed *either a nurse aide training or* competency evaluation program *(NATCEP)* or a competency evaluation program *(CEP) or* has been deemed or determined competent as provided in §483.150(a) and (b) *may be employed as a nurse aide.*

*I*f an individual has not *successfully* completed a *NATCEP* program at the time of employment, that individual *may only function* as a nurse aide if the individual is *currently* in a *NATCEP* (**not**

a competency evaluation program *(CEP)* alone) *and* is a permanent employee in his or her first four months of employment in the facility.

***Procedures and Probes* §483.3*5(d)*(1-3)**

- *If there are concerns with a nurse aide's competency or qualification determine whether he/she successfully* completed *an approved NATCEP* or a *CEP*. If not, are *these individuals'* permanent employees who have worked in the facility for 4 months or less enrolled in a *NATCEP*?
- *Interview those* aides *to determine* where they received their *NATCEP* training, how long the training was and how long they have worked in the facility as a nurse aide.

If you identify deficient care practices by nurse aides who do not have evidence of having successfully completed a *NATCEP/CEP*, determine:

- If the aide is currently receiving training *in* a State-approved *NATCEP*; *and*
- If the aide has been trained, has demonstrated proficiency and determined to be proficient for the tasks to which he or she is assigned. See §483.152 for specific training that the aide is to receive.

For specific procedures for NATCEP/CEP refer to the State Operations Manual (SOM), Chapters 4 and 7.

F729
§483.*3*5(*d*)(*4*) Registry verification.
Before allowing an individual to serve as a nurse aide, a facility must receive registry verification that the individual has met competency evaluation requirements unless—

(i) The individual is a full-time employee in a training and competency evaluation program approved by the State; or

(ii)The individual can prove that he or she has recently successfully completed a training and competency evaluation program or competency evaluation program approved by the State and has not yet been included in the registry. Facilities must follow up to ensure that such an individual actually becomes registered.

§483.*3*5(*d*)(*5*) Multi-State registry verification.
Before allowing an individual to serve as a nurse aide, a facility must seek information from every State registry established under sections 1819(e)(2)(A) or 1919(e)(2)(A) of the Act *that* the facility believes will include information on the individual.

§483.*3*5(*d*)(*6*) Required retraining.
If, since an individual's most recent completion of a training and competency evaluation program, there has been a continuous period of 24 consecutive months during none of which the individual provided nursing or nursing-related services for monetary compensation, the individual must complete a new training and competency evaluation program or a new competency evaluation program.

GUIDANCE* §483.3*5(d)(6)
If the *nurse aide provides documentation to verify that* he or she performed nursing or nursing-related services for monetary compensation *(including providing assistance with activities of daily living (ADL) care)* for at least one documented day (e.g., 8 consecutive hours) during the previous 24 months, *he/she is not required to take a new nurse aide training and competency evaluation program or a new competency evaluation program (NATCEP/CEP). It is not required that these services be provided in a nursing home setting so long as the nurse aide was performing nursing or nursing-related services including assisting with ADLs*. The State is required to remove the individual's name from the registry if the services are not provided for monetary compensation during the 24-month period.

F730
§483.*3*5*(d)(7)* Regular in-service education.
The facility must complete a performance review of every nurse aide at least once every 12 months, and must provide regular in-service education based on the outcome of these reviews. *In-service training must comply with the requirements of §483.95(g).*

INTENT* §483.3*5(d)(7)
To focus on the performance review requirement and specific in-service education based on the outcome of those reviews for each individual nurse aide.

GUIDANCE* §483.3*5(d)(7)
NOTE: *Cite this Tag only when a performance review of a nurse aide is not conducted at least every 12 months or if the in-service education provided to an aide is not based on his/her performance review.*

Each nurse aide must have no less than twelve hours of in-service education per year based on *their individual* performance review. Calculate the date by which a nurse aide must receive annual in-service education by the*ir* employment date rather than the calendar year.

For specific requirements regarding the content and requirements of training for nurse aides DO NOT cite here but refer to F947, §483.95(g).

PROBES* §483.3*5(d)(7)
Surveyors should determine through information obtained by observations, interviews and verified by record reviews, whether a performance review of every nurse aide was conducted at least once every 12 months and if the regular in-service education was based on the outcome of these individual reviews.

- *What is the process for* review*ing* the performance *review* of nurse aides?
- *How are these reviews documented and does the documentation reflect at least twelve hours of in-service training per year based on an aide's individual performance review?*
- What evidence can the facility *produce* that demonstrates the in-service education *provided addresses* areas of weakness identified in performance reviews, special resident needs, and needs of residents with cognitive impairments?

F731

Effective November 28, 2017

§483.*35*(*e*) Nursing facilities
Waiver of requirement to provide licensed nurses on a 24-hour basis.
To the extent that a facility is unable to meet the requirements of paragraphs (a)(2) and (b)(1) of this section, a State may waive such requirements with respect to the facility if—

§483.3*5*(*e*)(1) The facility demonstrates to the satisfaction of the State that the facility has been unable, despite diligent efforts (including offering wages at the community prevailing rate for nursing facilities), to recruit appropriate personnel;

§483.3*5*(*e*)(2) The State determines that a waiver of the requirement will not endanger the health or safety of individuals staying in the facility;

§483.3*5*(*e*)(3) The State finds that, for any periods in which licensed nursing services are not available, a registered nurse or a physician is obligated to respond immediately to telephone calls from the facility;

§483.3*5*(*e*)(4) A waiver granted under the conditions listed in paragraph (e) of this section is subject to annual State review;

§483.3*5*(*e*)(5) In granting or renewing a waiver, a facility may be required by the State to use other qualified, licensed personnel;

§483.*35*(*e*)(6) The State agency granting a waiver of such requirements provides notice of the waiver to the *Office of the State* Long-Term Care Ombudsman (established under section 712 of the Older Americans Act of 1965) and the protection and advocacy system in the State for *individuals with a mental disorder who are eligible for such services as provided by the protection and advocacy agency*; and

§483.3*5*(*e*)(7) The nursing facility that is granted such a waiver by a State notifies residents of the facility *and their resident representatives* of the waiver.

§483.*35*(*f*) SNFs
Waiver of the requirement to provide services of a registered nurse for more than 40 hours a week.

§483.*35(f)*(1) The Secretary may waive the requirement that a SNF provide the services of a registered nurse for more than 40 hours a week, including a director of nursing specified in paragraph (b) of this section, if the Secretary finds that—

- **(i) The facility is located in a rural area and the supply of skilled nursing facility services in the area is not sufficient to meet the needs of individuals residing in the area;**
- **(ii) The facility has one full-time registered nurse who is regularly on duty at the facility 40 hours a week; and**
- **(iii) The facility either—**

(A) Has only patients whose physicians have indicated (through physicians' orders or admission notes) that they do not require the services of a registered nurse or a physician for a 48-hours period or;

(B) Has made arrangements for a registered nurse or a physician to spend time at the facility, as determined necessary by the physician, to provide necessary skilled nursing services on days when the regular full-time registered nurse is not on duty;

(iv) The Secretary provides notice of the waiver to the *Office of the State Long-Term Care Ombudsman (established under section 712 of the Older Americans Act of 1965)* and the protection and advocacy system in the State for *individuals with developmental disabilities or mental disorders*; and

(v) The facility that is granted such a waiver notifies residents of the facility *and their resident representatives of the waiver.*

§483.3*5*(*f*)*(*2) A waiver of the registered nurse requirement under paragraph (f)(1) of this section is subject to annual renewal by the Secretary.

INTENT §483.3*5(e)-(f)*
To give the facility flexibility, in limited circumstances, when the facility cannot meet nurse staffing requirements.

GUIDANCE* §483.3*5(e)-(f)
If the facility is Medicaid-certified only, the State has the authority to grant *a waiver of the RN requirement, and/or the 24-hour licensed nurse requirement.* CMS is delegated the waiver authority for SNFs, including dually-participating facilities (SNF/NFs). The Medicare waiver authority is far more limited than is the States' authority under Medicaid since a State may waive any element of the nurse staffing requirement, whereas the Secretary *(CMS)* may only waive the RN requirement. The requirements that a registered nurse provide services for 8 hours a day, 7 days a week (more than 40 hours a week), and that there be an RN designated as director of nursing on a full-time basis, may be waived by the Secretary *(CMS)* in the following circumstances:

- The facility is located in a rural area with an inadequate supply of SNF services to meet area needs. Rural is defined as "all areas not delineated as `urban`" by the Bureau of Census, based on the most recent census;
- The facility has one full-time registered nurse regularly working 40 hours a week. This may be the same individual, or part-time individuals. This nurse may or may not be the DON, and may perform some DON and some clinical duties if the facility so desires; **and either**;
  - The facility has only residents whose physicians have noted, in writing, do not need RN or physician care for a 48-hour period. This does not relieve the facility from responsibility for providing for emergency availability of a physician, when necessary, nor does it relieve the facility from being responsible for meeting all needs of the residents during those 48 hours; **OR**
  - A physician or RN will spend the necessary time at the facility to provide care residents need during the days that an RN is not on duty. This requirement refers to clinical care of the residents that need skilled nursing services.

- If a waiver of this requirement has been granted, conduct a survey of nursing services during each certification survey. Dually-participating facilities must meet the waiver provisions of the SNF.

A survey of Nursing Services must be conducted if a waiver has been granted or requested.

PROBES* §483.3*5(e)-(f)

Before granting a continuation of this waiver, or during the annual review*, coordinate with the State Survey Agency,* and at a minimum, determine:

- *The facility's recruitment efforts and its results.*
- How the facility ensures residents' needs are being met *in the absence of a licensed nurse*.
- *How* all nursing policies and procedures are followed on each shift during times when licensed services are waived?
- If there is a qualified *licensed nurse* to assess, evaluate, plan and implement resident care.
- If care is being carried out according to professional practice standards on each shift.
- Whether the survey team can assure the State that the absence of licensed nurses will not endanger the health or safety of residents.
- Whether there are trends in the facility, which might be indicators of decreased quality of care as a result of insufficient staffing to meet resident needs (e.g., increases in incident reports, the infection rate, hospitalizations, *loss of function, etc.*).
- Whether there is evidence that preventive measures (e.g., turning, ambulating) are taken to avoid poor quality of care outcomes and avoidable sudden changes in health status.
- Whether there is evidence that sudden changes in resident health status and emergency needs are being properly identified and managed by appropriate facility staff and in a timely manner.
- *Whether the residents or resident representatives been notified that the facility has a waiver to provide licensed nurses on a 24-hour basis.*
- Whether there is an increase in hospitalizations because licensed personnel are not available to provide appropriate services.
- Whether the facility meets all applicable requirements to continue to receive a waiver.
- Whether the staff indicates that an RN or physician is available to respond immediately to telephone calls when licensed nurses are not available.

If the SNF has a waiver of the more than 40 hours a week RN requirement:

- Is there an RN on duty 40 hours a week?
- If more than one RN provides the 40 hour per week coverage, how is information exchanged that maintains continuity of resident care?
- Does each *resident's* clinical record have documentation by the physician that the resident does not need services of a physician or an RN for a 48-hour period each week?
- Are there any emergency or routine services that should be, but are not, provided to residents during the days that a registered nurse is not on duty?
- If specific skilled care is necessary for a resident during the time that an RN is not on duty, does an RN or physician provide that service on an "as needed" basis?
- Did the facility notify the *residents of the facility and their resident representatives of the waiver?*

If the SNF requests continuation of the waiver to provide the services of a registered nurse for more than 40 hours a week, the survey team is to provide the *CMS Regional Office* with information needed to grant this continuation.

- Does the SNF meet all requirements necessary for continuation of the waiver?

PROCEDURES* §483.3*5(e)-(f)

The following procedure should be used to document that a facility has a waiver of nurse staffing requirements.

When a facility does not meet the nurse staffing requirements, cite the appropriate tag. If the facility does have a waiver, reference the tag number based on the type of facility. The type of facility (SNF, NF, or SNF/NF) determines what type of waiver is granted:

- For SNFs and SNF/NFs which may be waived from the requirement to provide more than 40 hours of registered nurse services a week, and for NFs which have been granted a waiver from the 56-hour registered nurse requirement, cite F*727*;
  - For NFs that have a waiver of the 24-hour licensed nursing requirement, cite F*725*, or
  - Both facility types could be waived for the requirement to designate a registered nurse as the director of nursing on a full-time basis. Cite F*731*.

If the facility has an approved nurse staffing waiver, it is **not** considered a deficiency. The facility does not need to submit a P*lan of Correction*.

F732

§483.3*5*(*g*) Nurse Staffing Information.

§483.3*5*(*g*)(1) Data requirements. The facility must post the following information on a daily basis:

(i) Facility name.

(ii) The current date.

(iii) The total number and the actual hours worked by the following categories of licensed and unlicensed nursing staff directly responsible for resident care per shift:

(A) Registered nurses.

(B) Licensed practical nurses or licensed vocational nurses (as defined under State law).

(C) Certified nurse aides.

(iv) Resident census.

§483.*3*5(*g*)(2) Posting requirements.

(i) The facility must post the nurse staffing data specified in paragraph (*g*)(1) of this section on a daily basis at the beginning of each shift.

(ii) Data must be posted as follows:

(A) Clear and readable format.

(B) In a prominent place readily accessible to residents and visitors.

Effective November 28, 2017

§483.35(*g*)(3) Public access to posted nurse staffing data. The facility must, upon oral or written request, make nurse staffing data available to the public for review at a cost not to exceed the community standard.

§483.35(*g*)(4) Facility data retention requirements. The facility must maintain the posted daily nurse staffing data for a minimum of 18 months, or as required by State law, whichever is greater.

INTENT* §483.35*(g)
To make staffing information readily available in a readable format to residents and visitors at any given time.

GUIDANCE* §483.35*(g)
The facility's "document" may be a form or spreadsheet, as long as all the required information is displayed clearly and in a visible place. The information should be displayed in a prominent place accessible to residents and visitors and presented in a clear and readable format. This information posted must be up-to-date and current.

The facility is required to list the total number of staff and the actual hours worked by the staff to meet this regulatory requirement. The information should reflect staff absences on that shift due to call-outs and illness.

Staffing must include all nursing staff who are paid by the facility (including contract staff). The nursing home would not include in the posting staff paid for through other sources; examples include hospice staff covered by the hospice benefit, or individuals hired by families to provide companionship or assistance to a specific resident.

KEY ELEMENTS OF NONCOMPLIANCE
To cite deficient practice at F732, the surveyor's investigation will generally show that the facility failed to do any one of the following:

- *Ensure staffing information was posted in a prominent place readily accessible to residents and visitors;* ***or***
- *Ensure staffing information was accurate and current;* ***or***
- *Ensure staffing information was complete and was not missing information (e.g.. specific units were not reflected on the posting);* ***or***
- *Maintain the posted daily nurse staffing data for a minimum of 18 months, or as required by State law, whichever is greater.*

F740
§483.40 Behavioral health services.
Each resident must receive and the facility must provide the necessary behavioral health care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care. Behavioral health encompasses a resident's whole emotional and mental well-being, which includes, but is not limited to, the prevention and treatment of mental and substance use disorders.

Effective November 28, 2017

DEFINITIONS §483.40
Definitions are provided to clarify terminology related to behavioral health services and the attainment or maintenance of a resident's highest practicable well-being.

"Highest practicable physical, mental, and psychosocial well-being" *is defined as the highest possible level of functioning and well-being, limited by the individual's recognized pathology and normal aging process. Highest practicable is determined through the comprehensive resident assessment and by recognizing and competently and thoroughly addressing the physical, mental or psychosocial needs of the individual.*

"Mental disorder" *is a syndrome characterized by a clinically significant disturbance in an individual's cognition, emotion regulation, or behavior that reflects a dysfunction in the psychological, biological, or developmental processes underlying mental functioning (American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders, Fifth edition. Arlington, VA: American Psychiatric Association Publishing, 2013.).*

"Substance use disorder" *is defined as recurrent use of alcohol and/or drugs that causes clinically and functionally significant impairment, such as health problems or disability (Adapted from: Substance Abuse and Mental Health Services Administration (SAMHSA) definition found at http://www.samhsa.gov/disorders/substance-use).*

GUIDANCE §483.40
Providing behavioral health care and services is an integral part of the person-centered environment. This involves an interdisciplinary approach to care, with qualified staff that demonstrate the competencies and skills necessary to provide appropriate services to the resident. Individualized approaches to care (including direct care and activities) are provided as part of a supportive physical, mental, and psychosocial environment, and are directed toward understanding, preventing, relieving, and/or accommodating a resident's distress or loss of abilities.

The facility must provide necessary behavioral health care and services which include:

- *Ensuring that the necessary care and services are person-centered and reflect the resident's goals for care, while maximizing the resident's dignity, autonomy, privacy, socialization, independence, choice, and safety;*
- *Ensuring that direct care staff interact and communicate in a manner that promotes mental and psychosocial well-being.*
- *Providing meaningful activities which promote engagement, and positive meaningful relationships between residents and staff, families, other residents and the community. Meaningful activities are those that address the resident's customary routines, interests, preferences, etc. and enhance the resident's well-being;*
- *Providing an environment and atmosphere that is conducive to mental and psychosocial well-being;*
- *Ensuring that pharmacological interventions are only used when non-pharmacological interventions are ineffective or when clinically indicated. For concerns about the use of pharmacological interventions, see Pharmacy Services requirements at §483.45.*

Effective November 28, 2017

Individualized Assessment and Person-Centered Planning:
In addition to the facility-wide approaches that address residents' emotional and psychosocial well-being, facilities are expected to ensure that residents' individualized behavioral health needs are met, through the Resident Assessment Instrument (RAI) Process.

All areas are to be addressed through the:

- *Minimum Data Set (MDS);*
- *Care Area Assessment Process;*
- *Care Plan Development;*
- *Care Plan Implementation; and*
- *Evaluation.*

Sections of the MDS related to behavioral health needs that may be helpful include, but are not limited to:

- *Section C. Cognitive Patterns;*
- *Section D. Mood;*
- *Section E. Behavior; and*
- *Section F. Activities.*

Utilizing Care Areas such as Psychosocial Well-Being, Mood State, and Behavioral Symptoms will also help to ensure the assessment and care planning processes are accomplished. It is also important for the facility to use an interdisciplinary team (IDT) approach that includes the resident, their family, or resident representative.

The following section discusses general information pertaining to depression, anxiety, and anxiety disorders, conditions that are frequently seen in nursing home residents and may require facilities to provide specialized services and supports that vary, based upon residents' individual needs.

Depression
Although people experience losses, it does not necessarily mean that they will become depressed. Depression is not a natural part of aging, however, older adults are at an increased risk. Symptoms may include fatigue, sleep and appetite disturbances, agitation, expressions of guilt, difficulty concentrating, apathy, withdrawal, and suicidal ideation. Late life depression may be harder to identify due to a resident's cognitive impairment, loss of functional ability, the complexity of multiple chronic medical problems that compound the problem, and the loss of significant relationships and roles in their life. Depression presents differently in older adults and it is the responsibility of the facility to ensure that an accurate diagnosis is established.

Anxiety and Anxiety Disorders
Anxiety is a common reaction to stress that involves occasional worry about circumstantial events. Anxiety disorders, however, include symptoms such as excessive fear and intense anxiety and can cause significant distress. Anxiety disorders are prevalent among older adults and may cause debilitating symptoms. The distinction between general anxiety and an anxiety disorder is subtle and can be difficult to identify. Accurate diagnosis by a qualified

professional is essential. Anxiety can be triggered by loss of function, changes in relationships, relocation, or medical illness. Importantly, anxiety may also be a symptom of other disorders, such as dementia, and care must be taken to ensure that other disorders are not inadvertently misdiagnosed as an anxiety disorder (or vice versa).

KEY ELEMENTS OF NONCOMPLIANCE §483.40

The facility is responsible for providing behavioral health care and services that create an environment that promotes emotional and psychosocial well-being meet each resident's needs and include individualized approaches to care.

To cite deficient practice at F740, the surveyor's investigation will generally show that the facility failed to:

- *Identify, address, and/or obtain necessary services for the behavioral health care needs of residents;*
- *Develop and implement person-centered care plans that include and support the behavioral health care needs, identified in the comprehensive assessment;*
- *Develop individualized interventions related to the resident's diagnosed conditions (e.g., assuring residents have access to community substance use services);*
- *Review and revise behavioral health care plans that have not been effective and/or when the resident has a change in condition;*
- *Learn the resident's history and prior level of functioning in order to identify appropriate goals and interventions;*
- *Identify individual resident responses to stressors and utilize person-centered interventions developed by the IDT to support each resident; or*
- *Achieve expected improvements or maintain the expected stable rate of decline based on the progression of the resident's diagnosed condition.*

Investigating Concerns Related to Behavioral Health Services

Use the Behavioral and Emotional Status Critical Element Pathway (CMS-20067), along with guidance, when determining if the facility meets the requirements pertaining to the behavioral health care needs of their residents. The facility must provide the necessary behavioral health care and services to support the resident in attaining or maintaining the highest practicable physical, mental, and psychosocial well-being.

Review, as needed, all appropriate resident assessments, associated care planning and care plan revisions, along with physician's orders to identify initial concerns and guide the investigation. Review the Minimum Data Set (MDS) and other supporting documentation to help determine if the facility is in compliance. Observe for evidence that behavioral health care needs are met and related services are provided. Staff are expected to assess and provide appropriate care for residents with behavioral health care needs. Interview the resident, his/her family, and/or representative and the IDT, as needed, to gather information about the behavioral health care and services in the nursing home. Corroborate the information obtained and any concerns noted during the survey, by building upon the investigation through additional observations, interviews, and record review. In determining compliance, additionally refer to the Psychosocial Severity Outcome Guide.

Effective November 28, 2017

DEFICIENCY CATEGORIZATION §483.40

An example of Severity Level 4 Non-compliance: Immediate Jeopardy to Resident Health or Safety includes, but is not limited to:

- *The surveyor was able to determine through an interview with a certified nurse aide (CNA), that the resident often became anxious and agitated in the evenings and attempted to leave the facility on multiple occasions over the last three months. Last week, he left the facility for 30 minutes before being found by facility staff. While outside the nursing home, he fell, resulting in several abrasions and a laceration on his forehead and right knee, which required transfer to acute care. Review of the resident's record neglected to provide documentation of potential underlying causes for his anxiety and agitation. Nor did his care plan include any interventions to reduce his expressions of distress and deter elopement. This was confirmed through interviews with the social worker, director of nursing, and medical director. The attending physician also confirmed that the IDT had not discussed potential causes for the resident's anxiousness and agitation and had not developed interventions to resolve these concerns.*

  The facility failed to investigate underlying causes of the resident's anxiety and agitation and failed to develop and implement individualized interventions for the resident, which led to numerous elopement episodes and injury.

An example of Severity Level 3 Non-compliance: Actual Harm that is not Immediate Jeopardy includes, but is not limited to:

- *A resident was admitted to the facility with a diagnosis of post-traumatic stress disorder, from war related trauma. The resident assessment identified that certain environmental triggers such as loud noises and being startled caused the resident distress and provoked screaming. The resident's care plan identified that his environment should not have loud noises and that staff should speak softly to the resident. Observations in the home revealed that the entry and exit doors had alarms that sounded with a loud horn each time they were opened. Additionally, staff were observed approaching the resident from behind and shaking his shoulder to get his attention. The resident was startled and screamed for fifteen minutes. The director of nursing (DON) stated that they hoped he would eventually get used to living in the home.*

  The facility identified triggers that were known to cause the resident distress and developed a care plan to support the resident's behavioral health care needs. However, the facility failed to implement the care planned approaches to care.

Severity Level 2: No Actual Harm with Likelihood for More Than Minimal Harm that is Not Immediate Jeopardy

- *A resident with a diagnosed anxiety disorder preferred staff to announce themselves before entering his room. His care plan identified the non-pharmacological approach of staff knocking on his door and requesting permission before entering. This had proved effective in reducing his anxiety.*

When interviewed, the resident indicated that facility staff usually followed this direction. He feels anxious on weekends when the workers from a temporary staffing agency provide care, because they frequently enter his room without asking permission. Although this increases his anxiety, he tries to live with it, but wished the nursing home would do something about it. During an interview, the DON mentioned that he was not aware of the resident's concern and that it was difficult to control all staff interactions with the resident. However, the DON agreed to investigate the situation and work to find a resolution.

The facility failed to ensure that all staff members, both those employed by the nursing home and those from the staffing agency, respected the privacy of each resident by announcing themselves prior to entering resident rooms. This led to increased anxiety for the resident.

Severity Level 1: No Actual Harm with Likelihood for Minimal Harm

- *Severity Level 1 does not apply for this regulatory requirement because any facility practice that results in a reduction of psychosocial well-being diminishes the resident's quality of life. Because more than minimal harm is likely, any deficiency for this requirement is at least a Severity Level 2. For additional guidance, see also the Psychosocial Outcome Severity Guide in Appendix P, Section E.*

POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION:
If there are concerns regarding the provision of dementia care treatment and services, review regulatory requirements at §483.40(b)(3) (F744).

If there are indications that a resident is in a secured/locked area without a clinical justification and/or placement is against the will of the resident, their family, and/or resident representative, review regulatory requirements at §483.12 and §483.12(a) (F603), Involuntary Seclusion.

If there are concerns about the resident assessment process to review for mood and psychosocial well-being see §483.20 (F636, F637, or F641), Resident Assessment.

F741
§483.40(a) The facility must have sufficient staff who provide direct services to residents with the appropriate competencies and skills sets to provide nursing and related services to assure resident safety and attain or maintain the highest practicable physical, mental and psychosocial well-being of each resident, as determined by resident assessments and individual plans of care and considering the number, acuity and diagnoses of the facility's resident population in accordance with §483.70(e). These competencies and skills sets include, but are not limited to, knowledge of and appropriate training and supervision for:

§483.40(a)(1) Caring for residents with mental and psychosocial disorders, as well as residents with a history of trauma and/or post-traumatic stress disorder, that have been identified in the facility assessment conducted pursuant to §483.70(e), and

as linked to history of trauma and/or post-traumatic stress disorder, will be implemented beginning November 28, 2019 (Phase 3).

§483.40(a)(2) Implementing non-pharmacological interventions.

INTENT §483.40(a), (a)(1) & (a)(2)
The intent of this requirement is to ensure that the facility has sufficient staff members who possess the basic competencies and skills sets to meet the behavioral health needs of residents for whom the facility has assessed and developed care plans. The facility must consider the acuity of the population and its assessment in accordance with §483.70(e). This includes residents with mental disorders, psychosocial disorders, or substance use disorders. Facility staff members must implement person-centered, care approaches designed to meet the individual needs of each resident. Additionally, for residents with behavioral health needs, non-pharmacological interventions must be developed and implemented.

NOTE: For sufficient staffing concerns that fall outside the scope of behavioral health care, review regulatory requirements at §483.35(a) (F725), Sufficient Staff and §483.35(a)(3) (F726), Competent Staff.

DEFINITIONS §483.40(a), (a)(1) & (a)(2)
Definitions are provided to clarify terminology related to behavioral health services and the attainment or maintenance of a resident's highest practicable well-being.

"Mental disorder" *is a syndrome characterized by a clinically significant disturbance in an individual's cognition, emotion regulation, or behavior that reflects a dysfunction in the psychological, biological, or developmental processes underlying mental functioning (American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders, Fifth edition. Arlington, VA: American Psychiatric Association Publishing, 2013).*

"Non-pharmacological intervention" *refers to approaches to care that do not involve medications, generally directed towards stabilizing and/or improving a resident's mental, physical, and psychosocial well-being.*

GUIDANCE §483.40(a), (a)(1) & (a)(2)
Sufficient Staff to Provide Behavioral Health Care and Services
The facility must address in its facility assessment under §483.70(e) (F838), the behavioral health needs that can be met and the numbers and types of staff needed to meet these needs.

If a resident qualifies for specialized Level II services under PASARR, please refer to §483.20(k) (F645). If the resident does not qualify for specialized services under PASARR, but requires more intensive behavioral health services (e.g., individual counseling), the facility must demonstrate reasonable attempts to provide for and/or arrange for such services. This would include ensuring that the types of service(s) needed is clearly identified based on the individual assessment, care plan and strategies to arrange such services.

Facilities must have sufficient direct care staff (nurse aides and licensed nurses) with

knowledge of behavioral health care and services in accordance with the care plans for all residents, including those with mental or psychosocial disorders.

Facilities may be concerned about accessing sufficient professional behavioral health resources (e.g., psychiatrists) to meet these requirements due to shortages in behavioral and mental health providers in their area. A facility will not be cited for non-compliance, if there are demonstrated attempts to access such services.

Facilities are not expected to provide services that are not covered by Medicare or Medicaid. They are expected to take reasonable steps to seek alternative sources (state, county or local programs) but if they are not successful, it is not the basis for a deficient practice.

Skill and Competency of Staff

The facility must identify the skills and competencies needed by staff to work effectively with residents (both with and without mental disorders and psychosocial disorders). Staff need to be knowledgeable about implementing non-pharmacological interventions. The skills and competencies needed to care for residents should be identified through an evidence-based process that could include the following: an analysis of Minimum Data Set (MDS) data, review of quality improvement data, resident-specific and population needs, review of literature, applicable regulations, etc. Once identified, staff must be aware of those disease processes that are relevant to enhance psychological and emotional well-being. Competency is established by observing the staff's ability to use this knowledge through the demonstration of skill and the implementation of specific, person-centered interventions identified in the care plan to meet residents' behavioral health care needs. Additionally, competency involves staff's ability to communicate and interact with residents in a way that promotes psychosocial and emotional well-being, as well as meaningful engagements.

Under §483.152 Requirements for approval of a nurse aide training and competency evaluation program, nurse aides are required to complete and provide documentation of training that includes, but is not limited to, competencies in areas such as:

- *Communication and interpersonal skills;*
- *Promoting residents' independence;*
- *Respecting residents' rights;*
- *Caring for the residents' environment;*
- *Mental health and social service needs; and*
- *Care of cognitively impaired residents.*

In phases one and two of implementation of the Reform of Requirements for Long-term Care Facilities, it is the expectation that all facility staff members, including non-nurse aide staff, assisting residents living with behavioral health needs, be competent in care areas, such as those mentioned previously. However, in phase three, under §483.95(i) (F949), Behavioral health, formalized training programs must be completed and documented for all staff that support and provide care for residents that have behavioral health needs.

All staff must have knowledge and skills sets to effectively interact with residents (communication, resident rights, meaningful activities.) Person-centered approaches to care

should be implemented based upon the comprehensive assessment, in accordance with the resident's customary daily routine, life-long patterns, interests, preferences, and choices, including the interdisciplinary team (IDT), the resident, resident's family, and/or representative(s). The IDT must be aware of potential underlying causes and/or triggers that may lead to expressions or indications of distress. Identifying the frequency, intensity, duration, and impact of a resident's expressions or indications of distress, as well as the location, surroundings or situation in which they occur, may help the IDT identify individualized interventions or approaches to care to support the resident's needs. Individualized, person-centered approaches to care must be implemented to address expressions or indications of distress. Staff must also monitor the effectiveness of the interventions, changing those approaches, if needed, in accordance with current standards of practice. Additionally, they must accurately document these actions in the resident's medical record and provide ongoing assessment as to whether they are improving or stabilizing the resident's status or causing adverse consequences.

The following discussion of non-pharmacological interventions supports all residents, however, residents living with behavioral health needs may require a more formalized, documented intervention plan.

Non-pharmacological Interventions

Examples of individualized, non-pharmacological interventions to help meet behavioral health needs may include, but are not limited to:

- *Ensuring adequate hydration and nutrition (e.g., enhancing taste and presentation of food, addressing food preferences to improve appetite and reduce the need for medications intended to stimulate appetite); exercise; and pain relief;*
- *Individualizing sleep and dining routines, as well as schedules to use the bathroom, to reduce the occurrence of incontinence, taking into consideration the potential need for increased dietary fiber to prevent or reduce constipation, and avoiding, where clinically inappropriate, the use of medications that may have significant adverse consequences (e.g., laxatives and stool softeners);*
- *Adjusting the environment to be more individually preferred and homelike (e.g., using soft lighting to avoid glare, providing areas that stimulate interest or allow safe, unobstructed walking, eliminating loud noises thereby reducing unnecessary auditory environment stimulation);*
- *Assigning staff to optimize familiarity and consistency with the resident and their needs (e.g., consistent caregiver assignment);*
- *Supporting the resident through meaningful activities that match his/her individual abilities (e.g., simplifying or segmenting tasks for a resident who has trouble following complex directions), interests, and needs, based upon the comprehensive assessment, and that may be reminiscent of lifelong work or activity patterns (e.g., providing an early morning activity for a farmer used to waking up early);*
- *Utilizing techniques such as music, art, massage, aromatherapy, reminiscing; and*
- *Assisting residents with substance use disorders to access counseling programs (e.g., substance use disorder services) to the fullest degree possible.*

For additional examples of individualized non-pharmacological interventions, see §483.15(f), Activities.

While there may be situations where a pharmacological intervention is indicated first, these situations do not negate the obligation of the facility to also develop and implement appropriate non- pharmacological interventions.

***Note**: This guidance is not intended to exclude the use of pharmacological interventions when they are clinically necessary and appropriate. Please see the Pharmacy Services section under §483.45(d) (F757), Unnecessary Drugs and §483.45(e) (F758), Psychotropic Drugs for additional guidance.*

INVESTIGATIVE PROTOCOL §483.40(a), (a)(1) & (a)(2)
Determination of Sufficient Staffing
One factor used to determine sufficiency of staff (including both quantity and competency of staff) is the facility's ability to provide needed care for residents as determined by resident assessments and individual care plans. A staffing deficiency must be supported by examples of care deficits caused by insufficient quantity or competency of staff. The surveyor's investigation will include whether inadequate quantity or competency of staff prevented residents from reaching the highest practicable level of well-being.

A deficiency of insufficient staffing is determined through observations, interviews, and/or record reviews. Information gathered through these sources will help the surveyor in determining non-compliance. Concerns such as expressions or indications of distress by residents or family members, residents living with mental, psychosocial, and/or substance use disorders who lack care plan interventions to address their individual needs, lack of resident engagement, and the incidence of elopement and resident altercations, can also offer insight into the sufficiency and competency of staff and the adequacy of training provided to them to care for residents with behavioral health needs.

Determination of Staff Competencies
As required under §483.70(e) (F838), the facility's assessment must include an evaluation of staff competencies that are necessary to provide the level and types of care needed for the resident population. The facility must have a process for evaluating these competencies.

If sufficient and/or competent staffing concerns are present during the surveyor's investigation or while completing the Sufficient and Competent Staffing Facility Task refer to the Behavioral and Emotional Status (CMS-20067) Critical Element Pathway.

KEY ELEMENTS OF NONCOMPLIANCE §483.40(a), (a)(1) & (a)(2)
To cite deficient practice at F741, the surveyor's investigation will generally show that the facility failed to:

- *Rule out underlying causes for the resident's behavioral health care needs through assessment, diagnosis, and treatment by qualified professionals, such as physicians, including psychiatrists or neurologists;*
- *Identify competencies and skills sets needed in the facility to work effectively with residents with mental disorders and other behavioral health needs;*
- *Provide sufficient staff who have the knowledge, training, competencies, and skills sets to address behavioral health care needs;*

- *Demonstrate reasonable attempts to secure professional behavioral health services, when needed;*
- *Utilize and implement non-pharmacological approaches to care, based upon the comprehensive assessment, and in accordance with the resident's abilities, customary daily routine, life-long patterns, interests, preferences, and choices;*
- *Monitor and provide ongoing assessment of the resident's behavioral health needs, as to whether the interventions are improving or stabilizing the resident's status or causing adverse consequences;*
- *Attempt alternate approaches to care for the resident's assessed behavioral health needs, if necessary; or*
- *Accurately document all relevant actions in the resident's medical record.*

***NOTE**: In the case of a negative resident outcome, the surveyor must investigate whether or not the facility considered all relevant factors that may have contributed to the outcome. Doing so, while also using the points described in the key elements will assist the survey team in determining if an identified concern was avoidable or unavoidable.*

DEFICIENCY CATEGORIZATION §483.40(a), (a)(1) & (a)(2)
An example of Severity Level 4 Non-compliance: Immediate Jeopardy to Resident Health or Safety includes, but is not limited to:

- *The care plan of a resident, diagnosed with depression and suicidal ideation, included close supervision and one-on-one activities with staff. Based upon documentation in the resident's record, the resident was often isolated in her room and increasingly spoke of wanting to die. Additionally, the resident had recently been transported to an acute care facility for a psychiatric evaluation, when she threatened to harm herself and was deemed inconsolable by facility staff. During an interview, the Director of Nursing (DON) indicated that on many evening and weekend shifts the facility did not have enough staff to provide close supervision or one-on-one activities for the resident. No other alternative arrangements had been developed, care planned, or implemented to ensure the resident's behavioral health needs were met.*

  The facility lacked sufficient staff with the required skills sets to implement the resident's care planned interventions. This led to increased expressions of distress and a threat of personal harm, resulting in the deterioration of the resident's mental and psychosocial well-being.

An example of Severity Level 3 Non-compliance: Actual Harm that is not Immediate Jeopardy includes, but is not limited to:

- *Facility staff failed to intervene when a visibly agitated and confused resident was pacing the hallways. Record review showed that these expressions of distress had occurred during the late afternoon and early evening for the past three weeks. A CNA told the surveyor that the DON said the resident had "sundowning;" however, when asked, she was unable to explain what that meant or what individualized interventions should be implemented. She was told to leave the resident alone and let him tire himself out.*

The facility lacked competent staff with the knowledge and skills sets to support and assist the resident who was experiencing agitation and confusion on a daily basis. This resulted in increased distress over the course of several weeks, without the development and implementation of individualized, non-pharmacological approaches to care.

An example of Severity Level 2 Non-compliance: No Actual Harm with Likelihood for More Than Minimal Harm that is Not Immediate Jeopardy includes, but is not limited to:

- *A surveyor heard a resident complaining to nursing home staff that he was late for his meeting again. The resident told the surveyor that he has missed his weekly Alcoholics Anonymous (AA) meeting held at the local church for the last three weeks and that this made him angry. Record review showed that attendance at these meetings was a part of his care plan. During an interview, a CNA, who helps the resident with his activities of daily living (ADL) on a consistent basis, stated that she was busy and did her best to make sure he was ready when his transportation arrived.*

  The facility failed to implement the resident's care planned interventions, causing him to consistently miss his AA meetings. This led to feelings of anger and had the potential to jeopardize the resident's sobriety.

Severity Level 1: No Actual Harm with Likelihood for Minimal Harm

- *Severity Level 1 does not apply for this regulatory requirement because any facility practice that results in a reduction of psychosocial well-being diminishes the resident's quality of life. Because more than minimal harm is likely, any deficiency for this requirement is at least a Severity Level 2. For additional guidance, see also the Psychosocial Outcome Severity Guide in Appendix P, Section E.*

F742
§483.*40*(*b*) Based on the comprehensive assessment of a resident, the facility must ensure that—

§483.*40*(*b*)(1)
A resident who displays *or is diagnosed with* mental *disorder* or psychosocial adjustment difficulty, *or who has a history of trauma and/or post-traumatic stress disorder*, receives appropriate treatment and services to correct the assessed problem *or to attain the highest practicable mental and psychosocial well-being*;

DEFINITIONS §483.40(b) & §483.40(b)(1)
Definitions are provided to clarify terminology related to behavioral health services and the attainment or maintenance of a resident's highest practicable well-being.

"Mental and psychosocial adjustment difficulty" *refers to the development of emotional and/or behavioral symptoms in response to an identifiable stressor(s) that has not been the resident's typical response to stressors in the past or an inability to adjust to stressors as evidenced by chronic emotional and/or behavioral symptoms. (Adapted from Diagnostic and Statistical Manual of Mental Disorders - Fifth edition. 2013, American Psychiatric Association.).*

Effective November 28, 2017

INTENT §483.40(b) & §483.40(b)(1)
The intent of this regulation is to ensure that a resident who upon admission, was assessed and displayed or was diagnosed with a mental or psychosocial adjustment difficulty or a history of trauma and/or post-traumatic stress disorder (PTSD), receives the appropriate treatment and services to correct the initial assessed problem or to attain the highest practicable mental and psychosocial well-being. Residents who were admitted to the nursing home with a mental or psychosocial adjustment difficulty, or who have a history of trauma and/or PTSD, must receive appropriate person-centered and individualized treatment and services to meet their assessed needs.

GUIDANCE §483.40(b) & §483.40(b)(1)
Residents who experience mental or psychosocial adjustment difficulty, or who have a history of trauma and/or post-traumatic stress disorder (PTSD) require specialized care and services to meet their individual needs. The facility must ensure that an interdisciplinary team (IDT), which includes the resident, the resident's family and/or representative, whenever possible, develops and implements approaches to care that are both clinically appropriate and person-centered. Expressions or indications of distress, lack of improvement or decline in resident functioning should be documented in the resident's record and steps taken to determine the underlying cause of the negative outcome.

For additional information regarding non-pharmacological interventions, see §483.40(a)(2) (F741), Implementing non-pharmacological interventions.

What is appropriate treatment and services to correct the assessed problem or to attain the highest practicable mental and psychosocial well-being?
The facility must provide the "appropriate treatment and services" to correct the assessed problem or to attain the highest practicable mental and psychosocial well-being. The determination of what is "appropriate" is person-centered and would be based on the individualized assessment and comprehensive care plan. To the extent that the care plan identifies particular treatment and services, the facility must make reasonable attempts to provide these services directly or assist residents with accessing such services.

A facility must determine through its facility assessment what types of behavioral health services it may be able to provide. Some examples of treatment and services for psychosocial adjustment difficulties may include providing residents with opportunities for autonomy; arrangements to keep residents in touch with their communities, cultural heritage, former lifestyle, and religious practices; and maintaining contact with friends and family. The coping skills of a person with a history of trauma or PTSD will vary, so assessment of symptoms and implementation of care strategies should be highly individualized. Facilities should use evidence-based interventions, if possible.

Background on Trauma and PTSD
A close relationship exists between mental and psychosocial adjustment difficulties*, histories of trauma, and PTSD.*

- *Adjustment difficulties:*

  - *Occur* within 3 months of the onset of a stressor and *last no longer than 6 months after the stressor or its consequences have ended;*
  - *Are characterized by distress that is out of proportion to the severity or intensity of the stressor, taking into account external context and cultural factors, and/or a significant impairment in social, occupational, or other important areas of functioning;*
  - *May be related to a single event or involve multiple stressors and may be recurrent or continuous;*
  - *May cause a depressed mood, anxiety, and/or aggression;*
  - *May be diagnosed following the death of a loved one when the intensity, quality, or persistence of grief exceeds what normally might be expected; and*
  - *Can occur for individuals with or without PTSD or a history of trauma.*
- *History of trauma:*
  - *Involves psychological distress, following a traumatic or stressful event, that is often variable;*
  - *May be connected to feelings of anxiety and/or fear;*
  - *Often involves expressions of anger or aggressiveness; and*
  - *Some individuals who experience trauma will develop PTSD.*
- *PTSD:*
  - *Involves the development of symptoms following exposure to one or more traumatic, life-threatening events;*
  - *Usually develops within the first 3 months after the trauma occurs, although there may be a delay in months or even years;*
  - *Symptoms may include, but are not limited to, the re-experiencing or re-living of the stressful event (e.g., flashbacks or disturbing dreams), emotional and behavioral expressions of distress (e.g., outbursts of anger, irritability, or hostility), extreme discontentment or inability to experience pleasure, as well as dissociation (e.g., detachment from reality, avoidance, or social withdrawal), hyperarousal (e.g., increased startle response or difficulty sleeping); and*
  - *May be severe or long-lasting when the stressor is interpersonal and intentional (e.g., torture or sexual violence).*

(Adapted from American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders, Fifth edition. Arlington, VA: American Psychiatric Association Publishing, 2013.)

Although PTSD is commonly viewed as a disorder experienced only by military veterans, it is not exclusively a consequence of combat or war zone exposure. Individuals who have been physically or sexually assaulted or who experienced a terrorist attack or natural disaster, among other things may also be affected by PTSD. Additionally, some older nursing home residents may have lived through a time of genocide and witnessed or been subjected to the intentional and systematic destruction of a racial, political, or cultural group such as that which occurred during the Holocaust in World War II.

Moving from the community into a long-term care facility, for an individual with a history of trauma or PTSD, can be a very difficult transition and cause worsening or reemergence of symptoms. Additionally, the structured environment of the nursing home can trigger memories of traumatic events and coping with these memories may be more difficult for older adults.

Effective November 28, 2017

KEY ELEMENTS OF NONCOMPLIANCE §483.40(b) & §483.40(b)(1)

To cite deficient practice at F742, the surveyor's investigation will generally show that the facility failed to:

- *Assess the resident's expressions or indications of distress to determine if services were needed;*
- *Provide services and individualized care approaches that address the assessed needs of the resident and are within the scope of the resources in the facility assessment;*
- *Develop an individualized care plan that addresses the assessed emotional and psychosocial needs of the resident;*
- *Assure that staff consistently implement the care approaches delineated in the care plan;*
- *Monitor and provide ongoing assessment as to whether the care approaches are meeting the emotional and psychosocial needs of the resident; or*
- *Review and revise care plans that have not been effective and/or when the resident has a change in condition and accurately document all of these actions in the resident's medical record.*

***NOTE**: For behavioral health care concerns that do not pertain to residents who display or are diagnosed with a mental disorder or psychosocial adjustment difficulty, or who have a history of trauma and/or post-traumatic stress disorder, review regulatory requirements at §483.40 (F740), Behavioral Health Services.*

INVESTIGATIVE PROTOCOL §483.40(b) & §483.40(b)(1)

Objectives

The objectives of this protocol are to determine, based on the comprehensive assessment of a resident, that the facility ensured that the resident who displays or is diagnosed with a mental or psychosocial adjustment difficulty, or who has a history of trauma and/or PTSD receives the care and services necessary to reach and maintain the highest level of mental and psychosocial functioning.

Procedures

In order to guide observations, briefly review the comprehensive assessment and interdisciplinary care plan.

Observations

Observe for manifestations related to mental and psychosocial adjustment difficulties, a history of trauma and/or PTSD which may, over a period of time, include:

- *Impaired verbal communication without physiological cause;*
- *Social isolation and withdrawal inconsistent with the resident's usual demeanor;*
- *Sleep pattern disturbance (e.g., disruptive change in sleep/rest pattern as related to one's biological and emotional needs);*
- *Deviation from past spiritual beliefs or rituals (alterations in one's belief system);*
- *Inability to control behavior, anger, and the potential for physical harm to oneself or others; and*
- *Stereotyped response to any stressor (i.e., the same characteristic response, regardless of the stimulus).*

NOTE: *Observe staff interactions with the resident in formal and informal situations and determine whether or not they implement interventions in accordance with the care plan.*

Interviews
Resident/Resident Representative
Interview the resident, resident's family, or representative(s), to the degree possible, to determine:

- *Awareness of the current condition(s) or history of the condition(s) or diagnosis/diagnoses;*
- *Participation in the development of a person-centered care plan;*
- *Whether or not resident choices and preferences are considered; and*
- *Validity of observations and data collection.*

Staff Interviews
Interview IDT member(s) as necessary to determine:

- *Whether or not care provided is consistent with the care plan; and*
- *That staff are knowledgeable about how to support the resident when they are expressing or indicating feelings of distress;*

Additionally, speaking to staff on various shifts can help to determine:

- *Staff knowledge of facility-specific guidelines and protocols related to the treatment of mental disorders and psychosocial adjustment difficulties, history of trauma, and PTSD;*
- *Whether certified nurse aides (CNA) know how, what, when, and to whom to report changes in condition;*
- *How facility staff monitor care plan implementation, and changes in condition; and*
- *How changes in both the care plan and the resident's condition are communicated to the staff.*

Record Review

- *Identify if the resident triggers Care Area Assessments (CAA) for activities, mood state, psychosocial well-being, and psychotropic drug use.*
  - *Consider whether the CAA process was used to assess the causal factors for decline, potential for decline, or lack of improvement.*
- *Review the resident's care plan for interventions to address the assessed problem.*
- *How are mental and psychosocial adjustment difficulties, a history of trauma, and/or PTSD addressed in the care plan?*
  - *Does it describe the expressions or indications of distress that the resident has experienced because of the assessed problem?*
  - *Does it describe the programs and activities that have been implemented to assist the resident in reaching and maintaining the highest level of mental and psychosocial functioning?*
  - *Is the care plan written in measurable language that allows assessment of its effectiveness?*
- *Are the data to be collected to evaluate the effectiveness of the care plan identified?*
- *Are the data collection done according to the care plan?*
- *Is there an assessment of the resident's usual and customary routines and preferences?*

- *Are accommodations made by the facility to support the resident by incorporating these routines and preferences in the care plan?*

- *Does record review indicate that the care and services outlined in the care plan are effective in decreasing the resident's expressions or indications of distress?*
- *If the data collected indicate that expressions or indications of distress are unchanged in frequency or severity over two or more assessment periods, is the plan reassessed and intervention approaches revised to support the resident in attaining the highest practicable mental and psychosocial well-being?*

NOTE: Clinical conditions that may produce apathy, malaise, and decreased energy levels that can be mistaken for depression associated with mental or psychosocial adjustment difficulty may include, *but are not limited to:*

- Metabolic *or endocrine disorders (e.g., Cushing's disease, diabetes/hypoglycemia, hypothyroidism);*
- Central nervous system disorders *(e.g., tumors and other mass lesions, Parkinson's disease, multiple sclerosis, Alzheimer's disease);*
- Miscellaneous *conditions (e.g., pernicious anemia, pancreatic disease, malignancy, infections, congestive heart failure, hypotension, dehydration, circadian rhythm disruption);*
- Over-medication *for treatment of other conditions; and*
- *Use* of restraints.

DEFICIENCY CATEGORIZATION §483.40(b) & §483.40(b)(1)
An example of Severity Level 4 Non-compliance: Immediate Jeopardy to Resident Health or Safety includes, but is not limited to:

- *A surveyor observed a resident, who was crying and exhibiting signs of distress, lying in bed in her room. During an interview, the resident told the surveyor that she had lost all hope, felt betrayed by her family and her faith, and was ready to die. The resident shared that her children sold her house before she came to the nursing home, but that she had planned to go back there to live once her health improved. The resident added that she had lived in that house for 55 years, raising her children and enjoying life. Record review showed that upon admission, the resident indicated her goal was to return home, but also that her house had been sold by her family.*

  Facility progress notes documented increased anxiety and depressive mood, as well as isolation from activities she had previously enjoyed, including attendance at religious services. Additionally, the resident had stopped eating or drinking. She was receiving IV fluids and the insertion of a feeding tube was being considered.

  An interview with the Care Plan Coordinator confirmed that the facility failed to develop an individualized care plan that addressed the assessed emotional and psychosocial needs of the resident. During an interview with the social worker, she indicated that she had been aware the house sold, but did not realize the resident was so distraught about it.

  The facility failed to acknowledge and assess the underlying causes of the resident's

expressions of distress or develop and implement a care plan that addressed this distress. This resulted in the deterioration of the resident's physical, mental, and psychosocial well-being.

An example of Severity Level 3 Non-compliance Actual Harm that is not Immediate Jeopardy includes, but is not limited to:

- *The facility determined that a resident's resistance to receiving staff assistance in the shower was a result of a traumatic event that occurred at home years ago when a home health aide left her in the shower unattended and she fell, fracturing her hip. The resident has never been able to return home since the event and is distrustful of the nursing home staff. Interventions listed on the care plan specified that she is to be assisted by two staff members in the shower. The resident is to be approached in an unhurried manner, with calm voices and soft lighting.*

  The surveyor observed the resident in the shower with only one certified nurse aide (CNA) in attendance and harsh lighting. During the shower the resident demonstrated anxiety and fear. She was yelling, crying, restless, and tried to get out of the shower chair many times during care. When observed 30 minutes after her shower, the resident was no longer yelling, however she still appeared fearful and her crying was just beginning to resolve.

  An interview with the CNA and director of nursing confirmed that the care plan interventions had not been followed.

  The facility failed to ensure that a resident, who has a history of trauma, received the appropriate treatment and services to reduce her anxiety and fear in the shower. Care planned interventions were not implemented, leading to increased expressions of distress by the resident and a decline in her mental and psychosocial well-being.

An example of Severity Level 2 Non-compliance: No Actual Harm with Likelihood for More Than Minimal Harm that is Not Immediate Jeopardy includes, but is not limited to:

- *A surveyor heard a resident yelling for help. Facility staff and the surveyor followed the sound to the resident's room where they found her lying in bed in a darkened room, clinging tightly to her wallet and blanket. The staff turned on the lights to assist in calming her down.*

  During an interview later that day, the resident shared that she had been robbed at knife point in her own home prior to being admitted to the nursing home last year. She also mentioned that, although she felt secure in the nursing home, she still had nightmares sometimes and the nurses are supposed to leave her bathroom light on at night. The resident also asked to be moved to a room closer to the nursing station, but that had not happened yet.

  Record review of the resident's assessment and care plan documented that the resident did have care planned interventions regarding her increased need for reassurance, due to the robbery prior to admission. Interventions included leaving the resident's

bathroom light on at night.

Interviews with facility staff confirmed that they sometimes forget to leave the bathroom light on at night for the resident. Additionally, the social worker confirmed that the possibility of a room closer to the nursing station had not yet been investigated.

The facility failed to implement person-centered, non-pharmacological approaches to care for a resident, with a history of trauma, causing the resident increased distress and fear.

Severity Level 1: No Actual Harm with Likelihood for Minimal Harm

- *Severity Level 1 does not apply for this regulatory requirement because any facility practice that results in a reduction of psychosocial well-being diminishes the resident's quality of life. Because more than minimal harm is likely, any deficiency for this requirement is at least a Severity Level 2. For additional guidance, see also the Psychosocial Outcome Severity Guide in Appendix P, Section E.*

F743
§483.*40*(*b*)(2) A resident whose assessment did not reveal *or who does not have a diagnosis of* a mental or psychosocial adjustment difficulty *or a documented history of trauma and/or post- traumatic stress disorder* does not display a pattern of decreased social interaction and/or increased withdrawn, angry, or depressive behaviors, unless the resident's clinical condition demonstrates that development of such a pattern was unavoidable; *and*

INTENT §483.40(b)(2)
The intent of this regulation is to ensure that a resident who, upon admission was not assessed or diagnosed with a mental or psychosocial adjustment difficulty or a documented history of trauma and/or post-traumatic stress disorder (PTSD), does not develop patterns of decreased social interaction and/or increased withdrawn, angry, or depressive behaviors while residing in the facility. However, after admission, if the resident is diagnosed with a condition that typically manifests a similar pattern of behaviors, documentation must validate why the pattern was unavoidable (e.g., symptoms did not initially manifest, family was unaware of previous trauma or were unavailable for interview, etc.). Development of an unavoidable pattern of behaviors refers to a situation where the interdisciplinary team, including the resident, their family, and/or resident representative, has completed comprehensive assessments, developed and implemented individualized, person-centered approaches to care through the care-planning process, revised care plans accordingly, and behavioral patterns still manifest.

GUIDANCE §483.40(b)(2)
Nursing home admission can be a stressful experience for a resident, his/her family, and/or representative. Behavioral health is an integral part of a resident's assessment process and care plan development. The assessment and care plan should include goals that are person-centered and individualized to reflect and maximize the resident's dignity, autonomy, privacy, socialization, independence, choice, and safety.

Facility staff must:

- *Monitor the resident closely for expressions or indications of distress;*
- *Assess and plan care for concerns identified in the resident's assessment;*
- *Accurately document the changes, including the frequency of occurrence and potential triggers in the resident's record;*
- *Share concerns with the interdisciplinary team (IDT) to determine underlying causes, including differential diagnosis;*
- *Ensure appropriate follow-up assessment, if needed; and*
- *Discuss potential modifications to the care plan.*

For additional information regarding non-pharmacological interventions, see §483.40(a)(2) (F741), Implementing non-pharmacological interventions.

KEY ELEMENTS OF NONCOMPLIANCE §483.40(b)(2)

To cite deficient practice at F743, the surveyor's investigation will generally show the facility failed to:

- *Identify that a resident developed decreased social interaction and/or increased withdrawn, angry, or depressive behaviors, and may have made verbalizations indicating these;*
- *Evaluate whether the resident's distress was attributable to their clinical condition and demonstrate that the change in behavior was unavoidable;*
- *Ensure an accurate diagnosis of a mental disorder or psychosocial adjustment difficulty, or PTSD was made by a qualified professional;*
- *Adequately assess and/or develop care plans for services and individualized care approaches that support the needs of residents who develop these patterns;*
- *Provide services with an individualized care approach that support the needs of residents with these indicators;*
- *Provide staff with training opportunities related to the person-centered care approaches that have been developed and implemented;*
- *Assure that staff consistently implement the approaches delineated in the care plan;*
- *Monitor and provide ongoing assessment as to whether the care approaches are meeting the needs of the resident; or*
- *Review and revise care planned interventions and accurately document the reason for revision in the resident's medical record.*

INVESTIGATIVE PROTOCOL §483.40(b)(2)

Objectives

The objective of this protocol is to determine whether or not the facility meets the regulatory requirements for a resident who has displayed a pattern of decreased social interaction and/or increased withdrawn, angry, or depressive expressions or indications of distress.

Procedures

Briefly review the comprehensive assessment and interdisciplinary care plan to guide observations.

Observations

Observe residents who appear to be isolated, withdrawn, angry, or have other expressions or

indications of mental or psychosocial difficulties, a history of trauma and/or PTSD. Additionally, observations may include, but are not limited to:

- *Staff and resident interactions;*
- *Demonstration of the staff's understanding, responsiveness, and proactive care for residents' needs; and*
- *Implementation of care plan interventions by staff.*

Interviews

Resident/Resident Representative

Interview the resident, resident's family, or representative(s), to the degree possible, to determine:

- *The level of social interaction and distress that was present upon admission;*
- *Whether social interaction has diminished or increased since admission;*
- *If withdrawal, anger, and depressive expressions or indications of distress have increased without a change in the resident's clinical condition;*
- *Participation in the development of a person-centered care plan; and*
- *Whether or not resident choices and preferences are considered.*

Staff Interviews

In the case where staff members have noted changes in a resident's social interactions and behaviors after admission to the facility, and the care plan does not reflect these changes, the surveyor must:

Interview IDT member(s) as necessary to determine:

- *Whether or not facility staff are aware of changes in the resident's social interactions and/or behavior;*
- *That staff are knowledgeable about how to support the resident when they are expressing or indicating feelings of distress;*
- *Whether or not facility staff, including the resident, their family, and/or resident representative have reviewed the resident's care plan and revised it as necessary, to reflect the resident's current needs and goals.*

Additionally, speaking to staff on various shifts can help to determine:

- *Their knowledge of facility-specific guidelines and protocols related to the treatment of mental disorders and psychosocial adjustment difficulties, history of trauma, and PTSD;*
- *Whether certified nurse aides know how, what, when, and to whom to report changes in condition, including changes in a resident's social interactions and behaviors (e.g., residents who have begun to withdraw, express anger, and/or depression);*
- *How facility staff monitor the implementation of the care plan, and respond to changes in the resident's social interactions and behaviors; and*
- *How changes in both the care plan and the resident's condition are communicated to the staff.*

Record Review

- *Determine whether or not upon admission, the resident had a diagnosis of or displayed a mental or psychosocial adjustment difficulty or a documented history of trauma and/or PTSD.*
- *Review the resident's medical record for documentation related to a pattern of decreased social interaction and/or increased withdrawn, angry, or depressive expressions or*

indications of distress. Review nursing, social service, mental health notes, or other discipline notes for description of the distress.

- *Review the Resident Assessment Instrument (RAI) and identify if the Minimum Data Set (MDS) captures and was used to assess the resident's conditions. Look to see that the resident Care Area Assessments (CAA) for activities, mood state, psychosocial well-being, and psychotropic drug use trigger for any reason in the absence of related diagnoses or difficulties, or history of trauma and/or PTSD.*
- *Consider whether the CAA process was used to identify and assess the reason and causal factors for decline, potential for decline, or lack of improvement.*
- *Is there an assessment of the resident's usual and customary routines and preferences?*
  - *Are accommodations made by the facility to support the resident by incorporating these routines and preferences in the care plan?*
- *Review the resident's care plan to determine if interventions are in place to alleviate the assessed distress.*
  - *Does it thoroughly describe the distress from a person-centered perspective?*
  - *Does it describe the programs and activities that have been implemented to assist the resident in reaching and maintaining the highest level of mental and psychosocial functioning?*
  - *Is the care plan written in measurable language that allows assessment of its effectiveness?*
  - *Does the record review indicate that the care and services outlined in the care plan are effective?*

DEFICIENCY CATEGORIZATION §483.40(b)(2)
An example of Severity Level 4 Non-compliance: Immediate Jeopardy to Resident Health or Safety includes, but is not limited to:

- *The facility failed to identify signs of distress exhibited by a resident who, according to the medical record, for the past month had begun rising from bed mid-morning and returning to bed immediately after dinner. This was a departure from her previous morning and night sleep patterns. Upon interview, staff communicated that as people age, they grow tired more easily and require more sleep. The staff also noted that the resident was often very tearful and seemed depressed, but again they felt that this was normal for older adults. Even though she experienced a significant weight loss and did not want to speak to a social worker when approached about these noted changes, the staff honored her wish to be left in bed. During the resident interview, she stated that she was tired and just wanted to sleep. She informed the surveyor that the last of her friends had just died, leaving her with no other childhood contacts or meaningful social relationships other than her family. She began crying and stated that she often cried, but tried not to in front of the staff because she was too proud. She felt that by sleeping a lot, she wouldn't have to face the fact that she also would die soon.*

  The facility's failure to identify that the resident was in distress and needed a mental health assessment caused a delay in receiving appropriate services and a deterioration in the resident's psychosocial well-being.

Effective November 28, 2017

An example of Severity Level 3: Actual Harm that is not Immediate Jeopardy includes, but is not limited to:

- *During the tour of the facility, the surveyor noticed a resident sitting by the front door of the facility wringing his hands and staring out the window. While engaged in conversation, he stated that he was afraid that he would miss his group again. He had to come to the nursing home after his wife's death and was having a hard time adjusting to the change. He stated that he joined a grief support group that he was finding helpful, but had not been able to attend for a few weeks. He was unable to sleep at night because of the worry about missing the group sessions.*

  His care plan indicated that the only intervention to address his grief was participation in a weekly support group meeting at the senior center. His goal was to attend group sessions, so he could better cope with the multiple losses he had experienced. An interview with the facility administrator revealed that the resident had been unable to attend group sessions for six weeks because the facility's only van was in the shop. During those weeks, the facility failed to provide alternative interventions and address the distress caused by the missed meetings. The resident's medical record reflected that in the past month, he appeared more anxious, depressed, and angry and staff described him as "not his pleasant self."

  The resident suffered a decline as a direct result of being unable to attend his weekly support group meetings and the facility did not seek any alternatives when transportation was unavailable.

An example of Severity Level 2: No Actual Harm with Likelihood for More Than Minimal Harm that is Not Immediate Jeopardy includes, but is not limited to:

- *After falling at home and fracturing her femur, a resident was admitted to the skilled nursing facility for rehabilitation services. She had no history of mental or psychosocial adjustment difficulty, trauma (other than the fall), and/or PTSD. When she was first admitted she was very involved in facility events and activities, and participated enthusiastically in therapy. During observation of the breakfast meal, the surveyor noticed that the resident appears quite tired and asked the physical therapist if therapy could be postponed until later in the afternoon so she could go back to bed. When questioned, the resident stated that she has not had a good night's sleep since admission, due to the woman in the next room yelling most of the night. The resident also stated that she does not want to complain since she knows that the woman yelling has dementia. However, it is getting harder for her to get enough rest and she finds herself feeling irritable and depressed from her lack of sleep. The physical therapist reported that the resident has not been progressing as well as she was when she was first admitted and when she attends therapy, she tires and becomes frustrated easily.*

  The resident's lack of rest and feeling of sadness stemmed from the staff's inability to realize that the distress of another resident was affecting other residents. The resident's sleep pattern had already been disrupted for several nights and she was too tired to participate in therapy. If the situation continues, it could lead to a decline in the resident's clinical condition.

Effective November 28, 2017

Severity Level 1: No Actual Harm with Likelihood for Minimal Harm

- *Severity Level 1 does not apply for this regulatory requirement because any facility practice that results in a reduction of psychosocial well-being diminishes the resident's quality of life. Because more than minimal harm is likely, any deficiency for this requirement is at least a Severity Level 2. For additional guidance, see also the Psychosocial Outcome Severity Guide in Appendix P, Section E.*

F744

§483.40(b)(3) A resident who displays or is diagnosed with dementia, receives the appropriate treatment and services to attain or maintain his or her highest practicable physical, mental, and psychosocial well-being.

DEFINITIONS §483.40(b)(3)

Definitions are provided to clarify terminology related to dementia and the attainment or maintenance of a resident's highest practicable well-being.

"Dementia" *is a general term to describe a group of symptoms related to loss of memory, judgment, language, complex motor skills, and other intellectual function, caused by the permanent damage or death of the brain's nerve cells, or neurons. However, dementia is not a specific disease. There are many types and causes of dementia with varying symptomology and rates of progression. (Adapted from: "About Dementia." Alzheimer's Foundation of America. 30 Nov 2016. Accessed at: https://www.alzfdn.org/AboutDementia/definition.html)*

"Highest practicable physical, mental, and psychosocial well-being" *is defined as the highest possible level of functioning and well-being, limited by the individual's recognized pathology and normal aging process. Highest practicable is determined through the comprehensive resident assessment and by recognizing and competently and thoroughly addressing the physical, mental or psychosocial needs of the individual.*

GUIDANCE §483.40(b)(3)

Providing care for residents living with dementia is an integral part of the person-centered environment, which is necessary to support a high quality of life with meaningful relationships and engagement. Fundamental principles of care for persons living with dementia involve an interdisciplinary approach that focuses holistically on the needs of the resident living with dementia, as well as the needs of the other residents in the nursing home. Additionally, it includes qualified staff that demonstrate the competencies and skills to support residents through the implementation of individualized approaches to care (including direct care and activities) that are directed toward understanding, preventing, relieving, and/or accommodating a resident's distress or loss of abilities.

If there are staffing concerns related to the provision of behavioral health services, refer to §483.40(a) (F741), Sufficient and Competent Staff.

The facility must provide dementia treatment and services which may include, but are not limited to the following:

- *Ensuring adequate medical care, diagnosis, and supports based on diagnosis;*

- *Ensuring that the necessary care and services are person-centered and reflect the resident's goals, while maximizing the resident's dignity, autonomy, privacy, socialization, independence, choice, and safety; and*
- *Utilizing individualized, non-pharmacological approaches to care (e.g., purposeful and meaningful activities). Meaningful activities are those that address the resident's customary routines, interests, preferences, and choices to enhance the resident's well-being.*

It is expected that a facility's approach to care for a resident living with dementia follows a systematic care process. In order to ensure that residents' individualized dementia care needs are met, the facility is expected to assess, develop, and implement care plans through an interdisciplinary team (IDT) approach that includes the resident, their family, and/or resident representative, to the extent possible. Care plan goals must be achievable and the facility must provide those resources necessary for an individual resident to be successful in reaching those goals. Surveyors must determine whether the failure to attain or maintain the highest practicable physical, mental, and psychosocial well-being (in accordance with the comprehensive assessment and care plan) was avoidable or unavoidable. An unavoidable facility failure refers to a situation where the IDT has completed comprehensive assessments, developed and implemented individualized, person-centered approaches to care through the care-planning process, revised care plans accordingly, and residents are unable to attain or maintain their highest practicable physical, mental, and psychosocial well-being.

Residents living with dementia require specialized services and supports, (e.g., specialized activities, nutrition, and environmental modifications) that vary, based on the individual's abilities and challenges related to their condition. Dementia causes significant intellectual functioning impairments that interfere with life, including activities and relationships. People living with dementia may lose their ability to communicate, solve problems, and cope with stressors. They may also experience fear, confusion, sadness, and agitation. While memory loss is a common indication of dementia, memory loss by itself does not mean that a person has dementia.

Although it is common in very elderly individuals, dementia is not a normal part of the aging process. There are several diseases that can cause symptoms of dementia (e.g., Alzheimer's disease, vascular dementia, Lewy body dementia). Other conditions can also cause dementia or dementia-like symptoms (including, e.g., reactions to medications, metabolic problems and endocrine abnormalities, nutritional deficiencies, and heart and lung problems).

Some individuals living with dementia may have co-existing symptoms, such as paranoia, delusions or hallucinations or psychiatric conditions, such as depression or bipolar affective disorder. Progressive dementia may exacerbate these symptoms and conditions.

Behavioral or psychological expressions are occasionally related to the brain disease in dementia; however, they may also be caused or exacerbated by environmental triggers. Such expressions or indications of distress often represent a person's attempt to communicate an unmet need, discomfort, or thoughts that they can no longer articulate.

Medications may be unnecessary and are likely to cause harm when given without a clinical

indication, at too high of a dose, for too long after the resident's distress has been resolved, or if the medications are not monitored. However, medications may be effective when the underlying cause of a resident's distress has been determined and non-pharmacologic approaches to care have been ineffective or for expressions of distress that have worsened. All approaches to care, non-pharmacological and pharmacological, need to be person-centered, monitored for efficacy, risks, benefits, and harm, and revised as necessary.

If there are concerns about medication use in dementia, refer to §483.45(d) (F757), Unnecessary Drugs and §483.45(e) (F758), Psychotropic Drugs.

KEY ELEMENTS OF NONCOMPLIANCE §483.40(b)(3)
To cite deficient practice at F744, the surveyor's investigation will generally show that the facility failed to:

- *Assess resident treatment and service needs through the Resident Assessment Instrument (RAI) process;*
- *Identify, address, and/or obtain necessary services for the dementia care needs of residents;*
- *Develop and implement person-centered care plans that include and support the dementia care needs, identified in the comprehensive assessment;*
- *Develop individualized interventions related to the resident's symptomology and rate of progression (e.g., providing verbal, behavioral, or environmental prompts to assist a resident with dementia in the completion of specific tasks);*
- *Review and revise care plans that have not been effective and/or when the resident has a change in condition;*
- *Modify the environment to accommodate resident care needs; or*
- *Achieve expected improvements or maintain the expected stable rate of decline.*

Investigating Concerns Related to Dementia Care Treatment and Services
Use the Dementia Care Critical Element Pathway (CMS-20133), along with guidance, when determining if the facility meets the requirements pertaining to the treatment and services for a resident who displays or is diagnosed with dementia. Treatment and services must meet the resident's highest practicable physical, mental, and psychosocial well-being.

Review, as needed, all appropriate resident assessments, associated care planning and care plan revisions, along with physician's orders to identify initial concerns and guide the investigation. Review the Minimum Data Set (MDS) and other supporting documentation to help determine if the facility is in compliance. Observe for evidence that dementia care needs are met and related services are provided. Staff are expected to assess and provide appropriate care for residents with dementia. Interview the resident, their family, and/or representative(s) and the IDT, as needed to gather information about dementia care in the nursing home. Corroborate the information obtained and any concerns noted during the survey, by building upon the investigation through additional observations, interviews, and record review. In determining compliance, additionally refer to the Psychosocial Severity Outcome Guide.

DEFICIENCY CATEGORIZATION §483.40(b)(3)
An example of Severity Level 4: Immediate Jeopardy to Resident Health or Safety includes,

but is not limited to:

- *Based upon a comprehensive assessment by a qualified professional, it was identified that a resident living with dementia required close supervision to prevent injury. The resident's care plan indicated that the facility had developed individualized interventions to support him. However, documentation in the resident's record provided information about an incident that had occurred recently as a result of lack of supervision. When left alone in the bathroom, the resident sustained second degree burns to his hand from hot water, requiring treatment at the emergency room. Following the incident, no revisions were made to the resident's care plan.*

  The facility failed to implement individualized interventions, as well as revise the care plan accordingly, to address the resident's dementia care needs, resulting in injury, as evidenced by observation, record review, and/or interview.

An example of Severity Level 3: Actual Harm that is not Immediate Jeopardy includes, but is not limited to:

- *The care plan for a resident with an identified diagnosis of dementia included the need for close supervision to prevent the resident from wandering into the rooms of other residents. However, the review of the care plan indicated that the facility had failed to develop person-centered interventions to prevent the resident from wandering. The record review also provided information about a resident-to-resident altercation that had occurred a week prior to the survey. The altercation involved a sweater that was removed from the room of another resident, who slapped and scratched the resident living with dementia, because she refused to return the garment. The resident received minor lacerations and bruising, which was cared for by the direct care staff at the nursing home. The care plan was revised to reflect the need to closely supervise.*

  During the survey, the resident was observed wandering in and out of resident rooms. When questioned, direct care staff were unaware that the resident required close supervision.

  The facility failed to develop and implement interventions to address the resident's dementia care needs, resulting in the resident's inability to achieve her highest level of functioning.

An Example of Severity Level 2: No Actual Harm with Likelihood for More Than Minimal Harm that is Not Immediate Jeopardy

- *A resident was observed standing in her doorway asking what day of the week it was. Two staff members were within hearing distance, but did not reply to the resident. The surveyor also noticed that there was no calendar in the resident's room.*

  Review of the resident's record showed that she had a diagnosis of dementia. The care plan noted that the resident has a tendency to forget what day of the week it is and can become anxious when not reminded. Interventions include that staff are to ensure that a current calendar is on her bedroom wall and remind the resident what day it is when she wakes up each morning and when facility staff are asked.

The facility failed to support the resident and implement care planned interventions to reduce her confusion, which had the potential to cause the resident anxiety.

Severity Level 1: No Actual Harm with Likelihood for Minimal Harm

- *Severity Level 1 does not apply for this regulatory requirement because any facility practice that results in a reduction of psychosocial well-being diminishes the resident's quality of life. Because more than minimal harm is likely, any deficiency for this requirement is at least a Severity Level 2. For additional guidance, see also the Psychosocial Outcome Severity Guide in Appendix P, Section E.*

NOTE: If there are indications that a resident is in a secured/locked area without a clinical justification and/or placement is against the will of the resident, their family, and/or resident representative, review regulatory requirements at §483.12 and §483.12(a) (F603), Involuntary Seclusion. [End of Tag F744.]

§483.40(c) If rehabilitative services such as but not limited to physical therapy, speech-language pathology, occupational therapy, and rehabilitative services for mental disorders and intellectual disability, are required in the resident's comprehensive plan of care, the facility must—

§483.40(c)(1) Provide the required services, including specialized rehabilitation services as required in §483.65; or

§483.40(c)(2) Obtain the required services from an outside resource (in accordance with §483.70(g) of this part) from a Medicare and/or Medicaid provider of specialized rehabilitative services.

NOTE: Concerns related to the provision of rehabilitative services are assessed and any related deficiencies are cited under §483.65, Specialized Rehabilitation Services. Concerns related to the obtainment of outside resources are assessed and any related deficiencies are cited under §483.70, Administration.

F745
§483.*40*(*d*) The facility must provide medically-related social services to attain or maintain the highest practicable physical, mental and psychosocial well-being of each resident.

INTENT §483.40(d)
To assure that sufficient and appropriate social services are provided to meet the resident's needs.

DEFINITIONS §483.40(d)
Definitions are provided to clarify terminology related to behavioral health services and the attainment or maintenance of a resident's highest practicable well-being.

"Medically-related social services" *means services provided by the facility's staff to assist*

residents in attaining or maintaining their mental and psychosocial health.

GUIDANCE §483.40(d)

All facilities are required to provide medically-related social services *for* each resident. Facilities *must* identify the need for medically-related social services and *ensure that* these services *are provided*. It is not required that a qualified social worker necessarily provide all of these services*, except as required by State law.*

If there are concerns about requirements involving qualified social workers, refer to §483.70(p) (F850), Social worker.

Examples of medically-related social services include, but are not limited to the following:

- *Advocating for residents and assisting them in the assertion of their rights within the facility in accordance with §483.10, Resident Rights, §483.12, Freedom from Abuse, Neglect, and Exploitation, §483.15, Transitions of Care, §483.20, Resident Assessments (PASARR), and §483.21, Comprehensive Person-Centered Care Planning;*
- *Assisting residents in voicing and obtaining resolution to grievances about treatment, living conditions, visitation rights, and accommodation of needs;*
- *Assisting or arranging for a resident's communication of needs through the resident's primary method of communication or in a language that the resident understands;*
- Making arrangements for obtaining *items, such as* clothing and personal items;
- Assisting *with* inform*ing and educating* residents*, their family, and/or representative(s)* about health care *options* and ramifications;
- Making referrals and obtaining *needed* services from outside entities (e.g., talking books, absentee ballots, community wheelchair transportation);
- Assisting residents with financial and legal matters (e.g., applying for pensions, referrals to lawyers, referrals to funeral homes for preplanning arrangements);
- *Transitions of care* services (e.g., *assisting the resident with identifying community placement options and completion of the application process,* arranging intake for home care services for residents returning home, assisting with transfer arrangements to other facilities);
- Providing or arranging *for* needed *mental and psychosocial* counseling services;
- Identifying and seeking ways to support residents' individual needs *through the assessment and care planning process*;
- *Encouraging* staff *to* maintain or enhance each resident's dignity in recognition of each resident's individuality;
- Assisting residents *with advance care planning, including but not limited to completion of advance directives (For additional information pertaining to advance directives, refer to §483.10(g)(12) (F578)), Advance Directives);*
- *Identifying and promoting individualized, non-pharmacological approaches to care* that meet the *mental and psychosocial* needs of each resident; *and*
- Meeting the needs of residents who are grieving *from losses and coping with stressful events*.

Situations in which the facility should provide social services or obtain needed services from outside entities include, but are not limited to the following:

- Lack of an effective family *or community* support system *or legal representative*;

- *Expressions or indications of distress that affect the resident's mental and psychosocial well-being, resulting from depression, chronic diseases (e.g., Alzheimer's disease and other dementia related diseases, schizophrenia, multiple sclerosis), difficulty with personal interaction and socialization skills, and resident to resident altercations;*
- Abuse of *any kind (e.g.,* alcohol or other drugs*, physical, psychological, sexual, neglect, exploitation)*;
- *Difficulty coping* with *change or loss (e.g., change in living arrangement, change in condition or functional ability, loss of meaningful employment or activities, loss of a loved one); and*
- Need for emotional support.

NOTE: When needed services are not covered by Medicaid, nursing facilities are still required to attempt to obtain these services *on behalf of the resident (e.g., arranging transportation services).*

F755
§483.*45* Pharmacy Services
The facility must provide routine and emergency drugs and biologicals to its residents, or obtain them under an agreement described in §483.*70*(*g*). The facility may permit unlicensed personnel to administer drugs if State law permits, but only under the general supervision of a licensed nurse.

§483.*45*(a) Procedures. A facility must provide pharmaceutical services (including procedures that assure the accurate acquiring, receiving, dispensing, and administering of all drugs and biologicals) to meet the needs of each resident.

§483.*45*(b) Service Consultation. The facility must employ or obtain the services of a licensed pharmacist who—

§483.*45*(b)(1) Provides consultation on all aspects of the provision of pharmacy services in the facility.

§483.45(b)(2) Establishes a system of records of receipt and disposition of all controlled drugs in sufficient detail to enable an accurate reconciliation; and

§483.45(b)(3) Determines that drug records are in order and that an account of all controlled drugs is maintained and periodically reconciled.

INTENT §483.*45(a) and (b)(1), (2), and (3)*
The intent of this requirement is that:

- In order to meet the needs of each resident, the facility accurately and safely provides or obtains pharmaceutical services, including the provision of routine and emergency medications and biologicals, and the services of a licensed pharmacist;
- The facility utilizes only persons authorized *by* state *or local, regulation, or other guidance* to administer medications *during the course of employment by a facility*;

- The licensed pharmacist collaborates with facility leadership and staff to coordinate pharmaceutical services within the facility*, guide development and evaluation of pharmaceutical services procedures, and help the facility identify, evaluate, and resolve pharmaceutical concerns which affect resident care, medical care or quality of life such as the:*
  - Provision of consultative services by a licensed pharmacist as necessary; and
  - Coordination of the pharmaceutical services if multiple pharmaceutical service providers are utilized (e.g., pharmacy, infusion, hospice, prescription drug plans [PDP]).
- *The facility, in coordination with the licensed pharmacist, provides for:*
  - *A system of medication records that enables periodic accurate reconciliation and accounting for all controlled medications;*
  - *Prompt identification of loss or potential diversion of controlled medications; and*
  - *Determination of the extent of loss or potential diversion of controlled medications.*

NOTE: Although the regulatory language refers to "drugs," the guidance in this document generally will refer to "medications," except in those situations where the term "drug" has become part of an established pharmaceutical term (e.g., adverse drug event, adverse drug reaction or consequence).

For purposes of this guidance, references to "the pharmacist" mean the licensed pharmacist, whether employed directly by the facility or through arrangement.

DEFINITIONS §483.*45*
Definitions are provided to clarify terminology related to pharmaceutical services and the management of each resident's medication regimen for effectiveness and safety.

"Acquiring medication" is the process by which a facility requests and obtains a medication.

"Biologicals" *are made from a variety of natural sources—human, animal, or microorganisms. Biologicals are used to treat, prevent, or diagnose diseases and medical conditions. They may include a wide range of products such as vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins.*

"Controlled Medications" *are substances that have an accepted medical use (medications which fall under US Drug Enforcement Agency (DEA) Schedules II—V), have a potential for abuse, ranging from low to high, and may also lead to physical or psychological dependence.*

"Dispensing" is a process that includes the interpretation of a prescription; selection, measurement, and packaging or repackaging of the product (as necessary); and labeling of the medication or device pursuant to a prescription/order.

"Disposition" is the process of returning and/or destroying *unused* medications.

Effective November 28, 2017

"Diversion of medications" *is* the transfer of a controlled substance or other medication from a lawful to an unlawful channel of distribution or use, as adapted from the Uniform Controlled Substances Act.

"Pharmaceutical Services" refers to:

- The process (including documentation, as applicable) of receiving and interpreting prescriber's orders; acquiring, receiving, storing, controlling, reconciling, compounding (e.g., intravenous antibiotics), dispensing, packaging, labeling, distributing, administering, monitoring responses to, using and/or disposing of all medications, biologicals, chemicals (e.g., povidone iodine, hydrogen peroxide);
- The provision of medication-related information to health care professionals and residents;
- The process of identifying, evaluating and addressing medication-related issues including the prevention and reporting of medication errors; and
- The provision, monitoring and/or the use of medication-related devices.

"Pharmacy assistant or technician" refers to the ancillary personnel who work under the supervision and delegation of the pharmacist, consistent with state requirements.

"Receiving medication"—for the purpose of this guidance—is the process *that a facility uses to ensure that* medication*s, accepted* from the facility's pharmacy or an outside source (e.g., vending pharmacy delivery agent, Veterans Administration, family member), *are accurate (e.g., doses, amount)*.
"Reconciliation"*—for the purpose of this guidance—refers to a system of recordkeeping that ensures an accurate inventory of medications by accounting for controlled medications that have been received, dispensed, administered, and/or, including the process of disposition.*

GUIDANCE §483.45
The provision of pharmaceutical services is an integral part of the care provided to nursing home residents. The management of complex medication regimens is challenging and requires diverse pharmaceutical services *and formal mechanisms to safely handle and control medications, to maintain accurate and timely medication records, and* to minimize medication-related adverse consequences or events. The overall goal of the pharmaceutical services system within a facility is to ensure the safe and effective use of medications.

Preventable medication-related adverse consequences and events are a serious concern in nursing homes. *The U.S. Department of Health and Human Services (HHS) Office of the Inspector General issued a report in February 2014, Adverse Events in Skilled Nursing Facilities: National Incidence among Medicare Beneficiaries (OEI-06-11-00370). The OIG found that one in three SNF residents experienced an adverse event or temporary harm event. Thirty-seven percent of these adverse events were related to medications and 66% of all medication-related events were preventable. Medication-related adverse events included excessive bleeding due to anticoagulant use without adequate monitoring and acute hypoglycemia. Consequences of medication-related adverse events included a prolonged SNF stay, hospitalization, life sustaining interventions, permanent harm, and death.*

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Factors that increase the risk of adverse consequences associated with medication use in the nursing home setting include complex medication regimens, numbers and types of medication used, physiological changes accompanying the aging process, as well as multiple comorbidities.

The consultative services of a pharmacist can promote safe and effective medication use. A pharmacist, *in collaboration with facility staff, establishes,* evaluates and coordinates all aspects of pharmaceutical services provided to all residents within a facility by all providers (e.g., pharmacy, prescription drug plan, prescribers). A pharmacist can also help in the development of medication-related documentation procedures, such as identification of abbreviations approved for use in the facility and can help guide the selection and use of medications in accordance with the authorized prescriber's orders, applicable state and federal requirements, manufacturers' specifications, characteristics of the resident population, and individual resident conditions.

Providing pharmaceutical consultation is an ongoing, interactive process with prospective, concurrent, and retrospective components. To accomplish some of these consultative responsibilities, pharmacists can use various methods and resources, such as technology, additional personnel (e.g., dispensing pharmacists, pharmacy technicians), and related policies and procedures.

Numerous recognized resources address different aspects of pharmaceutical services and medication utilization, such as:

- *US Department of Health and Human Services (DHHS), Food and Drug Administration (FDA) http://www.fda.gov/Drugs/default.htm;*
- The American Society of Consultant Pharmacists (ASCP) http://www.ascp.com;
- The American Society of Health System Pharmacists (ASHP) *http://www.ashp.org;*
- *AMDA - The Society for Post-Acute and Long-Term Care Medicine (American Medical Directors Association)* http://www.paltc.org/;
- *The National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP) http://www.nccmerp.org;*
- *American Society for Parenteral and Enteral Nutrition (ASPEN), https://www.nutritioncare.org/.*

NOTE: References to non-CMS sources do not constitute or imply endorsement of these organizations or their programs by CMS or the U.S. Department of Health and Human Services and were current as of the date of this publication.

A. PROVISION OF ROUTINE AND/OR EMERGENCY MEDICATIONS

The regulation at 42 CFR 483.*45* requires that the facility provide or obtain routine and emergency medications and biologicals in order to meet the needs of each resident. Facility procedures and applicable state laws may allow the facility to maintain a limited supply of medications in the facility for use during emergency or after-hours situations. Whether prescribed on a routine, emergency, or as needed basis, medications should be administered in a timely manner. Delayed acquisition of a medication may impede timely administration and adversely affect a resident's condition. Factors that may help determine timeliness and guide acquisition procedures include:

- Availability of medications to enable continuity of care for an anticipated admission or transfer of a resident from acute care or other institutional settings;
- Condition of the resident including the severity or instability of his/her condition, a significant change in condition, discomfort, risk factors, current signs and symptoms, and the potential impact of any delay in acquiring the medications;
- Category of medication, such as antibiotics or analgesics;
- Availability of medications in emergency supply, if applicable; and
- Ordered start time*/date* for a medication.

Procedures should identify how staff, who are responsible for medication administration:

- Ensure each resident has a sufficient supply of his or her prescribed medications (for example, a resident who is on pain management has an adequate supply of medication available to meet his or her needs). At a minimum, the system is expected to include a process for the timely ordering and reordering of a medication;
- Monitor the delivery *and receipt* of medications when they are ordered; and
- Determine the appropriate action, e.g., contact the prescriber or pharmacist, when a resident's medication(s) is not available for administration.

NOTE: *Facility staff may encounter situations in which a medication is not available in the resident's supply or the facility's emergency medication supply and then decide to "borrow" medications from another resident's supply. This practice of borrowing medications from other residents' supplies is not consistent with professional standards and contributes to medication errors. Concerns about whether the facility has a system in place to ensure each resident has a sufficient supply of medications for timely administration should be cited under this tag Pharmacy Services (F755). However, if staff borrow any medication from another resident's supply due to failure to order the medication and/or not following the facility's system for reordering medications, refer to §483.21, F658, Services Provided Meet Professional Standards. Instances of "borrowing" would not be considered to be drug diversion.*

Foreign Acquired Medications

It has been reported that some residents and/or facilities may be obtaining medications from foreign sources. Medications obtained from foreign sources may present safety issues since they have been manufactured or held outside of the jurisdiction of the United States (U.S.) regulatory system. These medications may not be safe and effective for their intended uses. The Federal Food, Drug, and Cosmetic Act (FFDCA) strictly limits the types of drugs that may be imported into the U.S. Medications imported into the U.S. may violate the FFDCA if they are unapproved by the FDA, labeled incorrectly, or dispensed without a valid prescription. The facility should, in collaboration with the pharmacist, assure that medications are provided or obtained from approved sources and do not violate the FFDCA.

If it is determined that the facility is providing/obtaining foreign medications *that are not FDA approved* for use by the residents, the State Agency must make referrals to appropriate agencies, such as the FDA; depending on the medication classification, the Drug Enforcement Administration; State Board of Nursing; State Board of Pharmacy; and the State Licensure Board for Nursing Home Administrators.

B. PHARMACEUTICAL SERVICES PROCEDURES

The pharmacist, in collaboration with the facility and medical director, helps develop and evaluate the implementation of pharmaceutical services procedures that address the needs of the residents, are consistent with state and federal requirements, and reflect current standards of practice. These procedures address, but are not limited to, acquiring; receiving; dispensing; administering; disposing; labeling and storage of medications; and personnel authorized to access or administer medications.

Acquisition of Medications

Examples of procedures addressing acquisition of medications include:

- Availability of an emergency supply of medications, if allowed by state law, including the types or categories of medications; amounts, dosages/strengths to be provided; location of the supply; personnel authorized to access the supply; record keeping; monitoring for expiration dates; and the steps for replacing the supply when medications are used;
- When, how to, and who may contact the pharmacy regarding acquisition of medications and the steps to follow for contacting the pharmacy for an original routine medication order, emergency medication order, and refills;
- The availability of medications when needed, that is, the medication is either in the facility (in the emergency supply) or obtained from a pharmacy that can be reached 24 hours a day, seven days a week;
- The receipt, labeling, storage, and administration of medications dispensed by the prescriber, if allowed by state requirements;
- Verification or clarification of an order to facilitate accurate acquisition of a medication when necessary (e.g., clarification when the resident has allergies to, or there are contraindications to the medication being *prescribed*);
- Procedure when delivery of a medication will be delayed or the medication is not or will not be available; and
- Transportation of medications from the dispensing pharmacy or vendor to the facility consistent with manufacturer's specifications, state and federal requirements, and standards of professional practice to prevent contamination, degradation, and diversion of medications.

Receiving Medication(s)

Examples of procedures addressing receipt of medications include:

- How the receipt of medications from dispensing pharmacies (and family members or others, where permitted by state requirements) will occur and how it will be reconciled with the prescriber's order and the requisition for the medication;
- How staff will be identified and authorized in accordance with applicable laws and requirements to receive the medications and how access to the medications will be controlled until the medications are delivered to the secured storage area; and
- Which staff will be responsible for assuring that medications are incorporated into the resident's specific allocation/storage area.

Effective November 28, 2017

Dispensing Medication(s)
Examples of procedures to assure compatible and safe medication delivery, to minimize medication administration errors, and to address the facility's expectations of the in-house pharmacy and/or outside dispensing pharmacies include:

- Delivery and receipt;
- Labeling; and
- The types of medication packaging (e.g., unit dose, multi-dose vial, blister cards).

Administering Medications
Examples of procedures addressing administration of medications include:

- Providing continuity of staff to ensure that medications are administered without unnecessary interruptions;
- Reporting medication administration errors, including how and to whom to report;
- Authorizing personnel, consistent with state requirements, to administer the medications, including medications needing intravenous administration (see Authorized Personnel section within this document);
- Assuring that the correct medication is administered in the correct dose, in accordance with manufacturer's specifications and with standards of practice, to the correct person via the correct route in the correct dosage form and at the correct time;
- Defining the schedules for administering medications to:
  - Maximize the effectiveness (optimal therapeutic effect) of the medication (for example, antibiotics, antihypertensives, insulin, pain medications, proton pump inhibitors, metered dose inhalers, and medications via enteral feeding tubes);
  - *Prevent* potential significant medication interactions such as *medication-medication or* medication-food interactions; and
  - *Honor* resident choices and activities, *as much as* possible, consistent with the *person-centered comprehensive* care *plan*;
- Defining general guidelines for specific monitoring related to medications, when ordered or indicated, including specific item(s) to monitor (e.g., blood pressure, pulse, blood sugar, weight), frequency (e.g., weekly, daily), timing (e.g., before or after administering the medication), and parameters for notifying the prescriber;
- Defining pertinent techniques and precautions that meet current standards of practice for administering medications through alternate routes such as eye, ear, buccal, injection, intravenous, atomizer/aerosol/ inhalation therapy, or enteral tubes. For example, for enteral feeding tubes, define procedures including but not limited to:
  - Types of medications that may be safely administered via enteral feeding tube;
  - Appropriate dosage forms;
  - Techniques to monitor and verify that the feeding tube is in the right location (e.g., stomach or small intestine, depending on the tube) before administering medications; *and*
  - Preparing drugs for enteral administration, administering drugs separately, diluting drugs as appropriate, and flushing the feeding tube before, between, and after drug administration, including the amount of water to be used for the flushing and administration of medications (and obtaining physician/practitioners order to address a resident with fluid restrictions).

NOTE: *Enteral feeding tube practice recommendations may be found in ASPEN Safe Practices for Enteral Nutrition Therapy, https://www.ismp.org/tools/articles/ASPEN.pdf (2009) and http://pen.sagepub.com/content/early/2016/11/09/0148607116673053.full.pdf (2016).*

References to non-CMS sources do not constitute or imply endorsement of these organizations or their programs by CMS or the U.S. Department of Health and Human Services and were current as of the date of this publication.

- Documenting the administration of medications, including:
  - The administration of routine medication(s), and, if not administered, an explanation of why not;
  - The administration of "as-needed" *(PRN)* medications including the justification and response;
  - The route, if other than oral (intended route may be preprinted on *Medication Administration Record (MAR)*; and
  - Location of administration sites such as transdermal patches and injections;
- Providing accessible current information about medications (e.g., medication information references) and medication-related devices and equipment (e.g., user's manual) *for all staff involved with the medication administration process*;
- Clarifying any order that is incomplete, illegible, or presents any other concerns, prior to administering the medication; and
- Reconciling medication orders including telephone orders, monthly or other periodic recapitulations, and MAR, including who may transcribe prescriber's orders and enter the orders onto the MAR.

Disposition of Medications

Examples of procedures addressing the disposition of medications include:

- Timely identification and removal (from current medication supply) of medications for disposition;
- Identification of storage method for medications awaiting final disposition;
- Control and accountability of medications awaiting final disposition consistent with standards of practice;
- Documentation of actual disposition of medications to include: resident name, medication name, strength, prescription number (as applicable), quantity, date of disposition, and involved facility staff, consultant(s) or other applicable individuals; and
- Method of disposition (including controlled medications) should prevent diversion and/or accidental exposure and is consistent with applicable state and federal requirements, local ordinances, and standards of practice;

Authorized Personnel

The facility may permit unlicensed personnel to administer medications if state law permits, but only under the general supervision of a licensed nurse.

The facility assures that all persons administering medications are authorized according to state and federal requirements, oriented to the facility's *medication-related* procedures, and have

access to current information regarding medications being used *by the residents*, including side effects of medications, contraindications, doses, etc.

Examples of procedures addressing authorized personnel include:

- How the facility assures ongoing competency of all staff (including temporary, agency, or on-call staff) authorized to administer medications and biologicals;
- Training regarding the operation, limitations, monitoring, and precautions associated with medication administration devices or other equipment, if used, such as:
  - IV pumps or other IV delivery systems including calculating dosage, infusion rates, and compatibility of medications to be added to the IV *or enteral feeding pump*;
  - Blood glucose meters, including calibration and cleaning between individual residents; and
  - Using, maintaining, cleaning, and disposing of the various types of devices for administration including nebulizers, inhalers, syringes, medication cups, spoons, and pill crushers;
- Identifying pharmacy personnel in addition to the pharmacist (e.g., pharmacy technicians, pharmacist assistants) who are authorized under state and federal requirements to access medications and biologicals.

C. SERVICES OF A LICENSED PHARMACIST

The facility is responsible for employing or contracting for the services of a pharmacist to provide consultation on all aspects of pharmaceutical services. The facility may provide for this service through any of several methods (in accordance with state requirements) such as direct employment or contractual agreement with a pharmacist. Whatever the arrangement or method employed, the facility and the pharmacist identify how they will collaborate for effective consultation regarding pharmaceutical services. The pharmacist reviews and evaluates the pharmaceutical services by helping the facility identify, evaluate, and address medication issues that may affect resident care, medical care, and quality of life.

The pharmacist is responsible for helping the facility obtain and maintain timely and appropriate pharmaceutical services that support residents' healthcare needs, *goals, and quality of life* that are consistent with current standards of practice, and that meet state and federal requirements. This includes, but is not limited to, collaborating with the facility and medical director to:

- Develop, implement, evaluate, and revise (as necessary) the procedures for the provision of all aspects of pharmaceutical services*, including procedures to support resident quality of life such as those that support safe, individualized medication administration programs*;
- Coordinate pharmaceutical services if and when multiple pharmaceutical service providers are utilized (e.g., pharmacy, infusion, hospice, prescription drug plans [PDP])
- Develop intravenous (IV) therapy procedures if used within the facility (consistent with state requirements) which may include: determining competency of staff and facility-based IV admixture procedures that address sterile compounding, dosage calculations, IV pump use, and flushing procedures;
- Determine (in accordance with or as permitted by state law) the contents of the emergency supply of medications and monitor the use, replacement, and disposition of the supply;

- Develop mechanisms for communicating, addressing, and resolving issues related to pharmaceutical services;
- Strive to assure that medications are requested, received, and administered in a timely manner as ordered by the authorized prescriber (in accordance with state requirements), including physicians, advanced practice nurses, pharmacists, and physician assistants;
- Provide feedback about performance and practices related to medication administration and medication errors.

In addition, the pharmacist may collaborate with the facility and medical director on other aspects of pharmaceutical services including, but not limited to:

- Developing procedures and guidance regarding when to contact a prescriber about a medication issue and/or adverse effects, including what information to gather before contacting the prescriber;
- Developing the process for receiving, transcribing, and recapitulating medication orders;
- Recommending the type(s) of medication delivery system(s) to standardize packaging, such as bottles, bubble packs, tear strips, in an effort to minimize medication errors;
- Developing and implementing procedures regarding automated medication delivery devices or cabinets, if automated devices or cabinets are used, including: the types or categories of medications, amounts stored, location of supply, personnel authorized to access the supply, record keeping, monitoring for expiration dates, method to ensure accurate removal of medications and the steps for replacing the supply when dosages are used, and monitoring the availability of medications within the system;
- Interacting with the quality assessment and assurance committee to develop procedures and evaluate pharmaceutical services including delivery and storage systems within the various locations of the facility in order to prevent, to the degree possible, loss or tampering with the medication supplies, and to define and monitor corrective actions for problems related to pharmaceutical services and medications, including medication errors;
- Recommending current resources to help staff identify medications and information on contraindications, side effects and/or adverse effects, dosage levels, and other pertinent information; and
- Identifying facility educational and informational needs about medications and providing information from sources such as nationally recognized organizations to the facility staff, practitioners, residents, and families.

NOTE: This does not imply that the pharmacist must personally present educational programs.

D. CONTROLLED MEDICATIONS

Regulations require that the facility have a system to account for controlled medications' receipt and disposition in sufficient detail to enable an accurate reconciliation, and that the facility conduct a periodic reconciliation. This system includes, but is not limited to:

- *Record of receipt of all controlled medications with sufficient detail to allow reconciliation (e.g., specifying the name and strength of the medication, the quantity and date received, and the resident's name). However, in some delivery systems (e.g., single unit package medication delivery system or automated dispensing systems utilizing*

single-unit packages of medications that are not dispensed pursuant to a specific order), the resident's name may not be applicable;

***NOTE**: If permitted by, and in accordance with, state requirements, the facility may store some controlled medications in an emergency medication supply. The facility's policies and procedures must address the reconciliation and monitoring of this supply.*

- *Records of personnel access, usage, and disposition of all controlled medications with sufficient detail to allow reconciliation (e.g., the MAR, proof-of-use sheets, or declining inventory sheets), including destruction, wastage, return to the pharmacy/manufacturer, or disposal in accordance with applicable State requirements;*
- *Periodic reconciliation of records of receipt, disposition, usage, and inventory for all controlled medications (as defined by facility procedures or when loss is identified). The reconciliation identifies loss or potential diversion of controlled medications so as to minimize the time between the actual loss or potential diversion and the time of detection and follow-up to determine the extent of loss. Because diversion can occur at any time, periodic reconciliation should accommodate actual facility experience, such that if there is any evidence or even suspicion that diversion may be occurring, then that may dictate conducting the periodic reconciliation as frequently as daily.. State or other federal requirements may specify the frequency of reconciliation.*
  - *If discrepancies are identified during the reconciliation, the pharmacist and the facility develop and implement recommendations for resolving them, and make referrals to law enforcement agencies as appropriate.*
  - *Data from injectable, scheduled drug tracking should be regularly reviewed and discrepancies or unusual access patterns are investigated including whether residents should be screened for exposure to blood borne pathogens. See §483.80 Infection Control, F880.*
  - *Liquid controlled medications are often dispensed in multi-dose containers which indicate approximate volume. The containers may also be opaque to protect the medication from light. It should be noted that absolute accuracy in tracking volume and use of liquid controlled medications may not be possible. The actual volume in these containers may be slightly over or under the manufacturer's stated volume depending on the shape and material of the container and the formulation of the medication such as thick liquid suspensions. The opaque container, measurement markings, manufacturer fill volume variation, and method for recording usage all make detection of diversion for liquid controlled medications more difficult. The general standard of practice for documenting usage of liquid controlled medications is to record the starting volume from the label, record each dose administered, subtract the dose administered from the previously recorded volume, and record the remaining amount. Any observed discrepancy between the recorded amount and what appears to be remaining in the container should be reported according to facility policy. Manufacturer's instructions may list the estimated volume variance (e.g., 30 mL plus or minus 2.5 mL). For liquid controlled medications, signs of diversion may include: an observable discrepancy between the written balances of remaining medication compared to the remaining amount in the bottle upon visual inspection; changes in the viscosity or color of the medication; reports of spills; and,*

as with other controlled medications, statements from a resident that the medication is not working.

- *Disposal methods for controlled medications must involve a secure and safe method to prevent diversion and/or accidental exposure.*
- *Fentanyl transdermal patches present a unique situation given the multiple boxed warnings, and the substantial amount of fentanyl remaining in the patch after removal, creating a potential for abuse, misuse, diversion, or accidental exposure. The Food and Drug Administration (FDA) and manufacturer instructions recommend that users dispose of used fentanyl patches by folding the patch in half with the sticky sides together and flushing the patch down the sink or toilet, due to the life threatening risks associated with exposure to or ingestion of the patch. https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=e15a7e9b-8025-49dd-9a6d-bafcccf1959f&type=display, see section 2.4.*

NOTE: *The pharmacist is not required by these regulations to perform the reconciliation of medications, but rather to evaluate and determine that the facility maintains an accurate account of all controlled medications and completes the reconciliation according to its procedures, consistent with State and federal requirements.*

PROCEDURES §483.45

Use the Medication Administration Observation and the Medication Storage and Labelling Critical Element Pathway, as appropriate, along with the above interpretive guidelines when determining if the facility meets the requirements for, or investigating concerns related to, the provision of Pharmacy Services.

KEY ELEMENTS OF NONCOMPLIANCE

To cite deficient practice at F755, the surveyor's investigation will generally show that the facility failed to:

- *Provide medications and/or biologicals, as ordered by the prescriber, to meet the needs of each resident; or*
- *Ensure that only appropriate personnel administer medications, consistent with applicable state law and regulations; or*
- *Provide pharmaceutical services to meet each resident's needs which includes: acquiring, receiving, dispensing, accurately administering, or disposing of medications; or*
- *Provide or arrange for a licensed pharmacist who consults on all aspects of pharmaceutical services; or*
- *Establish systems to accurately reconcile controlled medications using acceptable standards of practice; or*
- *Have safeguards and systems in place to control, account for, and periodically reconcile controlled medications in order to prevent loss, diversion, or accidental exposure.*

DEFICIENCY CATEGORIZATION

In addition to actual or potential physical harm, always consider whether psychosocial harm has occurred when determining severity level (See Appendix P, Section IV, E, Psychosocial Outcome Severity Guide).

Effective November 28, 2017

Examples of noncompliance that demonstrate severity at Level 4 include, but are not limited to:

- The facility, in collaboration with the pharmacist, failed to establish effective procedures to meet the needs of the residents, such as:
  - Assuring that pain medications were available to meet the needs of the resident-- *The facility failed* to *obtain the routine regularly scheduled pain medicine for a resident who was to receive it every six hours. The investigation confirmed that the resident had been without pain medication for 2 days, the equivalent of 8 missed doses. This failure resulted* in the resident complaining of excruciating, *unrelieved* pain (e.g., a pain score of 9 on a 10-point scale). *The pain was all-consuming and overwhelming, leading to sleep loss, and a loss in interest and ability to perform activities of daily living.*
  - Assuring that devices used to administer medications (such as IV pumps) were working properly, leading to an adverse consequence at the immediate jeopardy level*, in which a resident received an incorrect dose of IV medication.*
  - Provisions to assure that staff were trained or competent to use new medication-related devices (e.g., intravenous pump). This resulted in a resident receiving an *inappropriate* dose of medication requiring subsequent hospitalization.

Examples of Level 3, Actual harm (physical or psychosocial) that are not immediate jeopardy, include, but are not limited to:

- The facility *and* the pharmacist failed to assure that procedures were developed and implemented *so that all* medication orders were processed consistently and accurately through the stages of ordering, receiving, and administering medications (including transfer orders, admission orders, telephone orders, order renewals, and the MAR). For example, *an ordering* error led to an incorrect dose of a medication being administered and the resident *experienced* spontaneous bruising and *frequent nosebleeds* requiring medical intervention that was able to be *performed* in the nursing home.
- *The facility failed to implement a system to consistently and accurately reconcile controlled medications. As a result, when staff attempted to administer pain medication to a resident, staff found no available medications despite documentation which showed the medications were available. The resident experienced mild to moderate pain that prevented the resident from attending physical therapy.*

Examples of Level 2, No actual harm with a potential for more than minimal harm that is not immediate jeopardy, may include but are not limited to:

- As a result of failure of licensed staff to supervise medication administration by authorized unlicensed personnel, *two residents received their* oral antibiotic*s late on one day, however the residents did not experience any harm.*
- The facility failed to obtain or provide the services of a pharmacist or to collaborate with the pharmacist to assure that effective policies and procedures were established and implemented including, for example:
  - *A* resident did not receive medication for heartburn for *two or more* days and had difficulty sleeping *during that time* due to nocturnal heartburn. The level of

discomfort did not interfere with the resident's participating in activities or performing activities of daily living.

- As a result of failure to identify medications that should not be crushed for administration, a resident received a *newly ordered* medication that was crushed, contrary to the manufacturer's specifications. While the resident did not experience any harm, the potential for harm *to the resident* was present.

Severity Level 1: No Actual Harm with Potential for Minimal Harm

Severity Level 1 does not apply for this regulatory requirement because the failure of the facility to provide routine and emergency drugs and biologicals to its residents creates the potential for more than minimal harm. This provision, along with pharmaceutical procedures and services are essential aspects of both process and outcome requirements.

POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION

Examples of some of the related requirements that should be considered when *concerns have* been identified include the following:

- *42 CFR 483.12, F602, Right to be Free from Misappropriation/Exploitation*
  - *Determine if the facility diverted a resident's medication, including, but not limited to, controlled substances for staff use or personal gain. If it is determined that a resident's medications were diverted, the State Agency must make referrals to appropriate agencies, such as local law enforcement; Drug Enforcement Administration; State Board of Nursing; State Board of Pharmacy; the state Medicaid Fraud Control Unit, and possibly the State licensure board for Nursing Home Administrators.*
- 42 CFR 483.*35*, *F725,* Sufficient Staff *and F726, Competent Staff*
  - Determine if the facility had *competent* staff in sufficient numbers *available* to provide medications on a 24-hour basis to meet the needs of the residents, based upon the comprehensive assessment and care plan.
- 42 CFR 483.*70*(*h*), *F841,* Medical Director
  - Determine whether the medical director, in collaboration with the facility and the pharmacist, and based on current standards of practice, helped the facility develop procedures for the safe and accurate provision of medications to meet the needs of the residents.
- 42 CFR 483.75*(g), F867, Quality Assessment and Assurance*
  - *If concerns regarding pharmaceutical services have been identified, determine* whether the quality assessment and assurance committee has identified *and responded to* those concerns, as appropriate, *and* has developed, implemented, and monitored appropriate plans of action to correct identified quality deficiencies.
- 42 CFR 483.*70*(*i*), *F842, Medical* Records
  - Determine whether the facility has maintained clinical records, including medication administration, in accordance with accepted professional standards and practices that are complete, accurately documented, and readily accessible.

Effective November 28, 2017

F756
§483.*45*(c) Drug Regimen Review.
§483.*45*(c)(1) The drug regimen of each resident must be reviewed at least once a month by a licensed pharmacist.

§483.*45(*c)(2) ***This review must include a review of the resident's medical chart.***

§483.*45(*c)*(4)* The pharmacist must report any irregularities to the attending physician *and the facility's medical director* and director of nursing, and these reports must be acted upon.

- ***(i) Irregularities include, but are not limited to, any drug that meets the criteria set forth in paragraph (d) of this section for an unnecessary drug.***
- ***(ii) Any irregularities noted by the pharmacist during this review must be documented on a separate, written report that is sent to the attending physician and the facility's medical director and director of nursing and lists, at a minimum, the resident's name, the relevant drug, and the irregularity the pharmacist identified.***
- ***(iii) The attending physician must document in the resident's medical record that the identified irregularity has been reviewed and what, if any, action has been taken to address it. If there is to be no change in the medication, the attending physician should document his or her rationale in the resident's medical record.***

§483.*45*(c)*(5) The facility must develop and maintain policies and procedures for the monthly drug regimen review that include, but are not limited to, time frames for the different steps in the process and steps the pharmacist must take when he or she identifies an irregularity that requires urgent action to protect the resident.*

INTENT *§483.45(c)(1), (2), (4), and (5)*
The intent of this requirement is that the facility maintains the resident's highest practicable level of *physical, mental and psychosocial well-being* and prevents or minimizes adverse consequences related to medication therapy to the extent possible, by providing *oversight by a licensed pharmacist, attending physician, medical director, and the director of nursing (DON).*

NOTE: Although the regulatory language refers to "drug *regimen review*," the guidance in this document generally will refer to "medication *regimen review*," except in those situations where the term "drug" has become part of an established pharmaceutical term (e.g., adverse drug event, and adverse drug reaction or consequence).

DEFINITIONS *§483.45(c)(1), (2), (4), and (5)*
Definitions are provided to clarify terminology related to pharmaceutical services and the management of each resident's medication regimen for effectiveness and safety.

"Adverse consequence" *is a broad term referring to unwanted, uncomfortable, or dangerous effects that a drug may have*, such as impairment or decline in an individual's mental or physical condition or functional or psychosocial status. It may include various types of adverse drug reactions and interactions (e.g., medication-medication, medication-food, and medication-disease) *(adapted from The Merck Manual Professional Version,*

Effective November 28, 2017

http://www.merckmanuals.com/professional/clinical-pharmacology/adverse-drug-reactions/adverse-drug-reactions.)

NOTE: Adverse drug reaction (ADR) is a form of adverse consequence. It may be either a secondary effect of a medication that is usually undesirable and different from the therapeutic and helpful effects of the medication or any response to a medication that is noxious and unintended and occurs in doses used for prophylaxis, diagnosis, or therapy. The term "side effect" is often used interchangeably with ADR; however, side effects are but one of five ADR categories. The others are hypersensitivity, idiosyncratic response, toxic reactions, and adverse medication interactions. A side effect is an expected, well-known reaction that occurs with a predictable frequency and may or may not rise to the level of being an adverse consequence.

"Clinically significant" means effects, results, or consequences that materially affect or are likely to affect an individual's mental, physical, or psychosocial well-being either positively by preventing, stabilizing, or improving a condition or reducing a risk, or negatively by exacerbating, causing, or contributing to a symptom, illness, or decline in status.

"Dose" is the total amount/strength/concentration of a medication given at one time or over a period of time. The individual dose is the amount/strength/concentration received at each administration. The amount received over a 24-hour period may be referred to as the daily dose.

"Irregularity" *refers to use of medication that is inconsistent with accepted standards of practice for providing pharmaceutical services, not supported by medical evidence, and/or that impedes or interferes with achieving the intended outcomes of pharmaceutical services. An irregularity also includes, but is not limited to, use of medications without adequate indication, without adequate monitoring, in excessive doses, and/or in the presence of adverse consequences, as well as the identification of conditions that may warrant initiation of medication therapy. (See reference to F757 Unnecessary Drugs which defines unnecessary drugs in opening regulatory language.)*

"Medication Interaction" is the impact of another substance (such as another medication, herbal product, food or substances used in diagnostic studies) upon a medication. The interactions may alter absorption, distribution, metabolism, or elimination. These interactions may decrease the effectiveness of the medication or increase the potential for adverse consequences.

"Medication Regimen Review (MRR)" *or Drug Regimen Review* is a thorough evaluation of the medication regimen of a resident, with the goal of promoting positive outcomes and minimizing adverse consequences *and potential risks* associated with medication. The *MRR* includes *review of the medical record in order to* prevent, identify, report, and resolve medication-related problems, medication errors, or other irregularities. *The MRR also involves* collaborating with other members of the *IDT, including the resident, their family, and/or resident representative.*

Effective November 28, 2017

GUIDANCE §483.45(c)(1), (2), (4), and (5)

A. OVERVIEW

Many nursing home residents *have* been identified as being at high risk for adverse consequences related to medications. Some adverse consequences may mimic symptoms of chronic conditions, the aging process, or a newly emerging condition.

This guidance is not intended to imply that all adverse consequences related to medications are preventable, but rather to specify that a system exists to assure that medication usage is evaluated on an ongoing basis, that risks and problems are identified and acted upon, and that medication-related problems must be considered when the resident has a change in condition. This guidance will discuss the following aspects of the facility's MRR component of the pharmaceutical services systems:

- A pharmacist's review of the resident's medication regimen *and medical record* to identify and report irregularities; and
- Acting upon identified irregularities in order to minimize or prevent adverse consequences, to the extent possible.

NOTE: The surveyor's review of medication use is not intended to constitute the practice of medicine. However, surveyors are expected to investigate the basis for decisions and interventions affecting residents*, including whether or not the resident, resident's family and/or representative were informed about risks, benefits and treatment options and involved in the decision-making process.*

The review should take into account resident preferences and provide recommendations that assist facility staff in understanding and communicating to the resident any risks related to their preferences regarding medications or medication administration, as well as modifications that can be made to mitigate those risks.

Transitions in care such as a move from home or hospital to the nursing home, or vice versa, increase the risk of medication-related issues. Medications may be added, discontinued, omitted, or changed. It is important, therefore, to review the medications. Currently, safeguards to help identify medication issues *around transitions in care and throughout a resident's stay* include:

- The pharmacist performing the medication regimen review*, which includes a review of the resident's medical record,* at least monthly*;*
- *The pharmacist reporting any irregularities in a separate written report to the attending physician, medical director, and director of nursing; and*
- *The attending physician reviewing and acting on any identified irregularities.*

B. MEDICATION REGIMEN REVIEW (MRR)

The MRR is an important component of the overall management and monitoring of a resident's medication regimen. The pharmacist must review each resident's medication regimen at least once a month in order to identify irregularities and to identify clinically significant risks and/or *actual or potential* adverse consequences *which may* result from or *be* associated with medications. It may be necessary for the pharmacist to conduct the MRR more frequently, for example weekly, depending on the resident's condition and the risks for adverse consequences

related to current medications. Regulations prohibit the pharmacist from delegating the medication regimen reviews to *other* staff. The requirement for the MRR applies to *all residents (whether short or long-stay) without exceptions.*

The pharmacist performing the monthly MRR must also review the resident's medical record to appropriately monitor the medication regimen and ensure that the medications each resident receives are clinically indicated. Certain circumstances which may include residents who have multiple medical conditions, concurrent administration of certain medications, administration of medications which require close monitoring through lab work, and transitions of care may also increase the risk of adverse consequences. Review of the medical record as part of the MRR may prevent errors due to drug-drug interactions, omissions, duplication of therapy, or miscommunication during the transition from one team of care providers to another.

Facilities must develop policies and procedures to address the MRR. The policies and procedures must specifically address:

- *The appropriate time frames for the different steps in the MRR process; and*
- *The steps a pharmacist must follow when he or she identifies an irregularity that requires immediate action to protect the resident and prevent the occurrence of an adverse drug event.*

MRR policies and procedures should also address, but not be limited to:

- *MRRs for residents who are anticipated to stay less than 30 days;*
- *MRRs for residents who experience an acute change of condition and for whom an immediate MRR is requested after appropriate staff have notified the resident's physician, the medical director, and the director of nursing about the acute change.*

While conducting the MRR in the facility *is not required for compliance*, important information about indications for use, *actual or* potential medication irregularities or adverse consequences (such as symptoms of tardive dyskinesia, dizziness, anorexia, or falls) may be attainable only by talking to the staff, reviewing the medical record, and observing and speaking with the resident, *the resident's family and/or representative.* However, electronic health and medication records and other available technology may permit the pharmacist to conduct some components of the review outside the facility.

Electronic transmission of information may enable facilities to quickly communicate resident-specific information to an off-site pharmacy or pharmacist, however, electronic communication must remain secure to protect individually identifiable information as mandated by the Health Insurance Portability and Accountability Act (HIPAA) of 1996. With secure electronic communication the pharmacist may promptly identify actual or potential medication-related problems before a medication is initiated or soon afterwards. However, brief communication via secure devices to address or prevent immediate or potential problems does not constitute a complete MRR. All information that is needed to perform an MRR may not be available electronically, for example, flow sheets that monitor a resident's pain or that document other observations or symptoms.

Resources are available to facilitate evaluating medication concerns related to the performance of the MRR, such as:

- *U.S. Department of Health and Human Services, Food and Drug Administration (FDA) http://www.fda.gov/medwatch/safety.htm.*
- American Society of Consultant Pharmacists (ASCP) http://ascp.com/;
- American Medical Directors Association – *The Society for Post-Acute and Long-Term Care Medicine* (AMDA) http://www.paltc.org/;
- National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP) http://www.nccmerp.org;
- American Geriatrics Society (AGS) http://www.americangeriatrics.org; *and*

NOTE: References to non-CMS sources or sites on the Internet are provided as a service and do not constitute or imply endorsement of these organizations or their programs by CMS or the U.S. Department of Health and Human Services. CMS is not responsible for the content of pages found at these sites. URL addresses were current as of the date of this publication.

Identification of Irregularities

An objective of the MRR is to try to minimize or prevent adverse consequences by identifying irregularities including, for example: syndromes potentially related to medication therapy, emerging or existing adverse medication consequences *(e.g., drug reactions or medication errors).* The resident's record may contain information regarding possible and/or actual medication irregularities. Possible sources to obtain this information include: the medication administration records (MAR); prescribers' orders; progress, nursing and consultants' notes; the Resident Assessment Instrument (RAI); laboratory and diagnostic test results, and other sources of information about *documented expressions or indications of distress* and/or changes in condition. The pharmacist may also obtain information from the Quality Measures/Quality Indicator reports, the attending physician, facility staff, and (as appropriate) from interviewing, assessing, and/or observing the resident.

The pharmacist's review considers factors such as:

- Whether the physician and staff have documented objective findings, diagnoses, symptom(s), *and/or resident goals and preferences* to support indications for use;
- Whether the physician and staff have identified and acted upon, or should be notified about, the resident's allergies and/or potential side effects and significant medication interactions;
- Whether the medication dose, frequency, route of administration, and duration are consistent with the resident's condition, manufacturer's recommendations, and applicable standards of practice;
- Whether the physician and staff have documented progress towards, *decline from*, or maintenance of the *resident's* goal(s) for the medication therapy;
- *Whether the physician and staff have documented any attempts for gradual dose reduction (GDR) or added any non-pharmacological approaches, in an effort to reduce or discontinue a drug;*
- Whether the physician and staff have obtained and acted upon laboratory results, diagnostic studies, or other measurements (such as bowel function, intake and output) as applicable;

- Whether medication errors exist or circumstances exist that make them likely to occur; and
- Whether the physician and staff have noted and acted upon possible medication-related causes of recent or persistent changes in the resident's condition such as worsening of an existing problem or the emergence of new signs or symptoms. *Some examples of changes potentially related to medication use that could occur include:*
  - Anorexia and/or unplanned weight loss, or weight gain;
  - *Expressions or indications of distress, or other changes in a resident's psychosocial status;*
  - Bowel function changes including constipation, ileus, impaction;
  - Confusion, cognitive decline, worsening of dementia (including delirium);
  - Dehydration, fluid/electrolyte imbalance;
  - Excessive sedation, insomnia, or sleep disturbance;
  - Falls, dizziness, or evidence of impaired coordination;
  - Headaches, muscle pain, generalized aching or pain;
  - Rash, pruritus;
  - Spontaneous or unexplained bleeding, bruising; *and*
  - Urinary retention or incontinence.

Upon conducting the MRR, the pharmacist may identify and report *irregularities* in one or more of the following categories:

- The use of a medication without identifiable evidence of adequate indications for use*, such as, the use of a medication to treat a clinical condition without identifiable evidence that safer alternatives or more clinically appropriate medications have been considered;*
- *The use of homeopathic or herbal options (e.g., St. John's Wort) that may interfere with the effectiveness of clinically appropriate medications;*
- The use of an appropriate medication that is not helping attain the intended treatment *or resident's* goals because of timing of administration, dosing intervals, sufficiency of dose, techniques of administration, or other reasons;
- The use of a medication in an excessive dose (including duplicate therapy) or for excessive duration, thereby placing the resident at greater risk for adverse consequences or causing existing adverse consequences;
- The presence of an adverse consequence associated with the resident's current medication regimen;
- The use of a medication without evidence of adequate monitoring; i.e., either inadequate monitoring of the response to a medication or an inadequate response to the findings;
- Presence of medication errors or the risk for such errors;
- Presence of a clinical condition that might warrant initiation of medication therapy; and

NOTE: The presence of a diagnosis or symptom does not necessarily warrant medication, but often depends on the consideration of many factors simultaneously.

- A medication interaction associated with the current medication regimen.

NOTE: Concomitant use of *certain* medication combinations is not necessarily inappropriate. Often, several medications with documented interactions can be given together safely. However,

concomitant use of *certain* medications warrants careful consideration of potential alternatives, possible need to modify doses, and diligent monitoring.

Websites for organizations such as AMDA - The Society for Post-Acute and Long-Term Care Medicine (American Medical Directors Association) have made information available regarding problematic medication interactions in the long-term care population:

- *https://www.amda.com/tools/clinical/m3/topten.cfm; and*
- *https://www.crediblemeds.org/healthcare-providers/drug-drug-interaction, Woosley, RL and Romero, KA, www.Crediblemeds.org, QTdrugs List, [Accessed March6, 2017], AZCERT, Inc. 1822 Innovation Park Dr., Oro Valley, AZ 85755.*

NOTE: References to non-CMS sources do not constitute or imply endorsement of these organizations or their programs by CMS or the U.S. Department of Health and Human Services and were current as of the date of this publication.

Location and Notification of Medication Regimen Review Findings

The pharmacist is expected to document either that no irregularity was identified or the nature of any identified irregularities. The pharmacist is responsible for reporting any identified irregularities to the attending physician, *the facility's medical director,* and director of nursing. The timeliness of notification of irregularities depends on factors including the potential for or presence of serious adverse consequences; for example, immediate notification is indicated in cases of bleeding in a resident who is receiving anticoagulants or in cases of possible allergic reactions to antibiotic therapy. *The pharmacist must document any identified irregularities in a separate, written report. The report may be in paper or electronic form.* If no irregularities were identified during the review, the pharmacist includes a signed and dated statement to that effect.

The pharmacist does not need to document a continuing irregularity in the report each month *if the attending physician has documented a valid clinical rationale* for rejecting the pharmacist's recommendation unless *warranted by a change in the resident's condition or other circumstances.*

The pharmacist's findings are considered part of each resident's *medical* record *and as such are available to the resident/representative upon request.* If documentation of the findings is not in the active record, it is maintained within the facility and is readily available for review. Establishing a consistent location for the pharmacist's findings and recommendations can facilitate communication with the attending physician, the director of nursing, the remainder of the *IDT*, the medical director, the resident and his or her legal representative, *the* ombudsman, and surveyors.

Response to Irregularities Identified in the MRR

The medical record must show documentation that the attending physician reviewed any irregularities identified by the pharmacist. For those issues that require physician intervention, the *attending* physician either accepts and acts upon the report and recommendations or rejects all or some of the report *and should document his or her rationale of why the recommendation is rejected in the resident's medical record.* It is not acceptable for *an attending* physician to

document only that he/she disagrees with the report, without providing some *clinical* basis for disagreeing.

The facility should have a procedure for how to resolve situations where:

- *The attending physician does not concur with or take action on identified irregularities, and;*
- *The attending physician is also the medical director.*

KEY ELEMENTS OF NONCOMPLIANCE

To cite deficient practice at F756, the surveyor's investigation will generally show that:

- *The MRR was not conducted by a licensed pharmacist; or*
- The pharmacist failed to conduct *a complete* MRR, at least monthly (or more frequently, as indicated by the resident's condition) *for every resident of the facility*; *or*
- *The pharmacist's findings in the MRR did not show evidence that the pharmacist also reviewed the resident's chart, for example, the pharmacist did not reference the resident response to a particular medication that was cited as an irregularity.; or*
- The pharmacist failed to identify or report the absence of or inadequate indications for use of a medication, or a medication or medication combination with significant potential for adverse consequences or medication interactions*; or*
- *The pharmacist failed to identify and/or report medications prescribed or administered in excessive dose (including but not limited to duplicate therapy); or*
- *The pharmacist failed to identify and/or report medications prescribed or administered for excessive duration; or*
- *The pharmacist failed to identify and/or report medications prescribed or administered without adequate monitoring; or*
- The pharmacist failed to identify or report medications in a resident's regimen that could (as of the review date) be causing or associated with new, worsening, or progressive signs and symptoms*; or*
- The pharmacist failed to identify and report the absence of any explanation as to why or how the benefit of a medication(s) with potential for clinically significant adverse consequences outweighs the risk*; or*
- *The attending physician failed to document that he or she reviewed the pharmacist's identified irregularities and/or failed to document the action taken or not taken to address the irregularities; or*
- *The facility failed to develop, maintain, and implement policies and procedures which address the time frames for the steps in the MRR process; or*
- *The facility failed to develop and implement policies and procedures which address steps the pharmacist must take when he or she identifies an irregularity that requires urgent action to protect the resident.*

PROCEDURE

Use the Unnecessary Medications, Psychotropic Medications, and Medication Regimen Review Critical Element Pathway, as appropriate, along with the above interpretive guidelines when determining if the facility meets the requirements for, or investigating concerns related to Medication Regimen Review.

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DEFICIENCY CATEGORIZATION

In addition to actual or potential physical harm, always consider whether psychosocial harm has occurred when determining severity level (See Appendix P, Section IV, E, Psychosocial Outcome Severity Guide).

Examples of noncompliance that demonstrate severity at Level 4 include, but are not limited to:

- Despite identifying irregularities with the potential for serious harm or death *in a resident's medication regimen*, the pharmacist did not report the irregularities to the attending physician*, DON, and medical director* or action was *not* taken on the irregularities reported.
- *On the MRR, the pharmacist identified that a resident was prescribed an antipsychotic medication without a clinical indication. This placed the resident at likely risk for harm such as experiencing a fall, mental status changes, or sustained negative psychosocial outcomes. The medical record did not show evidence that the attending physician had reviewed and responded to the identified irregularity*.

Examples of Level 3, Actual harm (physical or psychosocial) that are not immediate jeopardy, include, but are not limited to:

- The pharmacist's MRR failed to identify the indication for continued use for opioid analgesics that had been prescribed for a resident's acute pain which had resolved. As a result of prolonged duration of use, the resident *continued to be or* became more lethargic *and/or* withdrawn.
- The pharmacist's MRR identified that the staff were crushing medications that should not be crushed. As a result of facility failure to act upon the notification, the resident experienced clinically significant adverse consequences such as hypoglycemia or hypotension that required medical intervention.
- The *attending* physician failed to act in response to the pharmacist's MRR which identified the indefinite continuation of an antidepressant in a resident who had no history of depression, who had been placed on the antidepressant without an evaluation to confirm presence of depression, and whose function and mood were not monitored while getting the medication for months. The resident experienced clinically significant adverse consequences such as falls *without serious injury*, constipation, or change in weight.

Examples of Level 2, No actual harm with a potential for more than minimal harm that is not immediate jeopardy, may include but are not limited to:

- The facility failed to respond to the pharmacist's notification that the resident was not receiving *an over-the-counter (OTC) dietary supplement that had been prescribed*. *Currently*, there was no change in the resident*'s* condition*, such as a weight loss*.
- The pharmacist's MRR failed to evaluate and report on the potential adverse consequences of a medication *that may increase the possible side effects of another clinically appropriate medication that had been prescribed. The resident had not yet experienced side effects from the combined medications.*

Severity Level 1 Considerations: No Actual Harm with Potential for Minimal Harm

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Severity Level 1 does not apply for this regulatory requirement because the failure to perform the MRR according to the regulatory provisions creates the potential for more than minimal harm.

POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION
Examples of some of the related requirements that should be considered when *concerns have* been identified include the following:

- 42 CFR 483.*10*(*g*)*(14), F580,* Notification of Changes
  - Review whether *a member of the IDT* contacted the attending physician regarding a significant change in the resident's condition in relation to a potential adverse consequence of a medication, or a need to alter treatment significantly (i.e., a need to discontinue an existing form of treatment due to adverse consequences, or to commence a different form of treatment).
- 42 CFR 483.*45*(*d*), *F757,* Unnecessary *Drugs and 42 CFR 483.45*(*e*), *F758, Psychotropic Medications*
  - Review whether the resident is receiving any medications without an indication for use, in excessive dose or duration, with inadequate monitoring, or in the presence of any adverse consequences that indicate that the dose should be reduced or discontinued.
- 42 CFR 483.*30*(a), *F710,* Physician Supervision
  - Review whether the attending physician supervised the resident's medical treatment, including assessing the resident's condition, identifying the need for and continuing use of medication to address the resident's needs, and identifying and addressing adverse consequences related to medications.
- 42 CFR 483.*30*(b), *F711* Physician Visits *and 42 CFR 483.30(c), F712, Frequency of Physician Visits*
  - Review whether the attending physician or another designated practitioner reviewed the resident's total program of care including the beneficial and adverse effects of medications and treatment, and provided a relevant progress note at each visit.
- 42 CFR 483.*45(a), (b)(1)-(3)*, *F755,* Pharmacy Services
  - Review whether the licensed pharmacist has provided consultation regarding all aspects of pharmaceutical services.
- 42 CFR 483.*70*(*h*), *F841,* Medical Director
    - Review whether the medical director, when requested by the facility, interacted with the attending physician regarding an inadequate response to identified or reported potential medication irregularities and adverse consequences.

F757
§483.*45(d)* Unnecessary Drugs—General.
Each resident's drug regimen must be free from unnecessary drugs. An unnecessary drug is any drug when used—

§483.*45(d)(1)* In excessive dose (including duplicate *drug* therapy); or

§483.*45(d)(2)* For excessive duration; or

Effective November 28, 2017

§483.4*5(d)(3)* Without adequate monitoring; or

§483.*45(d)(4)* Without adequate indications for its use; or

§483.*45(d)(5)* In the presence of adverse consequences which indicate the dose should be reduced or discontinued; or

§483.*45(d)(6)* Any combinations of the reasons stated *in paragraphs (d)(1) through (5) of this section.*

F758
§483.*45*(c)*(3) A psychotropic drug is any drug that affects brain activities associated with mental processes and behavior. These drugs include, but are not limited to, drugs in the following categories:*

(i) Anti-psychotic;
(ii) Anti-depressant;
(iii) Anti-anxiety; and
(iv) Hypnotic

§483.*45(e) Psychotropic* Drugs. Based on a comprehensive assessment of a resident, the facility must ensure that--

§483.*45(e)(1)* Residents who have not used *psychotropic* drugs are not given these drugs unless *the medication* is necessary to treat a specific condition as diagnosed and documented in the clinical record;

§483.*45(e)(2)* Residents who use *psychotropic* drugs receive gradual dose reductions, and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs;

§483.*45(e)(3) Residents do not receive psychotropic drugs pursuant to a PRN order unless that medication is necessary to treat a diagnosed specific condition that is documented in the clinical record; and*

§483.*45(e)(4) PRN orders for psychotropic drugs are limited to 14 days. Except as provided in §483.45(e)(5), if the attending physician or prescribing practitioner believes that it is appropriate for the PRN order to be extended beyond 14 days, he or she should document their rationale in the resident's medical record and indicate the duration for the PRN order.*

§483.*45(e)(5) PRN orders for anti-psychotic drugs are limited to 14 days and cannot be renewed unless the attending physician or prescribing practitioner evaluates the resident for the appropriateness of that medication.*

INTENT: §483.*45*(*d*) Unnecessary drugs *and 483.45(c)(3) and (e) Psychotropic Drugs*
The intent of this requirement is that:

- *each resident's entire drug/medication regimen is managed and monitored to promote or maintain the resident's highest practicable mental, physical, and psychosocial well-being;*
- *the facility implements gradual dose reductions(GDR) and non-pharmacological interventions, unless contraindicated, prior to initiating or instead of continuing psychotropic medication; and*
- *PRN orders for psychotropic medications are only used when the medication is necessary and PRN use is limited.*

NOTE: ***For concerns related to unnecessary medications, excluding psychotropic medications, surveyors should assess compliance with §483.45(d), F757.***

For concerns related to psychotropic medications only, including the unnecessary medication requirements, surveyors should assess compliance with §483.45(c) and (e), F758.

The Guidance for these two tags is combined to avoid unnecessary duplication.

Although the regulatory language refers to "drugs," the guidance in this document generally will refer to "medications," except in those situations where the term "drug" has become part of an established pharmaceutical term (e.g., adverse drug event, and adverse drug reaction or consequence).

For purposes of this guidance, references to "the pharmacist" mean the facility's licensed pharmacist, whether employed directly by the facility or through arrangement.

The surveyor's review of medication use is not intended to constitute the practice of medicine. However, surveyors are expected to investigate the basis for decisions and interventions affecting residents.

DEFINITIONS ***§483.45 (d) Unnecessary drugs and 483.45(c)(3) and (e) Psychotropic Drugs***
Definitions are provided to clarify terminology related to medications and to the evaluation and treatment of residents.

"Adverse consequence" *is a broad term referring to unwanted, uncomfortable, or dangerous effects that a drug may have, such as impairment or decline in an individual's mental or physical condition or functional or psychosocial status. It may include various types of adverse drug reactions and interactions (e.g., medication-medication, medication-food, and medication-disease) (adapted from The Merck Manual Professional Version, http://www.merckmanuals.com/professional/clinical-pharmacology/adverse-drug-reactions/adverse-drug-reactions.)*

NOTE: Adverse drug reaction (ADR) is a form of adverse consequences. It may be either a secondary effect of a medication that is usually undesirable and different from the therapeutic effect of the medication or any response to a medication that is noxious and unintended and occurs in doses for

prophylaxis, diagnosis, or treatment. The term "side effect" is often used interchangeably with ADR; however, side effects are but one of five ADR categories, the others being hypersensitivity, idiosyncratic response, toxic reactions, and adverse medication interactions. A side effect is an expected, well-known reaction that occurs with a predictable frequency and may or may not constitute an adverse consequence.

"Anticholinergic side effect" is an effect of a medication that opposes or inhibits the activity of the parasympathetic (cholinergic) nervous system to the point of causing symptoms such as dry mouth, blurred vision, tachycardia, urinary retention, constipation, confusion, delirium, hallucinations, flushing, and increased blood pressure. Types of medications that may produce anticholinergic side effects include:

- Antihistamines, antidepressants, anti-psychotics, antiemetics, muscle relaxants; and
- Certain medications used to treat cardiovascular conditions, Parkinson's disease, urinary incontinence, gastrointestinal issues and vertigo.

"Behavioral interventions" are individualized, non-pharmacological approaches to *care* that are provided as part of a supportive *physical and psychosocial* environment, directed *toward understanding, preventing, relieving, and/or accommodating a resident's distress or loss of abilities, as well as maintaining or improving a resident's mental, physical or psychosocial well-being*.

"Clinically significant" refers to effects, results, or consequences that materially affect or are likely to affect an individual's mental, physical, or psychosocial well-being either positively by preventing, stabilizing, or improving a condition or reducing a risk, or negatively by exacerbating, causing, or contributing to a symptom, illness, or decline in status.
"Expressions or indications of distress" *refers to a person's attempt to communicate unmet needs, discomfort, or thoughts that he or she may not be able to articulate. The expressions* may present as crying, *apathy*, or *withdrawal*, or as verbal or physical actions such as: pacing, cursing, hitting, kicking, pushing, scratching, tearing things, or grabbing others.

"Dose" is the total amount/strength/concentration of a medication given at one time or over a period of time. The individual dose is the amount/strength/concentration received at each administration. The amount received over a 24-hour period may be referred to as the daily dose.

"Excessive dose" *means the total amount of any medication (including duplicate therapy) given at one time or over a period of time that is greater than the amount recommended by the manufacturer's label, package insert, and accepted standards of practice for a resident's age and condition.*

"Duplicate therapy" refers to multiple medications of the same pharmacological class/category or any medication therapy that substantially duplicates a particular effect of another medication that the individual is taking.

<u>Effective November 28, 2017</u>

"Extrapyramidal symptoms (EPS)" are neurological side effects that can occur at any time from the first few days of treatment *with antipsychotic medication* to years later. EPS includes various syndromes such as:

- Akathisia, which refers to a distressing feeling of internal restlessness that may appear as constant motion, the inability to sit still, fidgeting, pacing, or rocking.
- Medication-induced Parkinsonism, which refers to a syndrome of Parkinson-like symptoms including tremors, shuffling gait, slowness of movement, expressionless face, drooling, postural unsteadiness and rigidity of muscles in the limbs, neck and trunk.
- Dystonia, which refers to an acute, painful, spastic contraction of muscle groups (commonly the neck, eyes and trunk) that often occurs soon after initiating treatment and is more common in younger individuals.

"Gradual Dose Reduction (GDR)" is the stepwise tapering of a dose to determine if symptoms, conditions, or risks can be managed by a lower dose or if the dose or medication can be discontinued.

"Indications for use" is the identified, documented clinical rationale for administering a medication that is based upon an assessment of the resident's condition and therapeutic goals and is consistent with manufacturer's recommendations and/or clinical practice guidelines, clinical standards of practice, medication references, clinical studies or evidence-based review articles that are published in medical and/or pharmacy journals.

"Neuroleptic Malignant Syndrome (NMS)" is a syndrome related to the use of medications, mainly antipsychotics, that typically presents with a sudden onset of diffuse muscle rigidity, high fever, labile blood pressure, tremor, and notable cognitive dysfunction. It is potentially fatal if not treated immediately, including stopping the offending medications.

"Psychotropic drug" *is defined in the regulations at §483.45(c)(3), as "any drug that affects brain activities associated with mental processes and behavior." Psychotropic drugs include, but are not limited to the following categories: anti-psychotics, anti-depressants, anti-anxiety, and hypnotics.*

"Serotonin Syndrome" is a potentially serious clinical condition resulting from overstimulation of serotonin receptors. It is commonly related to the use of multiple serotonin-stimulating medications (e.g., SSRIs, SNRIs, triptans, certain antibiotics). Symptoms may include restlessness, hallucinations, confusion, loss of coordination, fast heartbeat, rapid changes in blood pressure, increased body temperature, overactive reflexes, nausea, vomiting and diarrhea.

"Tardive dyskinesia" refers to abnormal, recurrent, involuntary movements that may be irreversible and typically present as lateral movements of the tongue or jaw, tongue thrusting, chewing, frequent blinking, brow arching, grimacing, and lip smacking, although the trunk or other parts of the body may also be affected.

GUIDANCE §483.45(d) Unnecessary drugs and §483.45(c)(3) and (e) Psychotropic Drugs

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Medications are an integral part of the care provided to residents of nursing facilities. They are administered to try to achieve various outcomes, such as curing an illness, arresting or slowing a disease process, reducing or eliminating symptoms, or *as part of diagnosing or* preventing a disease or symptom.

Proper medication selection and prescribing (including dose, duration, and type of medication(s)) may help stabilize or improve a resident's outcome, quality of life and functional capacity. Any medication or combination of medications—or the use of a medication without adequate indications, in excessive dose, for an excessive duration, or without adequate monitoring—may increase the risk of a broad range of adverse consequences such as medication interactions, depression, confusion, immobility, falls, hip fractures, *and death. The Beers Criteria for Potentially Inappropriate Medication Use in Older Adults provides information on safely prescribing medications for older adults, http://www.healthinaging.org/medications-older-adults/.*

NOTE: *References to non-CMS sources do not constitute or imply endorsement of these organizations or their programs by CMS or the U.S. Department of Health and Human Services and were current as of the date of this publication.*

Intrinsic factors including physiological changes accompanying the aging process, multiple comorbidities, and certain medical conditions may affect the absorption, distribution, metabolism or elimination of medications from the body and may also increase an individual's risk of adverse consequences.

While assuring that only those medications required to treat the resident's assessed condition are being used, reducing the need for and maximizing the effectiveness of medications are important considerations for all residents. Therefore, as part of all medication management (*especially psychotropic medications*), it is important for the *IDT* to *implement* non-pharmacological approaches *designed to meet the individual needs of each resident*. Educating facility staff and providers *about the importance of* implementing *individualized*, non-pharmacological approaches to *care* prior to the use of medications may minimize the need for medications or reduce the dose and duration of those medications. *Additional information as well as* examples of non-pharmacological interventions may *be found in other guidance for regulations at §483.40, Behavioral Health Services and §483.25, Quality of Care and Quality of Life.*

The indications for initiating, withdrawing, or withholding medication(s), as well as the use of non-pharmacological approaches, are determined by assessing the resident's underlying condition, current signs, symptoms*, and expressions*, and preferences and goals for treatment. This includes, where possible, the identification of the underlying cause(s), since a diagnosis alone may not warrant treatment with medication. Orders from multiple prescribers *or providers* can increase the resident's chances of receiving unnecessary medications.

Staff and practitioner access to current medication references and pertinent clinical protocols helps to promote safe administration and monitoring of medications. One of the existing mechanisms to warn prescribers about risks associated with medications is the Food and Drug Administration (FDA) requirement that manufacturers include within the medication labeling warnings about adverse reactions and potential safety hazards identified both before and after approval of a medication, and what to do if they occur

(Visit:http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/. Manufacturers are required to update labels to warn about newly identified safety hazards—regardless of whether causation has been proven and whether the medication is prescribed for a disease or condition that is not included in the "Indications and Usage" section of the labeling (so-called "off-label" or unapproved use). *Federal regulations at 21 CFR 201.57 (a)(4) and (c)(1) also require manufacturers to place statements about serious problems or contraindications in a prominently displayed box that appears on the medication labelling and in greater detail in the full prescribing information that accompanies the medication. The boxed warning is reserved for prescription drugs that pose a significant risk of serious or life-threatening adverse effects, based on medical studies.*

The facility's pharmacist is a valuable source of information about medications. Listings or descriptions of most significant risks, recommended doses, medication interactions, cautions, etc. can be found in widely available, standard references, and computer software and systems that provide up-to-date information. It is important to note that some of the medication information found in many of these references is not specific to older adults or individuals *residing in nursing homes*. *A list of resources and tools is provided at the end of this guidance.*

MEDICATION MANAGEMENT

Medication management is based in the care process and includes recognition or identification of the problem/need, assessment, diagnosis/cause identification, management/treatment, monitoring, and revising interventions, as warranted *as well as documenting medication management steps.* The attending physician plays a key leadership role in medication management by developing, monitoring, and modifying the medication regimen in conjunction with residents, *their families,* and/or representative(s) and other professionals and direct care staff (the *IDT*).

When selecting medications and non-pharmacological *approaches*, members of the *IDT*, *including the resident, his or her family, and/or representative(s)*, participate in the care process to identify, assess, address, advocate for, monitor, and communicate the resident's needs and changes in condition. This guidance is intended to help the surveyor determine whether the facility's medication management supports and promotes:

- *Involvement of the resident, his or her family, and/or the resident representative in the medication management process.*
- Selection of medications(s) based on assessing relative benefits and risks to the individual resident;
- Evaluation of a resident's physical, behavioral, *mental*, and psychosocial signs and symptoms, in order to identify the underlying cause(s), including adverse consequences of medications;
- Selection and use of medications in doses and for the duration appropriate to each resident's clinical conditions, age, and underlying causes of symptoms *and based on assessing relative benefit and risks to, and preferences and goals of, the individual resident;*
- The use of non-pharmacological *approaches*, *unless contraindicated*, to minimize the need for medications, permit use of the lowest possible dose, or allow medications to be discontinued; and

- The monitoring of medications for efficacy and adverse consequences.
- Resident Choice –If a resident *declines* treatment, the facility staff and physician should inform the resident about the risks related to the *lack* of the medication, and discuss appropriate alternatives such as offering the medication at another time or in another dosage form, or offer an alternative medication or non-pharmacological approach.
- Advance Directives – *A resident's advance directives* may include withdrawing or withholding medications. Whether or not a resident has an advance directive, the facility is responsible for giving treatment, support, and other care that is consistent with the resident's condition and applicable care instructions*, according to the resident's care plan. If there are concerns regarding Resident Choice or Advance Directives, consider investigating the requirements at §483.10, Resident Rights and §483.21, Care Planning.*

The resident's *medical* record documents and communicates to the entire team the basic elements of the care process *and the resident's goals and preferences*. Information about aspects of the care process related to medications may be found in various locations within the record, such as: hospital discharge summaries and transfer notes, progress notes and interdisciplinary notes, history and physical examination, Resident Assessment Instrument (RAI), plan of care, laboratory reports, professional consults, medication orders, Medication Regimen Review (MRR) reports, and Medication Administration Records (MAR).

The regulations associated with medication management include consideration of:

- *Indication and clinical need for medication;*
- *Dose (including duplicate therapy);*
- *Duration;*
- *Adequate monitoring for efficacy and adverse consequences; and*
- *Preventing, identifying, and responding to adverse consequences.*

With regard to psychotropic medications, the regulations additionally require:

- *Giving psychotropic medications only when necessary to treat a specific diagnosed and documented condition;*
- *Implementing GDR and other non-pharmacologic interventions for residents who receive psychotropic medications, unless contraindicated; and*
- *Limiting the timeframe for PRN psychotropic medications, which* ***are not*** *antipsychotic medications, to 14 days, unless a longer timeframe is deemed appropriate by the attending physician or the prescribing practitioner.*
- *Limiting PRN psychotropic medications, which* ***are*** *antipsychotic medications, to 14 days and not entering a new order without first evaluating the resident.*

NOTE: *While there may be isolated situations where a pharmacological intervention is required first, these situations do not negate the obligation of the facility to develop and implement non-pharmacological interventions. For additional information related to situations where a non-pharmacological intervention may be contraindicated, refer to §483.40(a)(2), Implementing non-pharmacological interventions.*

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Indication for Use

The resident's medical record must show documentation of adequate indications for a medication's use and the diagnosed condition for which a medication is prescribed.

An evaluation of the resident *by the IDT* helps to identify his/her needs, *goals,* comorbid conditions, and prognosis to determine factors (including medications and new or worsening medical conditions) that are affecting signs, symptoms, and test results. This evaluation process is important when *selecting initial medications and/or non-pharmacological approaches* and when deciding whether to modify or discontinue a current medication. The evaluation also clarifies:

- Whether other causes for the symptoms (including expressions or indications of distress that could mimic a psychiatric disorder) have been ruled out;
- Whether the physical, *mental, behavioral*, and/or psychosocial signs, symptoms, or related causes are persistent or clinically significant enough (e.g., causing functional decline) to warrant the initiation or continuation of medication therapy;
- Whether non-pharmacological *approaches* are implemented, unless *clinically* contraindicated f*or the resident or declined by the resident*;
- Whether a particular medication is clinically indicated to manage the symptom or condition; and
- Whether the intended or actual benefit *is understood by the resident and, if appropriate, his/her family and/or representative(s) and* is sufficient to justify the potential risk(s) or adverse consequences associated with the selected medication, dose, and duration.

The content and extent of the evaluation may vary with the situation and may employ various assessment instruments and diagnostic tools. Examples of information to be considered and evaluated may include, but are not limited to, the following:

- An appropriately detailed evaluation of mental, physical, psychosocial, and functional status, including comorbid conditions and pertinent psychiatric symptoms and diagnoses and a description of resident complaints, symptoms, and signs (including the onset, scope, frequency, intensity, precipitating factors, and other important features);
- Each resident's goals and preferences;
- Allergies to medications and foods and potential for medication interactions;
- A history of prior and current medications and non-pharmacological interventions (including therapeutic effectiveness and any adverse consequences);
- Recognition of the need for end-of-life or palliative care; and
- The *basis for declining* care, *medication,* and treatment and the identification of pertinent alternatives.
- *Documentation of indications of distress, delirium, or other changes in functional status.*

Circumstances that warrant evaluation of the resident and medication(s) include:

- Admission or re-admission;
- A clinically significant change in condition/status;
- A new, persistent, or recurrent clinically significant symptom or problem;
- A worsening of an existing problem or condition;
- An unexplained decline in function or cognition;
- A new medication order or renewal of orders; and

- An irregularity identified in the pharmacist's medication regimen review. *See F756 for guidance related to the medication regimen review.*
- *Orders for PRN psychotropic and/or antipsychotic medications which are not prescribed to treat a diagnosed specific condition or do not meet the PRN requirements for psychotropic and antipsychotic medications.*

Specific considerations related to these circumstances may include the following:

- Admission (or Readmission) – Some residents may be admitted on medications for an undocumented chronic condition or without a clear indication as to why a medication was begun or should be continued. It is expected that the attending physician, pharmacist, and staff subsequently determine if continuing the medication is justified by evaluating the resident's clinical condition, risks, existing medication regimen, *preferences, goals,* and related factors.
- Multiple prescribers – Regardless of who the prescribers are, the continuation of a medication needs to be evaluated to determine if the medication is still warranted in the context of the resident's other medications and comorbidities. Medications prescribed by a specialist or begun in another care setting, such as the hospital, need to have a clinically pertinent documented rationale *in the resident's medical record*.
- New medication order as an emergency measure – When a resident is experiencing an acute medical problem or psychiatric emergency (e.g., the resident's *expression or action* poses an immediate risk to the resident or others), medications may be required. In these situations, it is important to identify and address the underlying causes of the problem or symptoms. Once the acute phase has stabilized, the staff and prescriber consider whether medications are still relevant. Subsequently, the medication is reduced or discontinued as soon as possible or the clinical rationale for continuing the medication is documented. *If the new medication is a psychotropic or antipsychotic medication ordered on a PRN basis, the PRN order(s) must be consistent with the requirements for PRN use of psychotropic and antipsychotic medications at §483.45(e)(3), (4), and (5).*
  When psychopharmacological medications are used as an emergency measure, adjunctive approaches, such as individualized, non-pharmacological *approaches* and techniques *must* be implemented. Longer term management options should be discussed with the resident, their family, and/or representative(s).
- Psychiatric disorders or *expressions and/or indications of distress* – As with all symptoms, it is important to seek the underlying cause of the distress. *Some examples of potential causes include delirium, pain, psychiatric or neurological illness, environmental or psychological stressors, dementia, or substance intoxication or withdrawal. Non-pharmacologic approaches, unless clinically contraindicated, must be implemented to address expressions or indications of distress. However, medications may be effective when the underlying cause of a resident's distress has been determined, non-pharmacologic approaches to care have been ineffective, or expressions of distress have worsened. Medications may be unnecessary and are likely to cause harm when given without a clinical indication, at too high of a dose, for too long after the resident's distress has been resolved, or if the medications are not monitored. All approaches to care, including medications, need to be monitored for efficacy, risks, benefits, and harm and revised as necessary.*

Effective November 28, 2017

***NOTE**: Permission given by or a request made by the resident and/or representative does not serve as a sole justification for the medication itself.*

Dose

Medications are prescribed based on a variety of factors including the resident's diagnoses, signs and symptoms, current condition, age, coexisting medication regimen, review of lab and other test results, input from the *IDT* about the resident, *including the resident's preferences and goals,* the type of medication(s), and therapeutic goals being considered or used.

The route of administration influences a medication's absorption and ultimately the dose received. Examples of factors that can affect the absorption of medications delivered by transdermal patches include skin temperature and moisture, and the integrity of the patch. Similarly, the flow rate of intravenous solutions affects the amount received at a given time.

Duplicate therapy is generally not indicated, unless current clinical standards of practice and documented clinical rationale confirm the benefits of multiple medications from the same class or with similar therapeutic effects. Some examples of potentially problematic duplicate therapy include, *use of more than one product containing the same medication, concomitant use of drugs within the same class, or medications from different therapeutic categories with similar effects or properties. Additionally, the risk for duplication is particularly high during transitions of care, especially if medications are not tracked closely between locations or within the care settings.* Documentation is necessary to clarify the rationale for and benefits of duplicate therapy and the approach to monitoring for benefits and adverse consequences.

Duration

Periodic re-evaluation of the medication regimen is necessary to determine whether prolonged or indefinite use of a medication is indicated. The clinical rationale for continued use of a medication(s) may have been demonstrated in the clinical record, or the staff and prescriber may present pertinent clinical reasons for the duration of use. *Regarding PRN medications, it is important that the medical record include documentation related to the attending physician's or other prescriber's evaluation of the resident and of indication(s), specific circumstance(s) for use, and the desired frequency of administration for each medication. As part of the evaluation, gathering and analyzing information helps define clinical indications and provide baseline data for subsequent monitoring.* Common considerations for appropriate duration may include:

- A medication initiated as a result of a time-limited condition (for example, delirium, pain, infection, nausea and vomiting, cold and cough symptoms, or itching) is then discontinued when the condition has resolved, or there is documentation indicating why continued use is still relevant. Failure to review whether the underlying cause has resolved may lead to excessive duration.
- A medication administered beyond the stop date established *by* the prescriber, without evidence of clinical justification for continued use of the medication, may be considered excessive duration.
- *A medication, which is prescribed on a PRN basis, is requested by the resident and/ or/administered by staff on a regular basis, indicating a more regular schedule may be needed.*

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Monitoring for Efficacy and Adverse Consequences

The information gathered during the initial and ongoing evaluations *and through conversations with the resident and, as appropriate, his or her family or representative is* essential to:

- *Verify or differentiate the underlying diagnoses or other underlying causes of signs and symptoms.*
- Incorporate into a comprehensive care plan that reflects *person-centered* medication related goals and parameters for monitoring the resident's condition, including the likely medication effects and potential for adverse consequences. Examples of this information may include the FDA *boxed* warnings or *warnings of* adverse consequences that may be rare, but have sudden onset, or that may be irreversible. If the facility has established protocols for monitoring specific medications and the protocols are accessible for staff use, the care plan may refer staff to these protocols;
- Optimize the therapeutic benefit of medication therapy and minimize or prevent potential adverse consequences;
- Establish parameters for evaluating the ongoing need for the medication; and
- *Track progress and/or decline towards the therapeutic goal.*

Sources of information to facilitate defining the monitoring criteria or parameters may include cautions, warnings, and identified adverse consequences from:

- Manufacturers' package inserts and *boxed* warnings;
- Facility policies and procedures;
- Pharmacists;
- Clinical practice guidelines or clinical standards of practice;
- Medication references; and
- Clinical studies or evidence-based review articles that are published in medical and/or pharmacy journals.

Monitoring *and accurate documentation* of the resident's response to any medication(s) is essential to evaluate the ongoing benefits as well as risks of various medications. *Monitoring should also include evaluation of the effectiveness of non-pharmacological approaches, such as prior to administering PRN medications.*

Monitoring involves several steps, including:

- Identifying the essential information and how it will be obtained and reported-- It is important to consider who is responsible for obtaining the information, which information should be collected, and how the information will be documented. The information that is collected depends on therapeutic goals, detection of potential or actual adverse consequences, and consideration of risk factors, such as:
  - Medication-medication, medication-food interactions;
  - Clinical condition (for example renal disease);
  - Properties of the medication;
  - *Boxed* warnings; and
  - *Resident's* history of adverse consequences related to a similar medication.
- Determining the frequency of monitoring-- The frequency and duration of monitoring needed to identify therapeutic effectiveness*, achievement of resident goals,* and adverse consequences will depend on factors such as clinical standards of practice, facility

policies and procedures, manufacturer's specifications, and the resident's clinical condition *and choices*. Monitoring involves three aspects:
  - Periodic planned evaluation of progress toward the therapeutic goals;
  - Continued vigilance for adverse consequences; and
  - Evaluation of identified adverse consequences.
- Defining the methods for communicating, analyzing, and acting upon relevant information-- The monitoring process needs to identify who is to communicate with the prescriber, what information is to be conveyed, and when to ask the prescriber to evaluate and consider modifying the medication regimen.
- If the therapeutic goals are not being met or the resident is experiencing adverse consequences, it is essential for the prescriber in collaboration with facility staff*, the* pharmacist*, and the resident* to consider whether current medications and doses continue to be appropriate or should be reduced, changed, or discontinued. *Serum concentration monitoring may be necessary for some medications. Abnormal or toxic serum concentrations must be evaluated for dosage adjustments. If serum concentrations are within normal ranges, each resident should still be evaluated for effectiveness and side effects.*
- Re-evaluating and updating monitoring approaches-- Modification of monitoring may be necessary when the resident experiences changes, such as:
  - Acute onset of signs or symptoms or worsening of chronic disease;
  - Addition or discontinuation of medications and/or non-pharmacological *approaches, for example, a resident who takes warfarin regularly starts on a medication that interacts with warfarin, therefore more frequent blood work may be needed;*
  - Addition or discontinuation of care and services such as enteral feedings; and
  - Significant changes in diet that may affect medication absorption or effectiveness or increase adverse consequences.

Additional examples of circumstances that may indicate a need to modify the monitoring include: changes in manufacturer's specifications, FDA warnings, pertinent clinical practice guidelines, or other literature about how and what to monitor.

Adverse consequences related to medications are common enough to warrant serious attention and close monitoring. *An HHS Office of the Inspector General (OIG) report released in February 2014 found approximately one in five SNF residents experienced at least one adverse even during their SNF stay. Thirty-seven percent of these events were related to medications and were often preventable, See the full report, Adverse Events in Skilled Nursing Facilities: National Incidence among Medicare Beneficiaries at http://oig.hhs.gov/oei/reports/oei-06-11-00370.pdf*.

Some adverse consequences may be avoided by:
- Following relevant clinical guidelines and manufacturer's specifications for use, dose, administration, duration, and monitoring of the medication;
- Defining appropriate indications for use; and
- Determining that the resident:
  - Has no known allergies to the medication;

- Is not taking other medications, nutritional supplements including herbal products, or foods that would be incompatible with the prescribed medication; and
- Has no condition, history, or sensitivities that would preclude use of that medication.

- *Responding to the resident's reported experience with medications and treatments they have received.*

The risk for adverse consequences increases with both the number of medications being taken regularly and with medications from specific pharmacological classes, such as anticoagulants, diuretics, *psychotropic medications,* anti-infectives, and anticonvulsants.[32] Adverse consequences can range from minimal harm to functional decline, hospitalization, permanent injury, and death. *Use of a tool, such as the CMS Adverse Drug Event Trigger Tool may assist in identifying resident risk factors and triggers for adverse drug events as well as determine whether a facility has systems and processes in place to minimize risk factors and mitigate harm to residents. The tool is available on the CMS Nursing Home Quality Assurance and Performance Improvement website, https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/QAPI/Downloads/Adverse-Drug-Event-Trigger-Tool.pdf*.

One common adverse consequence is delirium, which presents as an alteration in attention and awareness associated with a change in cognition not explained by a current or emerging neurocognitive disorder. Delirium may result from medications as well as other factors including electrolyte imbalances or infections. While delirium is not always preventable, identifying and addressing risk factors may reduce the occurrence. In many facilities, a majority of the residents have dementia. Individuals who have dementia may be more sensitive to medication effects and may be at greater risk for delirium.[33]

Delirium may go undiagnosed, be misinterpreted as dementia, or misdiagnosed as a psychiatric disorder, such as bipolar disorder. Delirium develops rapidly over a short period of time, such as hours or days, and usually follows a fluctuating course throughout the day. Additionally, the resident may have difficulty paying attention and be less aware of his or her surroundings. Delirium can be characterized as hyperactive (e.g., extreme restlessness, climbing out of bed), hypoactive (e.g., sluggish and lethargic), or mixed (e.g., normal level of activity with lowered awareness). Delirium is particularly common post-hospitalization; signs and symptoms may be subtle and therefore are often missed. Although generally thought to be short lived, delirium can persist for months. Recognizing delirium is critical, as failure to act quickly to identify and treat the underlying causes may result in poor health outcomes or death.

Negative psychosocial outcomes can also occur in relation to unnecessary medications, including psychotropic medications. These adverse consequences may include: suicidal ideation, recurrent debilitating anxiety, extreme aggression or agitation, significant decline in former social patterns, social withdrawal, psychomotor agitation or retardation, inability to think or concentrate, and apathy.

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32 *Handler, S.M., Wright, R.M., Ruby, C.M., Hanlon, J.T. (2006). Epidemiology of medication-related adverse events in nursing homes. The American Journal of Geriatric Pharmacotherapy, 4, pp. 264-272. Retrieved from http://www.sciencedirect.com/science/article/pii/S1543594606000559*.

33 *Fong, T.G., Davis, D., Growdon, M.E., Albuquerque, A., Inouye, S.K. (2015). The interface between delirium and dementia in elderly adults. The Lancet, 14, pp.823-832. Retrieved from http://thelancet.com/journals/laneur/article/PIIS1474-4422(15)00101-5/fulltext*.

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Psychotropic Medications and Antipsychotic Medications (F758 Only Guidance)

As clarified in the section on Indication for Use, residents must not receive any medications which are not clinically indicated to treat a specific condition. The medical record must show documentation of the diagnosed condition for which a medication is prescribed. This requirement is especially important when prescribing psychotropic medications which, as defined in this guidance, include, but are not limited to, the categories of anti-psychotic, anti-depressant, anti-anxiety, and hypnotic medications. All medications included in the psychotropic medication definition may affect brain activities associated with mental processes and behavior. Use of psychotropic medications, other than antipsychotics, should not increase when efforts to decrease antipsychotic medications are being implemented, unless the other types of psychotropic medications are clinically indicated. Other medications which may affect brain activity such as central nervous system agents, mood stabilizers, anticonvulsants, muscle relaxants, anti-cholinergic medications, antihistamines, NMDA receptor modulators, and over the counter natural or herbal products must also only be given with a documented clinical indication consistent with accepted clinical standards of practice. Residents who take these medications must be monitored for any adverse consequences, specifically increased confusion or over-sedation. The regulations and guidance concerning psychotropic medications are not intended to to supplant the judgment of a physician or prescribing practitioner in consultation with facility staff, the resident and his/her representatives and in accordance with appropriate standards of practice. Rather, the regulations and guidance are intended to ensure psychotropic medications are used only when the medication(s) is appropriate to treat a resident's specific, diagnosed, and documented condition and the medication(s) is beneficial to the resident, as demonstrated by monitoring and documentation of the resident's response to the medication(s).

Use of Psychotropic Medications in Specific Circumstances

Acute or Emergency Situations*: When a psychotropic medication is being initiated or used to treat an emergency situation (i.e., acute onset or exacerbation of symptoms or immediate threat to health or safety of resident or others) related to a documented condition or diagnosis, a clinician in conjunction with the IDT must evaluate and document the situation to identify and address any contributing and underlying causes of the acute condition and verify the need for a psychotropic medication. Use of psychotropic medication to treat an emergency situation must be consistent with the requirements regarding PRN orders for psychotropic and antipsychotic medications and any continued use must be consistent with the requirements for gradual dose reduction (GDR).*

Enduring Conditions*: Psychotropic medications may be used to treat an enduring (i.e., non-acute; chronic or prolonged) condition. Before initiating or increasing a psychotropic medication for enduring conditions, the resident's symptoms and therapeutic goals must be clearly and specifically identified and documented. Additionally, the facility must ensure that the resident's expressions or indications of distress are:*

- *Not due to a medical condition or problem (e.g., pain, fluid or electrolyte imbalance, infection, obstipation, medication side effect or poly-pharmacy) that can be expected to improve or resolve as the underlying condition is treated or the offending medication(s) are discontinued;*
- *Not due to environmental stressors alone (e.g., alteration in the resident's customary location or daily routine, unfamiliar care provider, hunger or thirst, excessive noise for*

that individual, inadequate or inappropriate staff response), that can be addressed to improve the symptoms or maintain safety;

- *Not due to psychological stressors alone (e.g., loneliness, taunting, abuse), anxiety or fear stemming from misunderstanding related to his or her cognitive impairment (e.g., the mistaken belief that this is not where he/she lives or inability to find his or her clothes or glasses, unaddressed sensory deficits) that can be expected to improve or resolve as the situation is addressed; and*
- *Persistent--The medical record must contain clear documentation that the resident's distress persists and his or her quality of life is negatively affected and, unless contraindicated, that multiple, non-pharmacological approaches have been attempted and evaluated in any attempts to discontinue the psychotropic medication.*

New Admissions: *Many residents are admitted to a SNF/NF already on a psychotropic medication. The medication may have been started in the hospital or the community, which can make it challenging for the IDT to identify the indication for use. However, the attending physician in collaboration with the consultant pharmacist must re-evaluate the use of the psychotropic medication and consider whether or not the medication can be reduced or discontinued upon admission or soon after admission. Additionally, the facility is responsible for:*

- *Preadmission screening for mental illness and intellectual disabilities, see §483.20(k), F645 and F646; and*
- *Obtaining physician's orders for the resident's immediate care, see§483.20(a), F635.*

Monitoring of Psychotropic Medications: *When monitoring a resident receiving psychotropic medications, the facility must evaluate the effectiveness of the medications as well as look for potential adverse consequences. After initiating or increasing the dose of a psychotropic medication, the behavioral symptoms must be reevaluated periodically (at least during quarterly care plan review, if not more often) to determine the potential for reducing or discontinuing the dose based on therapeutic goals and any adverse effects or functional impairment.*

If the record shows evidence of adding other psychotropic medications or switching from one type of psychotropic medication to another category of psychotropic medication, surveyors must review the medical record to determine whether the prescribing practitioner provided a rationale.

Potential Adverse Consequences: *The facility assures that residents are being adequately monitored for adverse consequences such as:*

- ***General****: anticholinergic effects which may include flushing, blurred vision, dry mouth, altered mental status, difficulty urinating, falls, excessive sedation, constipation*
- ***Cardiovascular:*** *signs and symptoms of cardiac arrhythmias such as irregular heart beat or pulse, palpitations,lightheadedness, shortness of breath, diaphoresis, chest or arm pain, increased blood pressure, orthostatic hypotension*
- ***Metabolic:*** *increase in total cholesterol and triglycerides, unstable or poorly controlled blood sugar, weight gain*

- ***Neurologic:*** *agitation, distress, EPS, neuroleptic malignant syndrome (NMS), parkinsonism, tardive dyskinesia, cerebrovascular event (e.g., stroke, transient ischemic attack (TIA).*

If the psychotropic medication is identified as possibly causing or contributing to adverse consequences as identified above, the facility and prescriber must determine whether the medication should be continued and document the rationale for the decision. Additionally, the medical record should show evidence that the resident, family member or representative is aware of and involved in the decision. In some cases, the benefits of treatment may outweigh the risks or burdens of treatment, so the medication may be continued.

Antipsychotic Medications

As with all medications, the indication for any prescribed first generation (also referred to as typical or conventional antipsychotic medication) or second generation (also referred to as atypical antipsychotic medication) antipsychotic medication must be thoroughly documented in the medical record. While antipsychotic medication may be prescribed for expressions or indications of distress, the IDT must first identify and address any medical, physical, psychological causes, and/or social/environmental triggers. Any prescribed antipsychotic medication must be administered at the lowest possible dosage for the shortest period of time and is subject to the GDR requirements for psychotropic medications.

Antipsychotic medications (both first and second generation) have serious side effects and can be especially dangerous for elderly residents. When antipsychotic medications are used without an adequate rationale, or for the sole purpose of limiting or controlling expressions or indications of distress without first identifying the cause, there is little chance that they will be effective, and they commonly cause complications such as movement disorders, falls with injury, cerebrovascular adverse events (cerebrovascular accidents (CVA, commonly referred to as stroke), and transient ischemic events) and increased risk of death. The FDA Boxed Warning which accompanies second generation anti-psychotics states, "Elderly patients with dementia-related psychosis treated with atypical anti-psychotic drugs are at an increased risk of death," https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm053171.htm. The FDA issued a similar Boxed Warning for first generation antipsychotic drugs, https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm124830.htm. .

Diagnoses alone do not necessarily warrant the use of an antipsychotic medication. Antipsychotic medications may be indicated if:

- *behavioral symptoms present a danger to the resident or others;*
- *expressions or indications of distress that are significant distress to the resident;*
- *If not clinically contraindicated, multiple non-pharmacological approaches have been attempted, but did not relieve the symptoms which are presenting a danger or significant distress; and/or* [34]

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34 *Steinberg, M., Lyketsos, C.G. (2012). Atypical antipsychotic use in patients with dementia: managing safety concerns. The American Journal of Psychology, 169, pp. 900-906. Retrieved from http://ajp.psychiatryonline.org/doi/full/10.1176/appi.ajp.2012.12030342.*

- *GDR was attempted, but clinical symptoms returned.*

If antipsychotic medications are prescribed, documentation must clearly show the indication for the antipsychotic medication, the multiple attempts to implement care-planned, non-pharmacological approaches, and ongoing evaluation of the effectiveness of these interventions.

Gradual Dose Reduction for Psychotropic Medications

The requirements underlying this guidance emphasize the importance of seeking an appropriate dose and duration for each medication and minimizing the risk of adverse consequences. The purpose of tapering a medication is to find an optimal dose or to determine whether continued use of the medication is benefiting the resident. Tapering may be indicated when the resident's clinical condition has improved or stabilized, the underlying causes of the original target symptoms have resolved, and/or non-pharmacological *approaches* have been effective in reducing the symptoms.

There are various opportunities during the care process to evaluate the effects of medications on a resident's *physical, mental, and psychosocial well-being,* and to consider whether the medications should be continued, reduced, discontinued, or otherwise modified. Examples of these opportunities include:

- During the monthly medication regimen review, the pharmacist evaluates resident-related information for dose, duration, continued need, and the emergence of adverse consequences for all medications;
- When evaluating the resident's progress, the *attending physician or prescribing* practitioner reviews the total plan of care, orders, the resident's response to medication(s), and determines whether to continue, modify, or stop a medication; and
- During the quarterly MDS review, the facility evaluates mood, function, behavior, and other domains that may be affected by medications.

The time frames and duration of attempts to taper any medication *must be consistent with accepted standards of practice and* depend on factors including the coexisting medication regimen, the underlying causes of symptoms, individual risk factors, and pharmacologic characteristics of the medications. Some medications (e.g., antidepressants, sedative/hypnotics, opioids) require more gradual tapering so as to minimize or prevent withdrawal symptoms or other adverse consequences. *Close monitoring while medications are tapered will enable facility staff to determine whether a resident is experiencing side effects, changes in behavior, or withdrawal symptoms that originally prompted prescribing of the drug. However, some residents with specific, enduring, progressive, or terminal conditions such chronic depression, Parkinson's disease psychosis, or recurrent seizures may need specific types of psychotropic medications or other medications which affect brain activity indefinitely.*

NOTE: *If the resident's condition has not responded to treatment or has declined despite treatment, it is important to evaluate both the medication and the dose to determine whether the medication should be discontinued or the dosing shou*ld be altered, whether or not the facility has implemented GDR as required, or tapering.

Effective November 28, 2017

The regulation addressing the use of *psychotropic* medications identifies the process of tapering as a GDR and requires a GDR, unless clinically contraindicated.

Within the first year in which a resident is admitted on a *psychotropic* medication or after the *prescribing practitioner* has initiated a *psychotropic* medication, the facility must attempt a GDR in two separate quarters (with at least one month between the attempts), unless clinically contraindicated. After the first year, a GDR must be attempted annually, unless clinically contraindicated.

For any individual who is receiving *a psychotropic* medication to treat *expressions or indications of distress* related to dementia, the GDR may be considered clinically contraindicated *for reasons that include, but that are not limited to*:

- The resident's target symptoms returned or worsened after the most recent attempt at a GDR within the facility; and
- The physician has documented the clinical rationale for why any additional attempted dose reduction at that time would be likely to impair the resident's function or increase distressed behavior.

For any individual who is receiving *a psychotropic* medication to treat a disorder other than *expressions or indications of distress* related to dementia (for example, schizophrenia, bipolar mania, depression with psychotic features, or another medical condition, other than dementia, which may cause psychosis), the GDR may be considered *clinically* contraindicated *for reasons that include, but that are not limited to*:

- The continued use is in accordance with relevant current standards of practice and the physician has documented the clinical rationale for why any attempted dose reduction would be likely to impair the resident's function or exacerbate an underlying medical or psychiatric disorder; or
- The resident's target symptoms returned or worsened after the most recent attempt at a GDR within the facility and the physician has documented the clinical rationale for why any additional attempted dose reduction at that time would be likely to impair the resident's function or exacerbate an underlying medical or psychiatric disorder.

PRN Orders for Psychotropic and Antipsychotic Medications

In certain situations, psychotropic medications may be prescribed on a PRN basis, such as while the dose is adjusted, to address acute or intermittent symptoms, or in an emergency. However, residents must not have PRN orders for psychotropic medications unless the medication is necessary to treat a diagnosed specific condition. The attending physician or prescribing practitioner must document the diagnosed specific condition and indication for the PRN medication in the medical record.

The table below explains additional limitations for PRN psychotropic (other than antipsychotic medications) and PRN antipsychotic medications.

Type of PRN order	***Time Limitation***	***Exception***	***Required Actions***
PRN orders for psychotropic	*14 days*	*Order may be extended beyond 14*	*Attending physician or prescribing*

Effective November 28, 2017

Type of PRN order	*Time Limitation*	*Exception*	*Required Actions*
medications, excluding antipsychotics		*days if the attending physician or prescribing practitioner believes it is appropriate to extend the order.*	*practitioner should document the rationale for the extended time period in the medical record and indicate a specific duration.*
PRN orders for antipsychotic medications only	*14 days*	*None*	*If the attending physician or prescribing practitioner wishes to write a new order for the PRN antipsychotic, the attending physician or prescribing practitioner must first evaluate the resident to determine if the new order for the PRN antipsychotic is appropriate.*

The required evaluation of a resident before writing a new PRN order for an antipsychotic entails the attending physician or prescribing practitioner directly examining the resident and assessing the resident's current condition and progress to determine if the PRN antipsychotic medication is still needed. As part of the evaluation, the attending physician or prescribing practitioner should, at a minimum, determine and document the following in the resident's medical record:

- *Is the antipsychotic medication still needed on a PRN basis?*
- *What is the benefit of the medication to the resident?*
- *Have the resident's expressions or indications of distress improved as a result of the PRN medication?*

NOTE: *Report of the resident's condition from facility staff to the attending physician or prescribing practitioner does not constitute an evaluation.*

KEY ELEMENTS OF NONCOMPLIANCE
If any of the elements the sections below involve psychotropic medications, investigate F758. For all other medications, investigate F757.

To cite deficient practice at F757and/or F758, the surveyor's investigation will generally show:
Inadequate Indications for Use

NOTE: *For concerns related to a medication that involves an inadequate indication for use* <u>*and*</u> *evidence shows the medication is also being used for the purpose of discipline or staff*

convenience rather than to treat the resident's medical symptoms, surveyors should evaluate whether evidence shows the medication is being used to sedate the resident or restrict the resident's movement or cognition and assess compliance with §483.10(e)(1) and §483.12(a)(2), F605, Right to Be Free From Chemical Restraints instead of citing both at F605 and F757 or F758 for the same evidence.

- Failure to document a clinical reason or a clinically pertinent rationale, for using medication(s) for a specific resident *or for continuing medication(s) that may be causing an adverse consequence; or*
- Prescribing or administering a medication despite an allergy to that medication, or without clarifying whether a true allergy existed*; or*
- *Failure to* consider relative risks and benefits or potentially lower risk medications *before initiating medication(s) that present clinically significant risks; or*
- *Failure to provide* a clinically pertinent explanation *for concomitant use of two or more medications in the same pharmacological class*; or
- *Failure to* consider other factors *that may be causing expressions or indications of distress before initiating a psychotropic medication, such as an underlying medical condition (e.g., urinary tract infection, dehydration, delirium), environmental (lighting, noise) or psychosocial stressors; or*
- *Administering a psychotropic medication(s), which the resident has not previously received, when it is not necessary to treat a specific condition that has been diagnosed and documented in the clinical record; or*
- *Failure to attempt non-pharmacological approaches, unless clinically contraindicated, in efforts to discontinue psychotropic medications.*

Inadequate Monitoring –

- Failure to monitor the responses to or effects of a medication, *or*
- Failure to respond when monitoring indicates a lack of progress toward the therapeutic goal (e.g., relief of pain or normalization of thyroid function) or the emergence of an adverse consequence; *or*
- Failure to monitor for changes in psychosocial *engagement* resulting from adverse consequences of medications, (e.g., resident no longer participates in activities because medication causes confusion or lethargy); *or*
- Failure to monitor a medication consistent with the current standard of practice or manufacturer's guidelines*; or*
- Failure to carry out the monitoring that was ordered or failure to monitor for potential adverse consequences*; or*
- *Failure to consider whether the onset or worsening of symptoms, or a change of condition, may be related to a medication; or*
- *Failure to monitor effectiveness of non-pharmacological approaches, unless clinically contraindicated, before prescribing and administering medications.*

NOTE: *Additional information as well as examples of non-pharmacological approaches may be found in other guidance for regulations at §483.40, Behavioral Health Services and §483.25, Quality of Care and Quality of Life.*

Effective November 28, 2017

Excessive Dose (including duplicate therapy) –

- Giving a total amount of any medication at one time or over a period of time that exceeds the amount recommended by the manufacturer's recommendations, clinical practice guidelines, evidence-based studies from medical/pharmacy journals, or standards of practice for a resident's age and condition, without a documented clinically pertinent rationale; *or*
- Failure to consider periodically the continued necessity of the dose or the possibility of tapering a medication*; or*
- Failure to provide and/or document a clinical rationale for using multiple medications from the same pharmacological class.
- *Failure to consider each resident's clinical condition as a factor in determining an appropriate dose, as adverse consequences may occur even when medication serum concentration levels are in the therapeutic range.*

Excessive Duration –

- Continuation beyond the manufacturer's recommended time frames, the stop date or duration indicated on the medication order, facility-established stop order policies, or clinical practice guidelines, evidence-based studies from medical/pharmacy journals, or current standards of practice, without documented clinical justification*; or*
- Continuation of a medication after the desired therapeutic goal has been achieved*,* without evaluating whether *there is a continued need for* the medication, for example, use of an antibiotic beyond the recommended clinical guidelines or the facility policy without adequate reassessment *and evaluation* of the resident.

Adverse Consequences

- Failure to act upon (i.e., discontinue a medication or reduce the dose or provide clinical justification for why the benefit outweighs the adverse consequences) *or* report the presence of adverse consequence(s); *or*
- Failure to *monitor for the presence of* adverse consequences related to the use of *medications (particularly high risk medications, such as warfarin, insulin, opioids, or medications requiring monitoring of blood work*); *or*
- *Failure to respond to the presence of adverse consequences related to the use of medications (particularly high risk medications, such as warfarin, insulin, or opioids).*

Psychotropic Medications

- Failure to *present to the attending physician or prescribing practitioner the need to* attempt GDR in the absence of identified and documented clinical contraindications*; or*
- *Use of psychotropic medication(s) without documentation of the need for the medication(s) to treat a specific diagnosed condition; or*
- *PRN psychotropic medication ordered for longer than 14 days, without a documented rationale for continued use; or*
- Failure to implement *person-centered, non-pharmacological approaches in the* attempt to reduce or discontinue *a psychotropic* medication*; or*
- *Administering a new PRN antipsychotic medication for which the resident had a previous PRN order (for 14 days) but the medical record does not show that the attending*

physician or prescribing practitioner evaluated the resident for the appropriateness of the new order for the medication.

PROCEDURES: **§483.*45*(*d*) Unnecessary drugs *and §§483.45(c)(3) and (e) Psychotropic Drugs***
Investigating Concerns Related to Medication Regimen Review, Unnecessary Medications, and Psychotropic Medications

Use the Unnecessary Medications, Psychotropic Medications, and Medication Regimen Review Critical Element (CE) Pathway along with the interpretive guidelines when determining if the facility meets the requirements for, and when investigating concerns related to, Medication Regimen Review, Unnecessary Medications, and Psychotropic Medications.

Review the medications (prescription, over-the-counter medications, and nutritional supplements such as herbal products) currently ordered and/or discontinued by the prescriber at least back to the most recent signed recapitulation of all medications. Obtain a copy of the current orders if necessary. Gather information regarding the resident's mental, physical, functional, and psychosocial status and the medication-related therapeutic goals identified in the care plan as the basis for further review.

Use the table below to guide observations, record review, and interviews with the resident or representative and relevant staff. *Symptoms and signs described in the table may also be related to a resident's condition or disease. The surveyor may seek clarification about the basis of specific signs and symptoms from the attending physician and/or pharmacist.*

SYMPTOMS, SIGNS, AND CONDITIONS THAT MAY BE ASSOCIATED WITH MEDICATIONS	REVIEW FOR HOW *THE IDT* MANAGED MEDICATIONS FOR THE RESIDENT
Determine if the resident has been transferred to acute care since the last survey and/or has recently (e.g., the previous 3 months) experienced a change in condition or currently has signs and symptoms, such as: • Anorexia and/or unplanned weight loss, or weight gain • Apathy • Behavioral changes, unusual patterns (including increased *expressions or indications of distress,* social isolation or withdrawal) • Bleeding or bruising, spontaneous or unexplained • Bowel dysfunction including diarrhea, constipation and impaction • Dehydration, fluid/electrolyte imbalance • Depression, mood disturbance	Review the record (including the care plan, comprehensive assessment, and other parts of the record as appropriate) to determine whether it reflects the following elements related to medication management for the resident: • Clinical indications for use of the medication • *Implementation* of *person-centered*, non-pharmacological *approaches to care* • Dose, including excessive dose and duplicate therapy • Duration, including excessive duration • Consideration of potential for tapering/GDR or rationale for clinical contraindication

Effective November 28, 2017

SYMPTOMS, SIGNS, AND CONDITIONS THAT MAY BE ASSOCIATED WITH MEDICATIONS	REVIEW FOR HOW *THE IDT* MANAGED MEDICATIONS FOR THE RESIDENT

• Dysphagia, swallowing difficulty
• Falls, dizziness, or evidence of impaired coordination
• Gastrointestinal bleeding
• Headaches, muscle pain, generalized or nonspecific aching or pain
• Lethargy
• Mental status changes, (e.g., new or worsening confusion, new cognitive decline, worsening of dementia (including delirium), inability to concentrate)
• Psychomotor agitation (e.g., restlessness, inability to sit still, pacing, hand-wringing, or pulling or rubbing of the skin, clothing, or other objects).
• Psychomotor retardation (e.g., slowed speech, thinking, and body movements)
• Rash, pruritus
• Respiratory difficulty or changes
• Sedation (excessive), insomnia, or sleep disturbance
• Seizure activity
• Urinary retention or incontinence
 	
If observations or record review indicate symptoms or changes in condition that may be related to medications, determine whether the facility considered medications as a potential cause of the change or symptom.
	• Monitoring for and reporting of:
	  o Response to medications and progress toward therapeutic goals *and resident's goals*
	  o Emergence of medication-related adverse consequences
	• Adverse consequences, if present and potentially medication-related, note if there was:
	  o Recognition, evaluation, reporting, and management by the *IDT*
	  o Physician action regarding potential medication-related adverse consequences
	• *The residents goals and preferences for medications and treatments*

Interview the resident, *his or her family, and representative(s) and the IDT, as needed to gather information about use of medications in the nursing home.*

NOTE: This review is not intended to direct medication therapy. However, surveyors are expected to review factors related to the implementation, use, monitoring, *and documentation* of medications.

The surveyor is not expected to prove that an adverse consequence was directly caused by a medication or combination of medications, but rather that there was a failure in the care process related to considering and acting upon such possibilities.

If during the course of this review, the surveyor needs to contact the attending physician regarding questions related to the medication regimen, it is recommended that the facility's staff have the opportunity to provide the necessary information about the resident and the concerns to the physician for his/her review prior to responding to the surveyor's inquiries.

POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION

Examples of some of the related requirements that may be considered when *concerns have* been identified include the following:

- 42 CFR 483.*10(g)(14), F580,* Notification of Changes
  - Review whether the facility contacted the attending physician regarding a significant change in the resident's condition in relation to a potential adverse consequence of a medication, or if the resident has not responded to medication therapy as anticipated and/or indicated.
- 42 CFR 483.10 (*c*), *F552, Planning and Implementing Care*
  - Determine whether the resident was advised of her/his medical condition and therapy and was informed about her/his treatment including medications and the right to refuse treatments.
- 42 CFR 483.24(c), F679, Activities
  - Review whether the facility provides activities that address a resident's needs and may permit discontinuation or reduction of psychotropic medications. Review also whether adverse consequences of medications interfere with a resident's ability to participate in activities.
- 42 CFR 483.24(*a*), *F676, Activities of Daily Living*
  - Review whether the facility had identified, evaluated, and responded to a new or rapidly progressive decline in function, development or worsening of movement disorders, increased fatigue and activity intolerance that affected the resident's ADL ability in relation to potential medication adverse consequences.
- 42 CFR 483.*40, F740, Behavioral Health Services*
  - Review whether the facility had identified, evaluated, and responded to a change in behavior and/or psychosocial changes, including depression or other mood disturbance, distress, restlessness, increasing confusion, or delirium in relation to potential medication adverse consequences.
- 42 CFR 483.*30(a), F710,* Physician Supervision
  - Review if the attending physician supervised the resident's medical treatment, including assessing the resident's condition and medications, identifying the clinical rationale, and monitoring for and addressing adverse consequences.
- 42 CFR 483.*30(b), F711,* Physician Visits *and 42 CFR 483.30(c), F712, Frequency of Physician Visits*
  - Review if the attending physician or designee reviewed the resident's total program of care and wrote, signed, and dated progress notes covering pertinent aspects of the medication regimen and related issues.
- 42 CFR 483.*70(h), F841,* Medical Director
  - Review whether the medical director, when requested by the facility, interacted with the attending physician regarding a failure to respond or an inadequate response to identified or reported potential medication irregularities and adverse consequences;

and whether the medical director collaborated with the facility to help develop, implement, and evaluate policies and procedures for the safe and effective use of medications in the care of residents.

DEFICIENCY CATEGORIZATION

See also the Psychosocial Outcome Severity Guide in Appendix P, Section E for additional information on evaluating the severity of psychosocial outcomes.

Examples of noncompliance that demonstrate severity at Level 4 include, but are not limited to:

- *Facility failure to take appropriate action (e.g., suspending administration of the anticoagulant) in response to an elevated INR for a resident who is receiving warfarin, resulting in either the potential or actual need to transfuse or hospitalize the resident.*
- Failure to respond appropriately to an INR level that is *above or* below the target range for treatment of atrial fibrillation, prevention of deep vein thrombosis (DVT) or pulmonary embolus, or other documented indication.
- Failure to recognize developing serotonin syndrome (e.g., confusion, motor restlessness, tremor) in a resident receiving a SSRI *antidepressant*, leading to the addition of medications with additive serotonin effect or medication to suppress the symptoms.
- Failure to recognize and respond to signs and symptoms of neuroleptic malignant syndrome (NMS).
- In the presence of *initial* gastrointestinal bleeding, *i.e. blood in stool,* the failure to recognize medication therapies (such as NSAIDs or COX-2 inhibitors, bisphosphonates) as potentially causing or contributing to the gastrointestinal bleed, resulting in the continued administration of the medication, until the resident required hospitalization for severe bleeding.
- Failure to recognize that symptoms of increased confusion and that newly developed inability to do activities of daily living are the result of *an increased dose* of *a psychotropic medication* given without adequate clinical indication.
- Failure to recognize that *use* of an antipsychotic *medication, originally* prescribed for *agitation*, has caused significant changes in the resident's *quality of life*. The resident no longer participates in activities *that they previously enjoyed*, has difficulty concentrating and carrying on conversations, and spends most of the day *isolated* in *his or her* room, sleeping in a recliner or in bed. *Use* of the antipsychotic *medication* without *an adequate clinical* indication, *GDR attempts, and non-pharmacological approaches* resulted in psychosocial harm.
- Failure to re-evaluate *the appropriateness of continuing* a *PRN* antipsychotic *medication*, originally prescribed for acute delirium, which resulted in significant side effects from the medication. *T*he resident, who had been ambulatory, stayed in bed most of the day, developed a stage III pressure ulcer, and new onset of orthostatic hypotension, putting the resident at risk for falls.

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Examples of Level 3, Actual harm (physical or psychosocial) that are not immediate jeopardy, include, but are not limited to:

- *The facility failed to evaluate a resident's new medication regimen as the source of a resident's recent nausea. The prescriber then added a medication to treat the nausea, which caused agitation and insomnia.*
- Failure to evaluate a resident for a *GDR* for *a psychotropic* medication originally prescribed to treat delirium. Delirium symptoms subsided but *the* resident *remained* drowsy and inactive.

Examples of Level 2, No actual harm with a potential for more than minimal harm that is not immediate jeopardy, may include but are not limited to:

- *Facility failure to identify and act upon minor symptoms of allergic response to medications, such as a rash with mild itching to the abdomen and no other symptoms, causing minimal discomfort.*
- *The* facility fail*ed* to monitor for response to *interventions* or for the emergence or presence of adverse consequences *for a* resident receiving a psychotropic medication. The resident has *not yet* experienced an adverse consequence or decline in function, *but there is no evidence that the facility periodically monitors for* social *withdrawal, loss of interest in activities that were previously enjoyed*, or over sedation.
- *Facility failure to monitor for response or for the emergence or presence of adverse consequences for a resident who has not yet experienced an adverse consequence or decline in function, such as by* monitoring hydration status and basic metabolic profile for a resident receiving diuretics or ACE inhibitors.

Severity Level 1: No Actual Harm with Potential for Minimal Harm

Severity Level 1 does not apply for this regulatory requirement because the failure of the facility to provide appropriate care and services to manage the resident's medication regimen to avoid unnecessary medications and minimize negative outcome places residents at risk for more than minimal harm.

RESOURCES AND TOOLS

The following resources and tools provide information on medications including box warnings, appropriate dosing, medication categories, drug interactions, and medication safety information. Some of these resources also assist in identifying the correct class of a medication (e.g., identifying whether a medication is an antipsychotic or *other category* of psychotropic medication). *Additionally, the list includes some of the recognized clinical resources available for understanding the overall treatment and management of medical problems, symptoms and medication consequences and precautions.*

- U.S. Department of Health and Human Services, National Institute of Mental Health Web site, which includes publications and clinical research information www.nimh.nih.gov
- MedlinePlus, https://www.nlm.nih.gov/medlineplus/druginformation.html
- National Library of Medicine Drug Information Portal, http://druginfo.nlm.nih.gov/drugportal/drug/categories *(medication class information)*.

Effective November 28, 2017

- The Food and Drug Administration (FDA) webpage, Medwatch: The FDA Safety Information and Adverse Event Reporting Program, http://www.fda.gov/Safety/MedWatch/default.htm
- The University of Maryland Medical Center Drug Interaction Tool, http://umm.edu/health/medical/drug-interaction-tool
- *American Medical Directors Association, www.amda.com*
- *American Society of Consultant Pharmacists, www.ASCP.com*

This list is not all-inclusive. CMS is not responsible for the content or accessibility of pages found at these sites. URL addresses were current as of the date of this publication.

F759
§483.*45*(*f*) Medication Errors.
The facility must ensure that *its*—

§483.*45*(*f*)(*1*) Medication error rates *are not* 5 percent or greater; and

F760
The facility must ensure that *its*—
§483.*45*(*f*)(2) Residents are free of any significant medication errors.

DEFINITIONS
"Medication Error" *means* the observed *or identified* preparation or administration of medications or biologicals which is not in accordance with:

1. The prescriber's order;
2. Manufacturer's specifications (not recommendations) regarding the preparation and administration of the medication or biological; *or*
3. Accepted professional standards and principles which apply to professionals providing services. Accepted professional standards and principles include the various practice regulations in each State, and current commonly accepted health standards established by national organizations, boards, and councils.

"**Significant medication error**" means one which causes the resident discomfort or jeopardizes his or her health and safety. Criteria for judging significant medication errors as well as examples are provided *below*. *Significance* may be subjective or relative depending on the individual situation *and duration*, e.g., constipation that is unrelieved *because an ordered* laxative *is omitted for one day,* result*ing* in a medication error*,* may *cause a resident* slight *dis*comfort or perhaps no *dis*comfort at all. *However, if this omission leads to* constipation *that* persists for greater than three days, the *medication error* may be *deemed* significant *since* constipation *that* cause*s an* obstruction or fecal impaction can *directly* jeopardize the resident's health and safety.

"**Medication error rate**" is determined by calculating the percentage of medication errors observed during a medication administration observation. The numerator in the ratio is the total number of errors that the survey team observes, both significant and non-significant. The denominator consists of the total number of observations or "opportunities for errors" and

includes all the doses the survey team observed being administered plus the doses ordered but not administered. The equation for calculating a medication error rate is as follows:

Medication Error Rate = Number of Errors Observed divided by the Opportunities for Errors (doses given plus doses ordered but not given) X 100.

The error rate must be 5% or greater in order to cite *F759*. Rounding up of a lower rate (e.g., 4.6%) to a 5% rate is not permitted. *A medication error rate of 5% or greater may indicate that systemic problems exist. The survey team should consider investigating additional potential noncompliance issues, such as F755– Pharmacy Services, related to the facility's medication distribution system.*

NOTE: Significant and non-significant medication errors observed at 5% or greater during the Medication Administration Observation task should be cited at *F759*. However, any **significant** medication error, *whether or not the error rate is 5% or greater*, should be cited at *F760*.

Significant and Non-significant Medication Errors
Determining Significance
The relative significance of medication errors is a matter of professional judgment. Follow three general guidelines in determining whether a medication error is significant or not:

- Resident Condition - The resident's condition is an important factor to take into consideration. For example, a *diuretic (*fluid pill*)* erroneously administered to a dehydrated resident may have serious consequences, but if administered to a resident with a normal fluid balance may not. If the resident's condition requires rigid control, *such as with strict intake and output measurement, daily weights, or monitoring of lab values*, a single missed or wrong dose can be highly significant*;*
- Drug Category - If the medication is from a category that usually requires the resident to be titrated to a specific blood level, a single medication error could alter that level and precipitate a reoccurrence of symptoms or toxicity. This is especially important with a medication that has a Narrow Therapeutic Index (NTI) (i.e., a medication in which the therapeutic dose is very close to the toxic dose). Examples of medications with NTI *include:* phenytoin (Dilantin), carbamazepine (Tegretol)*;* warfarin (Coumadin)*;* digoxin *(*Lanoxin)*;* theophylline (TheoDur)*;* lithium salts (Eskalith, Lithobid)*; and*
- Frequency of Error - If an error is occurring *repeatedly*, there *may be* more reason to classify the error as significant. For example, if a resident's medication was omitted several times, *it may be appropriate, depending on consideration of resident condition and medication categor, to classify that error as significant. (See Dose Reconciliation Technique to the Observation Technique below)*.

Significant medication errors are *cited at F760* in the following circumstances:

- *When the surveyor observes a significant medication error during a medication preparation and/or administration (regardless of whether the overall facility error rate is 5% or greater);*
- *When the surveyor identifies a significant medication error(s) during the course of a resident record review.*

Effective November 28, 2017

While observation is the preferred method for citing medication errors, the surveyor may identify medication errors based on evidence from other sources, such as documentation of a change in the resident's condition determined to be due to medication errors, reports from family members that medication was given incorrectly and investigation supports that a medication error occurred, or discrepancies in the MAR that lead to identification of a medication error. The surveyor must conduct any follow up investigation to obtain corroborating information regarding the error, such as interviews with the nurse, Director of Nursing, or the pharmacist, and review other relevant documents. Surveyors should evaluate whether past non-compliance exists using the survey protocol.

Medication errors identified through methods other than observation are not counted in the medication pass observation and not cited at F759, but, any significant medication errors would be cited at F760 if evidence supports the citation.

Examples of Significant and Non-Significant Medication Errors
Some of the error *examples* are identified as significant. This designation is based *on accepted clinical standards of practice* without regard to the status of the resident *because* these error *examples show* a high potential for creating problems for the typical long-term care facility resident. Those errors identified as non-significant have also been designated primarily on the basis of the nature of the medication. Resident status*, actual or potential resident response to the error,* and frequency of error could *cause such errors to be classified* as significant.

Examples of Medication Errors
In the following tables, S=Significant; NS=Not Significant.

Omissions (Medication ordered but not administered at least once):

Medication Order	Significance
Metoprolol Succinate 100mg daily	S
Furosemide 40mg twice daily	S
*Trazodone 25*mg *at bedtime*	NS
Ibuprofen 400mg *three times daily*	NS
Artificial tears 2 *drops* both eyes *three times daily*	NS
Fiber supplement one packet *twice daily*	NS
Multivitamin one daily	NS
Calcium Carbonate Chewable 1 tablet three times a day after meals	NS

Unauthorized Medication (Medications administered without a physician's order):

Medication Order	Significance
Warfarin 4mg *Amoxicillin 500 mg*	S *S*
Allopurinol 100mg *Ferrous Sulfate 325mg*	S NS

Effective November 28, 2017

Medication Order	Significance
Acetaminophen 325 mg	NS

Wrong Dose:

Medication Order	Administered	Significance
Digoxin 0.125mg everyday *Morphine Sulfate 20mg/ml 0.25 ml*	0.25mg *0.5ml*	S *S*
Calcium Carbonate 600 mg	*500mg*	NS

Wrong Route of Administration:

Medication Order	Administered	Significance
Neomycin and Polymyxin B Ear Drops 4 to 5 *drops to* left *ear four times a day*	Left Eye	S

Wrong Dosage Form:

Medication Order	Administered	Significance
Dilantin Kapseals 100 mg three Kapseals *by mouth at bedtime*	Prompt Phenytoin 100 mg three capsules *by mouth at bedtime*	S*
Docusate Sodium Liquid 100mg *twice daily*	Capsule	NS

* Parke Davis Kapseals have an extended rate of absorption. Prompt phenytoin capsules do not.

Wrong Medication:

Medication Order	Administered	Significance
Vibramycin	Vancomycin	S
Tums	Oscal	NS

Wrong Time:

Medication Order	Administered	Significance
Oxycodone 5mg 2 Tabs 20 min. before painful treatment	2 Tabs given after treatment	S
Losartan 50mg daily at 8 a.m.	At 9:30 am	NS

Medication Errors Due to Failure to Follow Manufacturers Specifications or Accepted Professional Standards

Failure to "Shake Well" *or Mix a Suspension*

The failure to "shake" a medication that is labeled "shake well" may lead to a diluted dose or overly concentrated dose depending on the product and the elapsed time since the last "shake." Some medications, for example phenytoin, *require* correct preparation *to achieve the desired therapeutic effect. Surveyors may also observe facility staff mixing suspensions that should not be shaken vigorously but instead "rolled."* Any *rolling* motion used is acceptable *as long as the suspension appears uniformly milky and the rolling action has not created bubbles which can affect measurement and administration of the correct dose.*

Effective November 28, 2017

Crushing* Medications *and Administering Medications via Feeding Tube

The crushing of tablets or capsules for which the manufacturer instructs to "do not crush" requires further investigation *by the surveyor.* Some exceptions to the "Do Not Crush" instruction include:

- If the prescriber orders a medication to be crushed which the manufacturer states should not be crushed, the prescriber or the pharmacist must explain, in the clinical record, why crushing the medication will not adversely affect the resident. Additionally, the pharmacist should inform the facility staff to observe for pertinent adverse effects.
- If the facility can provide literature from the medication manufacturer or from a *peer-*reviewed health journal to justify why modification of the dosage form will not compromise resident care.

*The standard of practice is that **c**rushed medications should not be combined and given all at once, either orally (e.g., in pudding or other similar food) or via feeding tube. Crushing and combining medications may result in physical and chemical incompatibilities leading to an altered therapeutic response, or cause feeding tube occlusions when the medications are administered via feeding tube. Additionally, a resident may not want or may be unable to finish eating the food into which combined crushed medications were added or the resident's feeding tube could malfunction, all of which could prevent complete administration of the crushed medications. In these situations, staff would not know which medications the resident actually received because they were crushed and combined but not fully administered.*

If the surveyor observes medications being crushed and combined, then the number of errors would be equal to the number of medications crushed whether the medications are to be administered orally or via feeding tube. For example, if four medications were crushed and added altogether to applesauce or combined to be administered all at once via feeding tube, then four errors have occurred before the medications have been administered.

Flushing between each medication is also standard of practice and the lack of flushing between each medication is equivalent to combining medications, regardless of whether the medication is in crushed or liquid form, as it may result in physical and chemical incompatibilities leading to an altered therapeutic response, or cause feeding tube occlusions. If the surveyor observes that the nurse did not flush a feeding tube between each crushed or liquid medication, then the number of errors would be equal to the number of medications administered without the lack of appropriate flushing.

A facility is not required to flush the tubing between each medication if there is a physician's order that specifies a different flush schedule because of a fluid restriction. For a resident who requires fluid regulation, the physician's order should include the amount of water to be used for the flushing *between crushed medications* and administration of medications.

Before giving medications via feeding tube, the placement of the feeding tube should be confirmed in accordance with the facility's policy based on current standards of practice. Concerns related to placement and function of the feeding tube should be evaluated under the requirements at §483.25(g)(4)-(5), F693, Enteral Nutrition.

Lastly, the administration of enteral nutrition formula and administration of phenytoin (Dilantin) must be separated to minimize interaction, *according to drug and enteral formula manufacturer recommendations. The* surveyor should consider *the* simultaneous administration *of phenytoin and enteral nutrition formula as* a medication error.

NOTE: *Additional information related to administering medications via feeding tube may be found in ASPEN Safe Practices for Enteral Nutrition Therapy at https://www.ismp.org/tools/articles/ASPEN.pdf (2009) and http://pen.sagepub.com/content/early/2016/11/09/0148607116673053.full.pdf (2016). References to non-CMS sources do not constitute or imply endorsement of these organizations or their programs by CMS or the U.S. Department of Health and Human Services and were current as of the date of this publication.*

Giving Adequate Fluids with Medications

Administering medications without adequate fluid when the manufacturer specifies that adequate fluids be taken with the medication requires further investigation. *Taking medications with inadequate fluid may interfere with the medication working properly. Most medications can be taken with water, but there are exceptions, as further explained below.* If the resident *declines* to take adequate fluid, the facility *is not* at fault so long as they made a good faith effort to offer fluid, and provided any assistance that may be necessary to drink the fluid. *Additionally, the surveyor should look for evidence that the IDT considered other medication options or routes of administration for residents who decline to take adequate fluids or who are fluid restricted.* For example, the surveyor *would* count fluids consumed during meals or snacks (such as coffee, juice, milk, soft drinks, etc.) as fluids taken with the medication, as long as they have consumed within a reasonable time of taking the medication (e.g., within approximately 30 minutes).

Medications that are recommended to be given with adequate fluid include, but are not limited to:

- Bulk laxatives (e.g., Metamucil, Fiberall, Serutan, Konsyl, Citrucel);
- *Alendronate—should be taken with 6-8 ounces of plain water only.*
- Potassium supplements (solid or liquid dosage forms) such as: Kaochlor, Klorvess, Kaon, K-Lor, K-Tab, K-Dur, K-Lyte, Slow K, Klotrix, Micro K, or Ten K should be administered with or after meals with a full glass (e.g., approximately 4 - 8 ounces of water or fruit juice). This will minimize the possibility of gastrointestinal irritation and saline cathartic effect.

Medications that must be taken with food or antacids

The administration of medications without food or antacids when the manufacturer specifies that food or antacids be taken with or before the medication is considered a medication error. The most commonly used medications that should be taken with food or antacids are the Nonsteroidal Anti-Inflammatory Drugs (NSAIDs). There is evidence that *older individuals living with multiple diagnoses* are at greater risk of gastritis and GI bleeds. Determine if the time of administration *takes* into account the need to give the medication with food.

Effective November 28, 2017

Nutritional and Dietary Supplements
Nutritional supplements are medical foods that are used to complement a resident's dietary needs. Examples of these are total parenteral products, enteral products, and meal replacement products (e.g., Ensure, Glucerna and Promote.)

Herbal and alternative products are considered to be dietary supplements. They are not regulated by the Food and Drug Administration (e.g., they are not reviewed for safety and effectiveness like medications) and their composition is not standardized (e.g., the composition varies among manufacturers). If a dietary supplement is given to a resident between meals and has a vitamin(s) as one or more of its ingredients, it should be documented and evaluated as a dietary supplement, rather than a medication. For clinical purposes, it is important to document a resident's intake of such substances elsewhere in the clinical record and to monitor their potential effects, as they can interact with other medications.

NOTE: Because nutritional and dietary supplements are not considered to be medications for purposes of the medication administration observation, noncompliance with the administration of these products should not be included in the calculation of the facility's medication error rate. *The exception to this would be vitamins and minerals which are generally considered a category of dietary supplements.* Medication errors involving vitamins and/or minerals should be documented at *F759* and counted towards the error rate calculation. Medication errors involving vitamins and minerals would not be considered to be a significant medication error unless the criteria at *F760* were met.

It is expected that the facility staff, along with the prescriber and consulting pharmacist, are aware of, review for, and document any potential adverse consequences between medications, nutritional supplements, and dietary supplements that a resident is receiving.

Medications *Administered* into the Eye
Facility staff must follow the manufacturer's product information for administration instructions. Facility staff must verify the eye(s) into which eye medication will be administered. When observing the administration of eye drops, confirm that the medication makes full contact with the *lower* conjunctival sac, so that the medication is washed over the eye when the resident closes eyelid*; the eye drop(s) should not fall onto the cornea and the tip of the eye drop bottle should not touch any portion of the eye.* The eye drop must contact the eye for a sufficient period of time before the next eye drop is *administered*. The time for optimal eye drop absorption is approximately 3 to 5 minutes. *Systemic effects of eye medications may be reduced if the nurse or resident presses* the tear duct for one minute after eye drop administration or gently closes the eye for approximately three minutes after the administration. *For additional information related to administration of eye drops, see http://www.aaaai.org/Aaaai/media/MediaLibrary/PDF%20Documents/Libraries/NEW-WEBSITE-LOGOeyedropinstruction_orig_HI.pdf and http://journals.lww.com/nursing/Citation/2007/05000/Administering_eyedrops.14.aspx*

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Sublingual Medications
If the resident persists in swallowing a sublingual tablet (e.g., nitroglycerin) despite efforts to train otherwise, the facility should endeavor to seek an alternative.

Metered Dose Inhalers (MDI)
Ensuring that a device is administered correctly is vital to optimizing inhalation therapy. The surveyor would observe the administration of MDIs for the following:

- Shake the container well;
- Position the inhaler in front of or in the resident's mouth. Alternatively a spacer or valved holding chamber may be used;
- For cognitively impaired residents, many clinicians believe that the closed mouth technique is easier for the resident and more likely to be successful. However, the open mouth technique often results in better and deeper penetration of the medication*(s)* into the lungs, when this method can be used.
- If more than one puff is required (whether the same medication or a different medication), follow the manufacturer's product information for administration instructions including the acceptable wait time between inhalations.

NOTE: If the person administering the medication follows all the procedures outlined above, and there is *an isolated* failure to administer the medication because the resident is *unable to understand the procedure (for example, a resident with dementia*), this should not be counted as a medication error. The surveyor *would* evaluate the facility's responsibility to assess the resident's circumstance, and possibly attempt other dosage forms such as oral dosage forms or nebulizers. *If the facility staff repeatedly fail to administer the inhaler due to circumstances related to the resident's condition, then the surveyor would cite a medication error. The surveyor should look for evidence of staff communication with the prescriber and/or the consultant pharmacist to address inability to administer a resident's medication(s) as prescribed. The surveyor should also investigate appropriate tags related to the circumstances which prevent the administration of an inhaler or other medication(s), such as care of residents with dementia.*

For concerns related to care of residents with dementia, the surveyor should also consider the requirements at §483.40 Behavioral Health Services.

Determining Medication Errors
Timing Errors
If a medication is *prescribed* before meals (AC) and administered after meals (PC), always count this as a medication error. Likewise, if a medication is *prescribed* PC and is given AC, count as a medication error. Count a wrong time error if the medication is administered 60 *or more* minutes earlier or later than its scheduled time of administration, but **only** if that wrong time error can cause the resident discomfort or jeopardize the resident's health and safety. Counting a medication with a long half-life (e.g., digoxin) as a wrong time error when it is 15 minutes late is improper because this medication has a long half-life (beyond 24 hours) and 15 minutes has no significant impact on the resident. The same is true for many other wrong time errors (except AC AND PC errors).

To determine the scheduled time, examine the facility's policy relative to dosing schedules. The facility's policy should dictate when it administers a.m. doses, or when it administers the first dose in a 4-times-a-day dosing schedule.

Residents have the right to choose health care schedules consistent with their interests and preferences, and the nursing home should gather this information in order to be proactive in assisting residents to fulfill their choices. The adjustment of medication administration times, to meet the individual needs and preferences of residents, must be considered by the nursing home. However, medication administration scheduling must still consider physician prescription, manufacturer's guidelines, and the types of medication, including time-critical medications. Some medications require administration within a narrow window of time to ensure resident safety or achieve a therapeutic effect while other medications are not affected by a more flexible schedule. Additionally, a facility may, for example, set up a medication ordered twice a day (BID) on a different schedule for one resident than for another resident, based upon individual preferences.

Prescriber's Orders

The latest recapitulation of medication orders is sufficient for determining whether a valid order exists provided the prescriber has signed the "recap." The signed "recap," if the facility uses the "recap" system and subsequent orders constitute a legal authorization to administer the medication.

Omitted Dose

One of the most frequent types of errors is a dose of medication that is ordered but not given *(omitted)*. If a surveyor detects an omitted dose, *investigate the omission further through interviews with the responsible person(s) (and/or his/her supervisor) and all relevant individuals if a medication cart is shared.* Ask the person administering medications, if possible, to describe the system for administering the medications given. Occasionally, a respiratory therapist may administer inhalers, a designated treatment person may only administer topical treatments, a hospice nurse may administer hospice medications, another person may administer eye drops or as needed medications, etc.

***INVESTIGATIVE* PROCEDURES**

Use the Medication Administration Observation Facility Task, as appropriate, along with the interpretive guidelines, when determining if the facility meets the requirements for, or investigating concerns related to, Medication Administration and Medication Errors.

Medication Administration Observation Methodology

The survey team should observe the administration of medications on several different medication "passes" *to capture different staff members who administer medications as well as multiple routes and times of administration. However, when observing medication pass for one resident at a specific time, plan to observe all of the medications prescribed to be given at that time for that resident. Following this process will help to identify if omissions have occurred.* Record what is observed; and reconcile the record of observation with the prescriber's medication orders to determine whether or not medication errors have occurred.

Effective November 28, 2017

Paper review may help identify possible errors, however detection of blank spaces on a medication administration record does not *alone* constitute the *occurrence* of actual medication errors. *The surveyor(s) conducting medication observation will need to follow-up on any observed concerns through additional record review and interviews*.

Observation Technique

The survey team must know what medications, in what strength, dosage forms, *and administration route* are being administered. This is accomplished prior to medication administration and may be done in a number of ways depending on the medication distribution system used (e.g. unit dose, vial system, punch card).

Medication Preparation *and* Administration Observation

1. Identify the medication by observing the label. When *a* punch card or unit dose system is used, the survey team can usually observe the label and adequately identify the medication. *For multi-medication packet systems, staff identify medications by dose and descriptions provided by the pharmacy. Ask* the nurse *how* medication*(s)* being *administered is identified so the resident receives the correct medication(s).*
2. Observe and record the administration of medications ("pass"). *Findings at this juncture should be focused on what the surveyor observes, not what the medication administration record states.* Follow the person administering medications and observe residents receiving medications (e.g., actually swallowing oral dosage forms). Be neutral and as unobtrusive as possible during this process.
   - The surveyor should ask appropriate staff to explain the facility policy or system for the identification of residents.
   - Multiple tablets or capsules required to deliver a dose of *a single* medication count as one observation *and one opportunity for error*;
   - Observe infection prevention practices by staff administering medications, including the procedures used for insulin pens and single dose vial use, *in addition to the disinfection of blood glucose monitors (BGMs)*. If the staff *administering medications* fail to *use* appropriate infection *prevention and* control standards of practice, it should also be evaluated under *§483.80, Infection Prevention and Control Program*.
3. Reconcile the surveyor's record of observation with *physician or prescribing practitioner* orders.
   - Compare the record of observation with the most current orders for medications.
   - *For each medication on the surveyor's record of observation, determine if the medication was administered:*
     - *According to a valid prescriber's order(s);*
     - *To the correct resident;*
     - *At the correct time;*
     - *In the correct dose;*
     - *By the correct route; and*
     - *According to correct accepted standards of practice and manufacturer's specifications.*
   - For medications not on the surveyor's list: Examine the record for medication orders that were not administered and should have been. Such circumstances may represent omitted doses, one of the most frequent types of errors.

- The surveyor should now have a complete record of what was observed and what should have occurred according to the prescribers' orders. Determine the number of errors by adding the errors on each resident. Before concluding for certain that an error has occurred, discuss the apparent error*, if possible,* with the person who administered the medications, *as there* may be a logical explanation for an apparent error. For example, the surveyor observed that a resident had received Lasix 20 mg, but the order was for 40 mg. This was an apparent error in dosage. But the nurse showed the surveyor another more recent order which discontinued the 40 mg order and replaced it with a 20 mg order.

4. Reporting Errors -- *At the exit conference, the survey team* describe*s* to facility *staff* each error that *they* detect*ed.* The survey team is not required to analyze the errors and come to any conclusions on how the facility can correct them. Do not attempt to categorize errors into various classifications (e.g., wrong dose, wrong resident). Stress that an error occurred and that future errors must be avoided.

Intervening During Medication Administration -- *There may be times when the surveyor should intervene before the person administering the medication makes a suspected medication error. This would occur in the event the surveyor becomes aware of the concern before reconciling the medication administration observations with the physician's orders.*

Examples of this may include, but are not limited to, situations where the surveyor understands that the resident is about to receive:

- *An unusually large dose of medication;*
- *A medication via the wrong route, such as ear drops in the eyes; or*
- *An inaccurate amount of medication (difference in what was seen prepared versus what the staff member stated they were preparing, such as amount of insulin).*

When the surveyor encounters such a situation, he or she should bring it to the attention of the person about to administer the medication. The timing of this would take place at the point in which that person has committed to administering the medication, such as upon entering the resident's room or approaching the resident. The surveyor should question the person away from the resident, such as at the medication cart or in the medication room, in a way that is respectful of the person administering medication and will not bring unnecessary alarm to the resident. The intent is to confirm whether a medication error (significant or non-significant) was or was not about to occur.

If a surveyor intervened, prior to medication reconciliation, to prevent a medication error from occurring, each potential medication error would be counted toward the facility's medication error rate. If the error is discovered later by the surveyor during the medication reconciliation, the observation would still be counted toward the facility's medication error rate. The facility is responsible for ensuring that medication error rates are not 5 percent or greater and that residents are free of any significant medication errors.

Dose Reconciliation Technique Supplement to the Observation Technique -- When an omission error has been detected through the observation technique, the dose reconciliation technique can sometimes enable the survey team to learn how frequently an error has occurred in the past. Learning about the frequency of an error can assist in judging the significance of the

error. (See Significant and Non-Significant Medication Errors above.) The dose reconciliation technique requires a comparison of the number of doses remaining in a supply of medications with the number of days the medication has been in use and the directions for use. For example, if a medication *was* in use for 5 days with direction to administer the medication 4 times a day, then 20 doses should have been used. If a count of the supply of that medication shows that only 18 doses were used (i.e., two extra doses exist) and no explanation for the discrepancy exists (e.g., resident *declined* the dose, or resident was hospitalized), then two omission errors may have occurred. *The surveyor should investigate further through interviews and record review to determine if actual medication errors occurred.*

Use the dose reconciliation technique *when* the number of medications received, and the date and the specific "pass" when that particular medication was started *are captured in the resident's medical record*. Unless this information is available, do not use this technique. If this information is not available, there is no Federal authority under which the survey team may require it, except for controlled drugs.

F761
§483.*45*(*g*) Labeling of Drugs and Biologicals
Drugs and biologicals used in the facility must be labeled in accordance with currently accepted professional principles, and include the appropriate accessory and cautionary instructions, and the expiration date when applicable.

§483.*45*(*h*) Storage of Drugs and Biologicals

§483.4*5*(*h*)(1) In accordance with State and Federal laws, the facility must store all drugs and biologicals in locked compartments under proper temperature controls, and permit only authorized personnel to have access to the keys.

§483.*45*(*h*)(2) The facility must provide separately locked, permanently affixed compartments for storage of controlled drugs listed in Schedule II of the Comprehensive Drug Abuse Prevention and Control Act of 1976 and other drugs subject to abuse, except when the facility uses single unit package drug distribution systems in which the quantity stored is minimal and a missing dose can be readily detected.

INTENT §*483.45(g) Labeling of Drugs and Biologicals and §483.45(h) Storage of Drugs and Biologicals*
The intent of this requirement is that the facility, in coordination with the licensed pharmacist, provides for:

- Accurate labeling to facilitate consideration of precautions and safe administration, of medications; and
- Safe and secure storage (including proper temperature controls, *appropriate humidity and light controls,* limited access, and mechanisms to minimize loss or diversion) of all medication.

NOTE: For purposes of this guidance, references to "the pharmacist" mean the licensed pharmacist, whether employed directly by the facility or through arrangement.

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DEFINITIONS §483.*45*(*g*) *Labeling of Drugs and Biologicals and §483.45(h) Storage of Drugs and Biologicals*

"Biologicals" *are made from a variety of natural sources—human, animal, or microorganisms. Biologics are used to treat, prevent, or diagnose diseases and medical conditions. They may include a wide range of products such as vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins.*

"Controlled Medications" *are substances that have an accepted medical use (medications which fall under US Drug Enforcement Agency (DEA) Schedules II—V), have a potential for abuse, ranging from low to high, and may also lead to physical or psychological dependence.*

GUIDANCE §483.*45*(*g*) *Labeling of Drugs and Biologicals and §483.45(h) Storage of Drugs and Biologicals*

LABELING OF MEDICATIONS AND BIOLOGICALS

This section requires facility compliance with currently accepted labeling requirements, even though the pharmacies are responsible for the actual labeling. Labeling of medications and biologicals dispensed by the pharmacy must be consistent with applicable federal and State requirements and currently accepted pharmaceutical principles and practices. Although medication delivery and labeling systems may vary, the medication label at a minimum includes the medication name (generic and/or brand), *prescribed dose,* strength, the expiration date when applicable, the resident's name, and route of administration. The medication should also be labelled with *or accompanied by* appropriate instructions and precautions (such as shake well, *take* with meals, do not crush, special storage instructions).

For medications designed for multiple administrations (e.g., inhalers, eye drops), the label *identifies the specific* resident for whom it was prescribed.

When medications are prepared or compounded for intravenous infusion, the label contains the name and volume of the solution, resident's name, infusion rate, name and quantity of each additive, date of preparation, initials of compounder, date and time of administration, initials of person administering medication if different than compounder, ancillary precautions as applicable, and date after which the mixture must not be used. *The FDA and the Institute for Safe Medication Practices provide labelling guidance and recommendations aimed at preventing errors, https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM349009.pdf and https://www.ismp.org/tools/guidelines/labelFormats/comments/default.asp.*

For over-the-counter (OTC) medications in bulk containers (e.g., in states that permit bulk OTC medications to be stocked in the facility), the label contains the original manufacturer's or pharmacy-applied label indicating the medication name, strength, quantity, accessory instructions, lot number, and expiration date when applicable. The facility ensures that

medication labeling in response to order changes is accurate and consistent with applicable state requirements.

Additionally, to minimize contamination, facility staff should date the label of any multi-use vial when the vial is first accessed and access the vial in a dedicated medication preparation area:

- *If a multi-dose vial has been opened or accessed (e.g., needle-punctured), the vial should be dated and discarded within 28 days unless the manufacturer specifies a different (shorter or longer) date for that opened vial.*
- *If a multi-dose vial has not been opened or accessed (e.g., needle-punctured), it should be discarded according to the manufacturer's expiration date.*

The Centers for Disease Control and Prevention website provides additional information regarding multi-use vials,
http://www.cdc.gov/injectionsafety/providers/provider_faqs_multivials.html.

MEDICATION ACCESS AND STORAGE

A facility is required to secure all medications in a locked storage area and to limit access to authorized personnel (for example, pharmacy technicians or assistants who have been delegated access to medications by the facility's pharmacist as a function of their jobs) consistent with state or federal requirements and professional standards of practice.
Storage areas may include, but are not limited to, drawers, cabinets, medication rooms, refrigerators, *and* carts. Depending on how the facility locks and stores medications, access to a medication room may not necessarily provide access to the medications (for example, medications stored in a locked cart, locked cabinets, a locked refrigerator, or locked drawers within the medication room). When medications are not stored in separately locked compartments within a storage area, only appropriately authorized staff may have access to the storage area.

Access to medications can be controlled by keys, security codes or cards, or other technology such as fingerprints. Schedule *II-V* medications must be maintained in separately locked, permanently affixed compartments. The access system (e.g. key, security codes) used to lock Schedule II-*V* medications and other medications subject to abuse, cannot be the same access system used to obtain the non-scheduled medications. The facility must have a system to limit who has security access and when access is used.

Exception: Controlled medications and those *medications* subject to abuse may be stored with non-controlled medications as part of a single unit package medication distribution system, if the supply of the medication(s) is minimal and a shortage is readily detectable.
During a medication pass, medications must be under the direct observation of the person administering the medications or locked in the medication storage area/cart. In addition, the facility should have procedures for the control and safe storage of medications for those residents who can self-administer medications. *(See F554, 483.10(c)(7) for guidance related to the right to self-administer medications).*

Safe medication storage includes the provision of appropriate environmental controls. Because many medications can be altered by exposure to improper temperature, light, or humidity, it is

important that the facility implement procedures that address and monitor the safe storage and handling of medications in accordance with manufacturers' specifications, State requirements and standards of practice (e.g., United States Pharmacopeia (USP) standards).

PROCEDURES

Use the Medication Administration Observation Facility Task and the Medication Storage and Labeling Critical Element pathway, as appropriate, along with the above interpretive guidelines when determining if the facility meets the requirements for, or investigating concerns related to, Medication Labeling and Storage.

KEY ELEMENTS OF NONCOMPLIANCE §*483.*45*(*g*) Labeling of Drugs and Biologicals and §483.45(h) Storage of Drugs and Biologicals

To cite deficient practice at F761, the surveyor's investigation will generally show that the facility failed to:

- *Ensure that all drugs and biologicals used in the facility are labeled in accordance with professional standards,* including expiration dates and with appropriate accessory and cautionary instructions; or
- *Store all drugs and biologicals in locked compartments, including the storage of* schedule II-*V* medications in separately locked, permanently affixed compartments, *permitting only authorized personnel to have access* except when the facility uses single unit medication distribution systems in which the quantity stored is minimal and a missing dose can be readily detected, *or*
- Store medications at proper temperatures *and other appropriate environmental controls* to preserve their integrity.

DEFICIENCY CATEGORIZATION

In addition to actual or potential physical harm, always consider whether psychosocial harm has occurred when determining severity level (See Appendix P, Section IV, E, Psychosocial Outcome Severity Guide).

Examples of noncompliance that demonstrate severity at Level 4 include, but are not limited to:

- The facility failed to *assure that medications were secure and inaccessible to unauthorized staff and residents. As a result, a resident accessed and ingested medications that caused clinically significant adverse consequences necessitating hospitalization to stabilize the resident*; or
- As a result of an incorrect label on the package, staff administered the wrong medication or wrong dose(s) of a medication (e.g., anticonvulsant, antihyperglycemic, benzodiazepine) with a potential for clinically significant adverse consequences, which resulted in, or had the potential for, serious harm or death (e.g., toxic levels of the medication, unresponsiveness, uncontrolled seizures).

An example of Level 3, Actual harm (physical or psychosocial) that is not immediate jeopardy, includes, but is not limited to:

- Medication labeling was incomplete and lacked instructions that the medication was not to be given with specific foods (e.g., milk or milk-based products) resulting in altered

effectiveness of the medication and worsening of the residents' symptoms, requiring medical intervention.

Examples of Level 2, No actual harm with a potential for more than minimal harm that is not immediate jeopardy, may include but are not limited to:

- The facility's medication cart was not kept locked or under direct observation of authorized staff *in an area where residents could access it. No medications were taken by residents but the potential for more than minimal harm exists*; or
- As a result of inaccurate labeling, the resident received the wrong medication or dose or the correct medication by the wrong route and experienced discomfort but did not require any interventions.

Severity Level 1 Considerations: No Actual Harm with Potential for Minimal Harm

- *Severity Level 1 does not apply for this regulatory requirement because the failure of the facility to accurately label and safely secure storage of all medications places residents at risk for more than minimal harm.*

§483.50 Laboratory, radiology, and other diagnostic services
(Rev.)

This regulation is intended to ensure that laboratory, radiology, and other diagnostic services meet the needs of residents, that results are reported promptly to the ordering provider to address potential concerns and for disease prevention, provide for resident assessment, diagnosis, and treatment, and that the facility has established policies and procedures, and is responsible for the quality and timeliness of services whether services are provided by the facility or an outside resource.

There are clinical and physiological risks when laboratory, radiology, or other diagnostic services are not performed in a timely manner or the results of these services are not reported and acted upon quickly. These delays may adversely affect a resident's diagnosis, treatment, assessment, and interventions. If a resident has been adversely affected, refer as appropriate, to Quality of Care, Quality of Life, Abuse, or Neglect. Also refer to Physician Services and Nursing Services if test results were not acted upon timely as per the facility's policies or the prescribing practitioner orders.

There is no Tag for this section; refer to other Tags for concerns related to noncompliance.

F770
§483.50(a) **Laboratory Services.**
§483.50(a)**(1) The facility must provide or obtain laboratory services to meet the needs of its residents. The facility is responsible for the quality and timeliness of the services.**

(i) If the facility provides its own laboratory services, the services must meet the applicable requirements for laboratories specified in part 493 of this chapter.

Effective November 28, 2017

DEFINITIONS §483.50(a)(1)(i)

"Laboratory service " *as referenced in §493.2,* is any examination of materials derived from the human body for purposes of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of human beings.

GUIDANCE §483.50(a)(1)(i)

If a facility provides its own laboratory services *or performs any laboratory tests directly (e.g., blood glucose monitoring, etc.)* the provisions of 42 CFR Part 493 apply and the facility must have a *current Clinical Laboratory Improvement Amendment (CLIA)* certificate appropriate for the level of testing performed within the facility.

Facilities collecting and/or preparing specimens and not performing testing are not considered to be providing laboratory services and do not need to meet the requirements of 42 CFR Part 493.

Surveyors should only verify that the facility has a current CLIA certificate and not attempt to determine compliance with the requirements in 42 CFR part 493; rather, refer questions or concerns to CLIA surveyors.

POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION

If noncompliance with §483.50(a)(1)(i) has been identified, the surveyor may have identified concerns with related structure, process, and/or outcome requirements. If an additional concern has been identified, the surveyor must investigate the identified concern. Do not cite any related or associated requirements before first conducting an investigation to determine compliance or non-compliance with the related or associated requirement. Examples include, but are not limited to, the following:

- *§483.30 - Physician Services*
- *§483.35 - Nursing Services*
- *§483.70(g) - Use of Outside Resources*
- *§483.70(h) - Medical Director*
- *§483.75 - Quality Assessment and Performance Improvement*

KEY ELEMENTS OF NONCOMPLIANCE

To cite deficient practice at F770, the surveyor's investigation will generally show that the facility failed to do any one or more of the following:

- *Have a current CLIA certificate appropriate for the level of testing it performs;* ***OR***
- *Meet the needs of residents with regard to the quality and/or timeliness of providing laboratory services and reporting laboratory results:* ***OR***
- *Provide or obtain laboratory services, to meet the needs of its residents.*

F771

§483.50(a)**(1) The facility must provide or obtain laboratory services to meet the needs of its residents. The facility is responsible for the quality and timeliness of the services.**

(ii) If the facility provides blood bank and transfusion services, it must meet the applicable requirements for laboratories specified in part 493 of this chapter.

Effective November 28, 2017

GUIDANCE §483.50(a)(1)(ii)

Transfusion services includes the process of transferring blood or blood components received from one person to another. Blood components include red blood cells, plasma, platelets, clotting factors, immunoglobulins, and white blood cells. Facilities must use processes for transfusion, including positive confirmation of the correct blood or blood components into the intended recipient.

Only authorized personnel in accordance with State law, including scope of practice laws, shall verify the correct identification of transfusion recipients and administer blood or blood components. Personnel performing blood and/or blood component transfusions shall have the competencies and training to perform these services and identify and manage adverse events appropriately.

For concerns related to staff competencies or training refer to:

- *Nursing Services §483.35(a)(3);*
- *Administration §483.70(f);*
- *Training §483.95.*

Recipients of transfusion services must be closely monitored during and after the transfusion for signs of adverse reactions and all transfusion-related activities must be documented in the resident's medical record. Examples of adverse events/reactions either during or after transfusion include, but may not be limited to:

- *Increase in temperature or pulse rate*
- *Conjunctival edema*
- *Edema of lips, tongue and uvula*
- *Erythema and edema of the periorbital area*
- *Generalized flushing*
- *Hypotension*
- *Localized angioedema*
- *Maculopapular rash*
- *Pruritus (itching)*
- *Respiratory distress; bronchospasm*
- *Urticaria (hives)*

The above examples are based on information from the American Association of Blood Banks (AABB) https://www.aabb.org .

PROCEDURES

If a nursing home provides blood transfusions (cross-matched at an outside laboratory), it must hold an appropriate CLIA certificate and must meet all of the requirements of §493.1103 for transfusion services and document all transfusion-related activities as required under §493.1103(d). The facility must have procedures for preventing transfusion reactions and promptly identify, investigate, and report blood and blood product transfusion reactions to the laboratory that provided the blood or blood products and as appropriate, to Federal and State authorities.

Effective November 28, 2017

If facility staff failed to properly identify the resident receiving the blood/blood products or failed to monitor the status of the resident during and/or after a transfusion, it should be cited under Quality of Care at F684.

Nursing home surveyors should not evaluate compliance with the requirements in 42 CFR part 493. Questions or concerns must be referred to State Agency or Regional Office CLIA surveyors to determine whether or not the nursing home provided transfusion services in accordance with the requirements for specified in part 493. If it is verified by State Agency or Regional Office CLIA surveyors that requirements in part 493 were not met cite a deficiency under this Tag F771.

The facility must have procedures for preventing transfusion reactions and promptly identify, investigate, and report blood and blood product transfusion reactions to the laboratory that provided the blood or blood products and as appropriate, to Federal and State authorities.

If the facility provides transfusion services, determine whether they have policies, procedures, and protocols for:

(a) Transfusion processes that include adverse reaction identification and corrective actions to be taken;
(b) Investigating all transfusion reactions; and
(c) Reporting all transfusion reactions to the appropriate officials and agencies.

Review the facility's procedures to ensure their process includes the positive identification of the blood or blood components to be transfused into the intended recipient.

If a facility has not established policies as referenced above ***do not*** *cite here but cite under §483.70(d) Governing body, F837. Also consider requirements at §483.70(h) Medical director, F841 for the responsibility to implement resident care policies.*

If a transfusion will be performed during the survey, observe the transfusion preparation process. Observe to determine whether or not a positive recipient verification and a second independent recipient verification were conducted prior to the initiation of the transfusion. If a surveyor has reason to suspect a resident is having an adverse reaction to a transfusion or the transfusion itself is not being properly administered, the surveyor shall immediately notify the facility Director of Nursing and the facility administrator.

Assure that blood and blood components are stored in a clean and orderly environment which ensures the integrity of the component. Whole blood, red blood cells, and thawed plasma shall be stored in accordance with §493.1103(c). If there are questions or concerns, consult with CLIA surveyors. If blood and blood components are not stored to ensure the integrity of these components do not cite here, cite under §483.45(h) - Storage of drugs and biologicals.

KEY ELEMENTS OF NONCOMPLIANCE
To cite deficient practice at F 771, the surveyor's investigation will generally show that the facility failed to:

Effective November 28, 2017

- *Provide transfusion services in accordance with the requirements for laboratories specified in part 493 to meet the needs of the residents.*

Stand Alone Tag – No Number
§483.50(a)(1)

(iii) If the laboratory chooses to refer specimens for testing to another laboratory, the referral laboratory must be certified in the appropriate specialties and subspecialties of services in accordance with the requirements of part 493 of this chapter.

There is no Tag for §483.50(a)(1)(iii). Nursing home surveyors should not attempt to determine compliance with the requirements in 42 CFR part 493 but should refer questions or concerns to the State Agency or CMS Regional Office for appropriate follow-up by CLIA surveyors.

F772
***§483.50(a)*(1) The facility must provide or obtain laboratory services to meet the needs of its residents. The facility is responsible for the quality and timeliness of the services.**

(iv) If the facility does not provide laboratory services on site, it must have an agreement to obtain these services from a laboratory that meets the applicable requirements of part 493 of this chapter.

GUIDANCE §483.50(a)(1)(iv)
If the facility does not provide laboratory services on site, it must have a written agreement to provide services from a laboratory which meets the requirements of 42 CFR part 493.

Nursing home surveyors should not attempt to determine compliance with the requirements in 42 CFR part 493 but should refer questions or concerns to the State Agency or CMS Regional Office for appropriate follow-up by CLIA surveyors. If verified by CLIA surveyors that requirements in part 493 were not met cite a deficiency under this Tag, F772.

F773
***§483.50(a)*(2) The facility must—**

(i) Provide or obtain laboratory services only when ordered *by a* physician*; physician assistant; nurse practitioner or clinical nurse specialist in accordance with State law, including scope of practice laws.*

(ii) Promptly notify the *ordering* physician*, physician assistant, nurse practitioner, or clinical nurse specialist of laboratory results that fall outside of clinical reference ranges in accordance with facility policies and procedures for notification of a practitioner or per the ordering physician's orders.*

GUIDANCE §483.50(a)(2)(i)(ii)
For purposes of this requirement "promptly" means that results shall be relayed with little or no delay to the ordering physician, physician assistant, nurse practitioner, or clinical nurse specialist according to facility policies and procedures for notification and the medical orders.

Facility policies and procedures should be developed in consultation with the medical director and follow current standards of practice. Such policies may include defining categories that are considered outside clinical reference ranges for laboratory values, the urgency of reporting values, and a process for monitoring the effectiveness of communication to ensure that communication was received, and delegation by the ordering provider to a qualified on-call individual as appropriate.

PROCEDURES

When reviewing the resident's medical record, surveyors would determine that laboratory services were provided only when ordered by a physician, physician assistant, nurse practitioner or clinical nurse specialist in accordance with State law, including scope of practice laws, and facility staff and the ordering provider(s) were promptly notified of the results.

If test results were not acted upon in a timely manner by the physician, physician assistant, nurse practitioner, clinical nurse specialist, or by facility staff as ordered, consider additional review for possible deficient practices under Medical Director, Nursing Services, Quality of Care or Quality of Life requirements. Do not cite any related or associated requirements before first conducting an investigation to determine compliance or non-compliance with the related or associated requirement.

KEY ELEMENTS OF NONCOMPLIANCE

To cite deficient practice at F773, the surveyor's investigation will generally show that the facility failed to do any one or more of the following:

- *Obtain or provide laboratory services without an order by a physician, physician assistant. nurse practitioner or clinical nurse specialist in accordance with State law, including scope of practice laws;* ***OR***
- *Promptly notify the ordering physician, physician assistant, nurse practitioner, or clinical nurse specialist of laboratory results according to facility policies and procedures for notification and the medical orders.*

F774

§483.50**(a)(2) The facility must—**

(iii) Assist the resident in making transportation arrangements to and from the source of service, if the resident needs assistance.

PROCEDURES

During record reviews and interviews with residents, family members or resident representatives, determine if residents were offered and assisted in making transportation arrangements. In order to assist a resident, the facility should consider the resident's clinical, physical, mental, and financial condition. For example, assisting a resident who has limited funds to be transported by a taxi when other, more inexpensive options are available would not really be assisting the resident. However, this standard is not requiring a facility to defray or cover the costs of transportation.

If appointments were cancelled due to difficulties with transportation including the costs of transportation, determine if this was due to the facility's procedures.

If there are concerns regarding charges to the resident for any of these services, refer to §§483.10(f)(10) and (11), Resident Rights Self-determination or §§483.10(g)(17) and (18), Information and Communication.

KEY ELEMENTS OF NONCOMPLIANCE
To cite deficient practice at F774, the surveyor's investigation will generally show that the facility failed to do any one or more of the following:

- *If required or requested, residents were not assisted in making transportation arrangements to and from the source of service;* ***OR***
- *If any delay in making these arrangements adversely affected resident care or treatment. If so, also refer to Quality of Care or Quality of Life requirements.*

F775
***§483.50*(a)(2) The facility must—**

(iv) File in the resident's clinical record laboratory reports that are dated and contain the name and address of the testing laboratory.

PROCEDURES
Review the resident's clinical record to determine laboratory reports are included and that the reports are dated and contain the name and address of the testing laboratory. If there are other medical record documentation concerns, refer to §483.70(i) - Medical Records.

KEY ELEMENTS OF NONCOMPLIANCE
To cite deficient practice at F775, the surveyor's investigation will generally show that the facility failed to do any one or more of the following:

- *Have laboratory reports filed in the resident's clinical record;* ***OR***
- *Laboratory reports were not dated;* ***OR***
- *Laboratory reports did not contain the name and address of the testing laboratory.*

F776
***§483.50(b)* Radiology and other diagnostic services.**
***§483.50(b)*(1) The facility must provide or obtain radiology and other diagnostic services to meet the needs of its residents. The facility is responsible for the quality and timeliness of the services.**

(i) If the facility provides its own diagnostic services, the services must meet the applicable conditions of participation for hospitals contained in §482.26 of this subchapter.

(ii) If the facility does not provide its own diagnostic services, it must have an agreement to obtain these services from a provider or supplier that is approved to provide these services under Medicare.

GUIDANCE §483.50(b)(1)(i)(ii)
If the facility provides its own radiologic or other diagnostic services, the services must meet the applicable requirements for radiologic services contained at §482.26 – Conditions of Participation for Hospitals- Radiologic Services. If there are questions or concerns refer to State

Agency or CMS Regional Office for appropriate discussion and follow-up with surveyors trained in assessing compliance with §482.26 (i.e., hospital surveyors).

If the facility does not provide its own radiologic or diagnostic services, it must have a written agreement to obtain these services from a provider or supplier that is approved to provide these services under Medicare. For concerns regarding this agreement, refer to §483.70(g) - Use of Outside Resources.

KEY ELEMENTS OF NONCOMPLIANCE

To cite deficient practice at F776, the surveyor's investigation will generally show that the facility failed to do any one or more of the following:

- *Provide or obtain radiology or other diagnostic services to meet the needs of its residents:* ***OR***
- *Meet the needs of residents with regard to the quality and/or timeliness of providing radiology or other diagnostic services:* ***OR***
- *Have a written agreement to obtain these services from a provider or supplier that is approved to provide these services under Medicare:* ***OR***
- *If the facility provides its own radiologic or other diagnostic services, the services do not meet the applicable requirements at §482.26.*

F777

§483.50(b)**(2) The facility must—**

(i) Provide or obtain radiology and other diagnostic services only when ordered by *a* physician*; physician assistant; nurse practitioner or clinical nurse specialist in accordance with State law, including scope of practice laws.*

(ii) Promptly notify the *ordering* physician*, physician assistant, nurse practitioner, or clinical nurse specialist of results that fall outside of clinical reference ranges in accordance with facility policies and procedures for notification of a practitioner or per the ordering physician's orders.*

GUIDANCE §483.50(b)(2)(i)(ii)

For purposes of this requirement "promptly" means that results shall be relayed, with little or no delay to the ordering physician, physician assistant, nurse practitioner, or clinical nurse specialist according to facility policies and procedures for notification and the medical orders.

Facility policies and procedures should be developed in consultation with the medical director and follow current standards of practice. Such policies may include defining categories where follow-up is required, the urgency of reporting specific concerns, and a process for monitoring the effectiveness of communication to ensure that communication was received, and delegation by the ordering provider to a qualified on-call individual as appropriate.

PROCEDURES

When reviewing the resident's medical record, surveyors would determine that radiology and other diagnostic services were provided only when ordered by a physician, physician assistant, nurse practitioner or clinical nurse specialist in accordance with State law, including scope of

practice laws, and facility staff and the ordering provider(s) were promptly notified of the results.

If results were not acted upon in a timely manner by the physician; physician assistant; nurse practitioner; clinical nurse specialist; or by facility staff as ordered, consider additional review for possible deficient practices under Medical Director, Nursing Services, Quality of Care or Quality of Life requirements. Do not cite any related or associated requirements before first conducting an investigation to determine compliance or non-compliance with the related or associated requirement.

KEY ELEMENTS OF NON-COMPLIANCE
To cite deficient practice at F777, the surveyor's investigation will generally show that the facility failed to do any one or more of the following:

- *Provide or obtain radiology or other diagnostic services within the timeframe(s) specified in the medical order(s), or obtained or provided these services without an order by a physician; physician assistant; nurse practitioner or clinical nurse specialist in accordance with State and scope of practice laws;* ***OR***
- *Promptly notify the ordering physician, physician assistant, nurse practitioner, or clinical nurse specialist of results according to facility policies and procedures for notification and the medical orders.*

F778
§483.50(b)**(2)(iii) Assist the resident in making transportation arrangements to and from the source of service, if the resident needs assistance.**

PROCEDURES
During record reviews and interviews with residents, family members or resident representatives, determine if residents were offered and assisted in making transportation arrangements. In order to "assist" a resident, the facility should consider the resident's clinical, physical, mental, and financial condition. For example, assisting a resident who has limited funds to be transported by a taxi or a private car service when other, more inexpensive options are available would not really be "assisting" the resident. However, this standard is not requiring a facility to defray or cover the costs of transportation either.

If any appointments were canceled due to difficulties with transportation including the costs of transportation, determine if this was a result of facility procedures.

If there are concerns regarding charges to the resident for any of these services, refer to §§483.10(f)(10) and (11) - Resident Rights - Self-determination or §§483.10(g(17) and (18) – Information and Communication.

KEY ELEMENTS OF NONCOMPLIANCE
To cite deficient practice at F778, the surveyor's investigation will generally show that the facility failed to do any one or more of the following:

- *If required or requested, assist residents in making transportation arrangements to and from the source of service;* ***OR***

- *If any delay by the facility in making these arrangements adversely affected resident care or treatment. If so, also refer to Quality of Care or Quality of Life requirements.*

F779
***§483.50*(b)(2)(iv) File in the resident's clinical record signed and dated reports of radiologic and other diagnostic services.**

PROCEDURES
Review resident clinical records to determine if reports of radiologic and other diagnostic services reports are filed and that they are signed and dated. If there are other medical record documentation concerns, refer to §483.70(i) - Medical Records.

KEY ELEMENTS OF NONCOMPLIANCE
To cite deficient practice at F779, the surveyor's investigation will generally show that the facility failed to do any one or more of the following:

- *Have reports filed in the resident's clinical record;* ***OR***
- *Reports were not dated or signed.*

F790
§483.55 Dental services.
The facility must assist residents in obtaining routine and 24-hour emergency dental care.

§483.55(a) Skilled Nursing Facilities
A facility—

§483.55(a)(1) Must provide or obtain from an outside resource, in accordance with with §483.*70(g)* of this part, routine and emergency dental services to meet the needs of each resident;

§483.55(a)(2) May charge a Medicare resident an additional amount for routine and emergency dental services;

§483.55(a)(3) Must have a policy identifying those circumstances when the loss or damage of dentures is the facility's responsibility and may not charge a resident for the loss or damage of dentures determined in accordance with facility policy to be the facility's responsibility;

***§483.55(a)(4)* Must if necessary *or if requested,* assist the resident;**
(i) In making appointments; and
(ii)* By arranging for transportation to and from *the dental services location; and

§483.55(a)(5) Must promptly, within 3 days, refer residents with lost or damaged dentures for dental services. If a referral does not occur within 3 days, the facility must provide documentation of what they did to ensure the resident could still eat and drink adequately while awaiting dental services and the extenuating circumstances that led to the delay.

Effective November 28, 2017

F791
§483.55 Dental Services
The facility must assist residents in obtaining routine and 24-hour emergency dental care.

§483.55(b) Nursing Facilities.
The facility—

§483.55(b)(1) Must provide or obtain from an outside resource, in accordance with §483.*70(g)* of this part, the following dental services to meet the needs of each resident:
(i) Routine dental services (to the extent covered under the State plan); and
(ii) Emergency dental services;

***§483.55(b)(2)* Must, if necessary *or if requested,* assist the resident—**
(i) In making appointments; and
(ii)* By arranging for transportation to and from *the dental services locations;

§483.55(b)(3)* Must promptly, *within 3 days,* refer residents with lost or damaged dentures *for dental services. If a referral does not occur within 3 days, the facility must provide documentation of what they did to ensure the resident could still eat and drink adequately while awaiting dental services and the extenuating circumstances that led to the delay;

§483.55(b)(4) Must have a policy identifying those circumstances when the loss or damage of dentures is the facility's responsibility and may not charge a resident for the loss or damage of dentures determined in accordance with facility policy to be the facility's responsibility; and

§483.55(b)(5) Must assist residents who are eligible and wish to participate to apply for reimbursement of dental services as an incurred medical expense under the State plan.

INTENT of §§483.55(a)[F790] & (b) [F791]
To ensure that resident*s* obtain needed dental services, including routine dental services; *to ensure the* facility *provides the assistance needed or requested to obtain these services; to ensure the resident is not inappropriately charged for these services; and if a referral does not occur within three business days, documentation of the facility's to ensure the resident could still eat and drink adequately while awaiting dental services and the extenuating circumstances that led to the delay.*

DEFINITIONS for §483.55(a)[F790] & (b) [F791]
"Emergency dental services" includes services needed to treat an episode of acute pain in teeth, gums, or palate; broken, or otherwise damaged teeth, or any other problem of the oral cavity that required immediate attention by a dentist.

"Promptly" means within 3 business days or less from the time the loss or damage to dentures is identified unless the facility can provide documentation of extenuating circumstances that resulted in the delay.

Effective November 28, 2017

"Routine dental services" means an annual inspection of the oral cavity for signs of disease, diagnosis of dental disease, dental radiographs as needed, dental cleaning, fillings (new and repairs), minor *partial or full denture* adjustments, smoothing of broken teeth, and limited prosthodontic procedures, e.g., taking impressions for dentures and fitting dentures.

GUIDANCE for §483.55(a)[F790] & (b) [F791]

A dentist *must be* available for each resident. The dentist can be directly employed by the facility or the facility can have a written contractual agreement with a dentist. The facility may also choose to have a written agreement for dentist services from a dental clinic, dental school or a dental hygienist all of whom are working within Federal and State laws and under the direct supervision of a dentist.

For Medicare and private pay residents, facilities are responsible for having the services available, but may *bill* an additional charge for the services.

For Medicaid residents, the facility must provide all emergency dental services and those routine dental services to the extent covered under the Medicaid state plan. The facility must inform the resident of the deduction for the incurred medical expense available under the Medicaid state plan and must assist the resident in applying for the deduction.

If any resident *is* unable to pay for dental services, the facility should attempt to find alternative funding sources or delivery systems so that the resident *may receive the services needed to meet their dental needs and* maintain his/her highest practicable level of well-being. *This can include finding other providers of dental services, such as a dental school or the provision of dental hygiene services on site at a facility.*

The facility must assist residents in making arrangements for transportation to their dental appointments when necessary or requested. The facility should attempt to minimize the financial burden on the resident by finding the lowest cost or no cost transportation option to dental health care appointments.

The facility must have a policy identifying those instances when the loss or damage of partial or full dentures is the facility's responsibility, such as when facility staff discards dentures placed on a meal tray. A blanket policy of facility non-responsibility for the loss or damage of dentures or a policy stating the facility is only responsible when the dentures are in actual physical possession of facility staff would not meet the requirement. In addition, the facility is prohibited from requesting or requiring residents or potential residents to waive any potential facility liability for losses of personal property. See §483.15(a)(2)(iii), F620, Admissions Policy.

Prompt referral means *no later than three (3) business days from the time* the *partial or full* dentures are lost or damaged. Referral does not mean that the resident must see the dentist at that time. *It* does mean that an earliest possible appointment (referral) is made, or that the facility is aggressively working *to have the dentures repaired or replaced if the dentist was contacted timely and determined the dentures could be repaired or replaced without a dental visit.*

If there is a delay in making the referral, the facility must document the circumstances that led to the delay. The facility must also be able to provide documentation demonstrating what they did

to ensure the resident could still adequately eat and drink while waiting for the issue with their dentures to be addressed.

If concerns are identified regarding providing ADL assistance for oral hygiene (such as assistance with brushing, flossing, denture cleaning), do not cite here. See guidance under §483.24(a), F677, Activities of Daily Living.

Summary of Procedures for §§483.55(a)[F790] & (b) [F791]

The process to review concerns are outlined in the Dental Care Area Pathway.

Record Review
Review the resident's records for identification of the resident's dental needs and the resident's responsiveness to dental services. The information found in the resident's assessment and care plans should be used to guide resident observations, and to determine whether the facility has met or is meeting related regulatory requirements including, but not limited to, person-centered care planning, resident assessment, and dental services. Finally, determine the resident's payer status (Medicare, Medicaid or private pay) for service eligibility determinations.

Observation
Observe the resident to determine if his or her dental status is consistent with the comprehensive assessment or if the resident exhibited signs of dental health concerns that may not have been identified.

Resident/Resident Representative Interview
Interview the resident and/or resident representative to determine if any concerns identified since the last survey were promptly addressed to the resident's or the resident representative's satisfaction. This includes determining if the facility provided the assistance to obtain dental services needed or requested by the resident or resident representative and whether the facility assisted the resident with arranging transportation to the dental appointment. If the identified concern is related to missing or damaged dentures, interview the resident and family/resident representative to determine if a referral was promptly (within three business days) made, if an explanation was provided if a referral was not promptly made, and if the facility took measures to ensure the resident was able to continue to eat or drink adequately while awaiting dental services.

KEY ELEMENTS OF NONCOMPLIANCE
To cite deficient practice, the surveyor's investigation will generally show that the facility any of the following:

For residents receiving Medicare and private pay residents, F790:

- *Failed to provide or obtain from an outside resource, in accordance with §483.70(g), routine and emergency dental services to meet the needs of each resident;* ***or***
- *Did not assist the resident as necessary or requested to make appointments for dental services and/or arrange for transportation to and from the dental service location;* ***or***
- *Did not promptly, within three business days, refer a resident with lost or damaged partial or full dentures and/or documented the extenuating circumstances that led to a delay;* ***or***

- *Did not document what the facility did to ensure a resident with missing or damaged dentures could still eat and drink adequately while awaiting dental services;* ***or***
- *Charged a resident for the loss or damage of partial or full dentures determined to by facility policy to be the facility's responsibility.*

For residents receiving Medicaid, F791:

- *Failed to provide or obtain from an outside resource, in accordance with §483.70(g), routine (to the extent covered by the State plan) and emergency dental services for each resident;* ***or***
- *Did not assist the resident as necessary or requested to make appointments for dental services or arrange for transportation to and from dental services locations;* ***or***
- *Did not promptly, within three days, refer a resident with lost or damaged partial or full dentures and/or documented the extenuating circumstances that led to a delay;* ***or***
- *Did not document what the facility did to ensure a resident with missing or damaged partial or full dentures could still eat and drink adequately while awaiting dental services;* ***or***
- *Charged a resident for the loss or damage of partial or full dentures determined to by facility policy to be the facility's responsibility;* ***or***
- *Failed to assist a resident(s) who are eligible to participate and/or wish to participate to apply for reimbursement of dental services as an incurred medical expense under the State plan;* ***or***
- *Charged a Medicaid resident an added fee for routine dental services covered by the State plan or for emergency dental services.*

ADDITIONAL TAGS FOR CONSIDERATION MAY INCLUDE, BUT ARE NOT LIMITED TO:

§483.10(g)(14), F580, Notification of Change

- *Determine whether staff notified all necessary care providers and resident representatives of change in dental/oral condition when required.*

§483.20(b)(i), (iii), F636, Comprehensive Assessment

- *Determine if the facility comprehensively assessed the resident's risk and/or underlying causes (to the extent possible) of the resident's dental/oral condition and the impact upon the resident's function, mood and cognition.*

§483.20(g), F641, Accuracy of Assessments

- *Determine whether the assessment accurately reflected the dental condition of the resident at the time of the assessment.*

§483.21(b)(1), F656, Comprehensive Care Plan

- *Determine if the facility developed a care plan based on the comprehensive assessment to address the resident's dental/oral condition.*

§483.25(g)(1)-(3), F692, Assisted Nutrition and Hydration

- *Determine if the staff ensured the resident maintained or did not experience an avoidable decline in nutritional status related to the resident's oral/dental condition.*

§483.25(k), F697, Pain Management

- *Determine whether staff have assessed, care-planned, and provided services to manage a resident's oral/dental pain.*

§483.35(a), F725, Sufficient and Competent Nursing Staff

- *Determine whether based on the resident's needs the facility had qualified staff in sufficient numbers and with the required competencies to identify dental concerns and provide necessary routine resident dental care.*

§483.40(d), F745, Social Services

- *Determine whether the facility provided medically-related social services by addressing any unmet needs related to dental/denture or oral care.*

§483.45(d), F757, Unnecessary Medications

- *Determine if the resident is experiencing an adverse dental/oral consequence of a medication which indicated the dose should have been reduced or discontinued, or any combination of the reasons stated in §§483.45(d)(1)-(5).*

§483.70(f)(5), F842, Medical Records

- *Determine whether the resident's records accurately and completely document the resident's dental/oral status and the care and services provided in accordance with current professional standards and practices.*

§483.70(g), F840, Use of Outside Resources

- *Determine whether dental services provided met professional standards and principles and the timeliness of those services.*

§483.70(h), F841, Medical Director

- *Determine if the medical director was involved in the development of dental/oral health policies/procedures and the coordination of care both on-site as well as availability of off-site providers and addressed any quality concerns.*

F800
§483.60 ***Food and nutrition services.***
The facility must provide each resident with a nourishing, palatable, well-balanced diet that meets *his or her* daily nutritional and special dietary needs*, taking into consideration the preferences of each resident.*

INTENT §483.*60 -* To ensure that facility staff support the nutritional well-being of the residents while respecting an individual's right to make choices about his or her diet.

GUIDANCE §483.*60*
This requirement *expects that there is ongoing* communication and coordination *among and* between *staff within all* departments to ensure that the resident assessment, care plan and actual food *and nutrition* service*s* meet *each resident's* daily nutritional and dietary needs *and choices.*

While it may be challenging to meet every residents' individual preferences, incorporating a residents' preferences and *dietary* needs will ensure residents are offered meaningful choices in *meals/*diets that are nutritionally adequate and satisfying to the individual. *Reasonable efforts to accommodate these choices and preferences must be addressed by facility staff.*

Also, cite this Tag if there *are overall* system*s* issue*s* relating to *how the facility manages and executes its* food *and nutrition* services.

Effective November 28, 2017

F801
§483.*60*(a) Staffing
The facility must employ ***sufficient staff with the appropriate competencies and skills sets to carry out the functions of the food and nutrition service, taking into consideration resident assessments, individual plans of care and the number, acuity and diagnoses of the facility's resident population in accordance with the facility assessment required at §483.70(e)***

This includes:
§483.*60*(a)(1) A qualified dietitian ***or other clinically qualified nutrition professional*** **either full-time, part-time, or on a consultant basis. A qualified dietitian** ***or other clinically qualified nutrition professional*** **is one who—**

- ***(i) Holds a bachelor's or higher degree granted by a regionally accredited college or university in the United States (or an equivalent foreign degree) with completion of the academic requirements of a program in nutrition or dietetics accredited by an appropriate national accreditation organization recognized for this purpose.***
- ***(ii) Has completed at least 900 hours of supervised dietetics practice under the supervision of a registered dietitian or nutrition professional.***
- ***(iii) Is licensed or certified as a dietitian or nutrition professional by the State in which the services are performed. In a State that does not provide for licensure or certification, the individual will be deemed to have met this requirement if he or she is recognized as a "registered dietitian" by the Commission on Dietetic Registration or its successor organization, or meets the requirements of paragraphs (a)(1)(i) and (ii) of this section.***
- ***(iv) For dietitians hired or contracted with prior to November 28, 2016, meets these requirements no later than 5 years after November 28, 2016 or as required by state law.***

§483.*60*(a)(2) If a qualified dietitian ***or other clinically qualified nutrition professional*** **is not employed full-time, the facility must designate a person to serve as the director of food** ***and nutrition*** **services** ***who—***

- ***(i) For designations prior to November 28, 2016, meets the following requirements no later than 5 years after November 28, 2016, or no later than 1 year after November 28, 2016 for designations after November 28, 2016, is:***
  - ***(A) A certified dietary manager; or***
  - ***(B) A certified food service manager; or***
  - ***(C) Has similar national certification for food service management and safety from a national certifying body; or***
  - ***D) Has an associate's or higher degree in food service management or in hospitality, if the course study includes food service or restaurant management, from an accredited institution of higher learning; and***
- ***(ii) In States that have established standards for food service managers or dietary managers, meets State requirements for food service managers or dietary managers, and***
- ***(iii) R*****eceives frequently scheduled consultations from a qualified dietitian** ***or other clinically qualified nutrition professional.***

Effective November 28, 2017

INTENT §483.*60* (a)*(1)-(2)* - *T*o ensure *there is sufficient and qualified staff with the appropriate competencies and skill sets to carry out food and nutrition services.*

DEFINITIONS §483.*60*(a)*(1)-(2)*
"Full-time" *means working 35 or more hours a week.*

"Part-time" *employees typically work fewer hours in a day or during a work week than full-time employees. The U.S. Department of Labor, Bureau of Statistics uses a definition of 34 or fewer hours a week as part-time work. Part-time workers may also be those who only work during certain parts of the year.*

"Consultants" *means an individual who gives professional advice or services. They are generally not direct employees of the facility and may work either full or part-time.*

GUIDANCE* §483.*60*(a)*(1)-(2)
Cite F801 for concerns regarding the qualifications of the dietitian, other clinical nutrition professionals, or the food services director. For concerns regarding support personnel refer to F802, Sufficient Dietary Support Personnel.

In addition, cite F801 if staff, specifically the qualified dietitian or other clinically qualified nutrition professional did not carry out the functions of the food and nutrition services. While these functions may be defined by facility management, at a minimum they should include, but are not limited to:

- Assessing the nutritional needs of residents;
- *Developing and evaluating regular and therapeutic diets, including texture of foods and liquids, to meet the specialized needs of residents;*
- Developing and implementing *person centered* education programs involving food and nutrition services for *all* facility staff;
- Overseeing the budget and purchasing of food and supplies*, and* food preparation, service and storage; and,
- *Participating in the quality assurance and performance improvement (QAPI), as described in §483.75, when food and nutrition services are involved.*

The qualified dietitian or other clinically qualified nutrition professional can decide to oversee and delegate some of the activities listed above to the director of food and nutrition services.

PROBES §483.*60*(a)*(1)-(2)*
If the survey team finds *concerns regarding a* resident*'s food and/or* nutritional status *determine*:

- *If* the practices of the dietitian, *nutrition professional, and/*or food services director contribute*d* to the identified *concerns*. If *so how*?
- *How facility management ensures that staff have the appropriate competencies and skills sets to carry out the functions of the food and nutrition service?*
- *If a food services director is employed by the facility, do they have frequent consultations with the dietitian or other nutrition professionals or consultants employed by the facility?*

Effective November 28, 2017

POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION* §483.*60*(a)*(1)-(2)

During the investigation of F801, the surveyor may have identified concerns with additional requirements related to outcome, process, and/or structure requirements. The surveyor is advised to investigate these related requirements before determining whether non-compliance may be present at these other tags. Examples of some of the related requirements that may be considered when non-compliance has been identified include, but are not limited to, the following but are not limited to:

- *§483.25(b)(1), F686, Pressure Injury*
  - *Determine if the facility identified, evaluated, and responded to a change in a resident's skin integrity.*
- *§§483.25(g)(1)-(3), F692, Nutrition/Hydration Status*
  - *Determine if the facility identified, evaluated, and responded to a change in nutritional parameters, anorexia, or unplanned weight loss, dysphagia, and/or swallowing disorders in relation to the resident's ability to eat.*
- *§§483.25(g)(4)-(5), F693, Tube Feeding Management*
  - *Determine if the facility identified, evaluated, and responded to the use of a naso-gastric and gastrostomy tubes.*

F802
§483.60(a) Staffing
The facility must employ *sufficient staff with the appropriate competencies and skills sets to carry out the functions of the food and nutrition service, taking into consideration resident assessments, individual plans of care and the number, acuity and diagnoses of the facility's resident population in accordance with the facility assessment required at §483.70(e).*

§483.60(a)(3) Support staff.
The facility must provide sufficient support personnel *to safely and effectively* carry out the functions of the *food and nutrition* service.

§483.60(b) A member of the Food and Nutrition Services staff must participate on the interdisciplinary team as required in § 483.21(b)(2)(ii).

DEFINITION* §483.*60(a)(3)-(b)
"**Sufficient support personnel**" *means having* enough *dietary and food and nutrition* staff to *safely carry out all of the functions of the food and nutrition services. This does not include staff, such as licensed nurses, nurse aides or paid feeding assistants, involved in assisting residents with eating.*

PROCEDURES §483.*60(a)(3) and (b)*

- *Through observations and interviews determine if there are sufficient support personnel to safely and effectively carry out the meal preparation and other food and nutrition services as defined by facility management.*
- *Observe and interview residents to determine if their needs and preferences are met, if the food is palatable, attractive, served at the proper temperatures and at appropriate times? If concerns are identified, determine if they may be related to insufficient or inadequately trained personnel.*

- *Do observations and/or interviews indicate there are sufficient staff to prepare and serve meals in a timely manner and to maintain food safety and temperature?*
- *Determine who represents food and nutrition services at interdisciplinary team meetings.*

When evaluating timeliness, factors that should be considered include but may not be limited to:

- *Meals or nutritional supplements are provided in accordance with a resident's medication requirements;*
- *Meals intended to be "hot" are served as such and are maintained at the desired temperature when provided to the resident;*
- *Meals or nutritional supplements are provided to residents within 45 minutes of either a residents request or less depending on the facility's scheduled time for meals.*

If a concern with having sufficient staff is identified, determine if the staffing levels provided were based on the facility assessment. If a concern with the facility assessment is identified, see §483.70(e), F838, Facility Assessment.

F803
§483.60(c) **Menus and nutritional adequacy.**
Menus must-

§483.60(c)(1) **Meet the nutritional needs of residents in accordance with** ***established national guidelines.;***

§483.60(c)(2) **Be prepared in advance;**

§483.60(c)(3) **Be followed;**

§483.60(c)(4) Reflect, based on a facility's reasonable efforts, the religious, cultural and ethnic needs of the resident population, as well as input received from residents and resident groups;

§483.60(c)(5) Be updated periodically;

§483.60(c)(6) Be reviewed by the facility's dietitian or other clinically qualified nutrition professional for nutritional adequacy; and

§483.60(c)(7) Nothing in this paragraph should be construed to limit the resident's right to make personal dietary choices.

INTENT §483.*60(c)(1)-(7)* *- To assure that menus are developed and prepared to meet resident choices including their nutritional, religious, cultural, and ethnic needs while using established national guidelines.*

DEFINITIONS **§483.*60(c)(1)-(7)***
"Reasonable effort" *means assessing individual resident needs and preferences and demonstrating actions to meet those needs and preferences, including reviewing availability of*

procurement sources of such food items, identifying preparation methods and approaches, and determining whether purchasing and serving such items can occur.

"Periodically" *means that a facility should update its menus to accommodate their changing resident population or resident needs as determined by their facility assessment. See F838. This includes ethnic, cultural, or religious factors that may potentially affect the care provided by the facility, including, but not limited to, activities and food and nutrition services.*

GUIDANCE* §483.*60(c)(1-7)
The facility must make reasonable efforts to provide food that is appetizing to and culturally appropriate for residents. This means learning the resident's needs and preferences and responding to them. For residents with dementia or other barriers or challenges to expressing their preferences, facility staff should document the steps taken to learn what those preferences are.

It is not required that there be individualized menus for all residents; however, alternatives aligned with individual needs and preferences should be available if the primary menu or immediate selections for a particular meal are not to a resident's liking. Facilities must make reasonable and good faith efforts to develop a menu based on resident requests and resident groups' feedback.

PROCEDURES §483.*60(c)(1-7)*
If during meal observations, a resident's dietary intake appears inadequate determine through interviews and record review if facility staff made reasonable efforts to review and/or adjust the menu and/or the individual resident's food plan to meet the nutritional, religious, cultural, and ethnic needs, and preferences of the resident.

If the survey team observes deviation from *a resident's* planned menu, review documentation, *i.e.,* diet card, *medical* record and interview *the resident,* food service manager or dietitian to support reason(s) for deviation from the planned menu.

PROBES §483.*60(c)(1-7)*
Through interviews, observations and record reviews determine if:

- Residents are receiving food in the amount, type, consistency and frequency to maintain normal body weight and acceptable nutritional values.
- *Resident preferences and needs are incorporated into the development of the individual food plan?*
- *A resident chooses not to consume certain foods or food groups such as the resident is a vegetarian or does not eat dairy, how does the facility ensure the resident's menu and/or the individual resident's food plan meets his or her nutritional needs?*
- *Menus meet basic nutritional needs by providing meals based on individual nutritional assessment, the individualized plan of care, and established national guidelines and are periodically updated to mitigate the risk of menu fatigue?*
- *Menus are reviewed and revised as needed by a qualified dietitian or other qualified nutrition professional?*

Effective November 28, 2017

NOTE: *S*tandard meal planning guide*s may be* used for menu planning and food purchasing. *They are* not intended to meet the nutritional needs *and preferences* of residents and must be adjusted to consider individual differences. Some residents will need more due to age, size, gender, physical activity, and state of health. There are many guides , i.e., American Diabetes Association, Academy of Nutrition and Dietetics, American Medical Association, or U.S. Department of Agriculture, that are available and appropriate for use when adjusted to meet each resident's needs.

DEFICIENCY CATEGORIZATION

- ***Examples of Level 4, immediate jeopardy to resident health and safety, include, but are not limited to:***
  - *The facility only maintains a one day supply of foods and drink on hand to prepare and serve their planned menus. This supply did not include foods to meet the nutritional needs or choices of residents. Several residents reported that they were often hungry and were told by staff that no snacks or other food was available.*
  - *Facility staff failed to follow a menu for a resident on a puree diet. The wrong texture of diet was provided which resulted in a choking incident for this resident. This placed the resident at risk for potential death or brain damage due to lack of oxygen from choking.*

- ***An example of Level 3, Actual harm (physical or psychological) that is not immediate jeopardy, includes, but is not limited to:***
  - *Based on a resident's current comprehensive assessment, the resident's nutritional needs changed; however facility staff did not change or updated a menu to meet the nutritional needs of this resident. As a result this resident experienced significant weight.*

- ***Examples of Level.2 - No actual harm with a potential for more than minimal harm (physical or psychological) that is not immediate jeopardy, include but are not limited to:***
  - *The facility failed to ensure the resident's menus and/or the individual resident's food plan met her/his nutritional needs and preferences.*
  - *A repetitive menu was provided to the residents resulting in complaints about the lack of variety in food options.*

- ***An example of Level 1 - No actual harm with a potential for minimal harm includes but is not limited to:***
  - *While no resident complaints were received during survey, it was observed that food items were being substituted with equally nutritious foods, but not noted or updated on the menu and residents were not notified of the change.*

F804
§483.*60*(d) Food *and drink*
Each resident receives and the facility provides—

Effective November 28, 2017

§483.*60*(d)(1) Food prepared by methods that conserve nutritive value, flavor, and appearance;

§483.*60*(d)(2) Food *and drink* that is palatable, attractive, and *at a safe and appetizing* temperature.

INTENT §483.*60*(d)(1)-(2) - *T*o assure that the nutritive value of food is not compromised and destroyed because of prolonged:

(1) Food storage, light, and air exposure; *or*
(2) Cooking of foods in a large volume of water; *or*
(3) Holding on steam table.

***DEFINITIONS* §483.*60*(d)(1)-(2)**
"Food attractiveness" refers to the appearance of the food when **served** to residents.

"Food palatability" refers to the taste and/or flavor of the food.

"Proper (safe and appetizing) temperature" *means both appetizing to the resident and minimizing the risk for scalding and burns.*

***GUIDANCE* §483.*60*(d)(1)-(2)**
Food should be palatable, attractive, and at *an appetizing* temperature as determined by the type of food to ensure resident's satisfaction, *while minimizing the risk for scalding and burns.*

Providing palatable, attractive, and appetizing food and drink to residents can help to encourage residents to increase the amount they eat and drink. Improved nutrition and hydration status can help prevent, or aid in the recovery from, illness or injury.

PROCEDURES §483.*60*(d)(1)-(2)
If there are complaints concerning food temperatures, palatability, or attractiveness from residents or through group interviews, observations of food not being eaten, or delay in passing of food trays, request a test tray from the dining area, floor or unit of most concern. In addition;

- *Review recipes, if needed, to determine if non-compliance exists.*
- *If a test tray was obtained, how did it support resident or observed concerns?*

PROBES §483.*60*(d)(1)-(2)

- Does food have a distinctly appetizing aroma and appearance, which is varied in color and texture?
- Is food generally well-seasoned (use of spices, herbs, etc.) and acceptable to residents? *If not, did the facility ensure all ingredients were available to make recipes as instructed for palatability?*
- Is food prepared in a way to preserve vitamins? Method of storage and preparation should cause minimum loss of nutrients. *For example, foods are prepared as directed or not held at hot temperatures for hours prior to meal service because prolonged hot temperatures can result in a loss of vitamins.*

- Is food served at preferable temperature for the resident (hot foods are served hot and cold foods are served cold and in accordance with resident preferences). (Not to be confused with the proper holding temperature. *Refer to §483.60(i) food safety requirements.*
- *Was the facility aware of the resident(s) complaint(s) about the food through resident council, the grievance/complaint process at the facility, or communication directly with staff? What did facility do to address the complaint(s)?*

F805
§483.*60*(d) Food *and drink*
Each resident receives and the facility provides—

§483.*60*(d)(3) Food prepared in a form designed to meet individual needs.

PROCEDURES §483.*60*(d)(3)

- Observe *meals and food preparation* to assure the food is *prepared and* appropriate to *meet* resident*'s* needs and according to *their* assessment and care plan.
- *Are there any observations of residents having difficulty chewing or swallowing their food?*
- Is the food cut, chopped, ground, *or pureed* for individual resident's needs?

F806
§483.*60*(d) Food *and drink*
Each resident receives and the facility provides—

§483.*60(d)(4) Food that accommodates resident allergies, intolerances, and preferences;*

§483.*60(d)(5) Appealing options* of similar nutritive value to residents who *choose not to eat* food *that is initially* served or *who request a different meal choice; and*

GUIDANCE* §483.*60* (d)*(4)-(5)
Facilities should be aware of each resident's allergies, intolerances, and preferences, and provide an appropriate alternative. A food substitute should be consistent with the usual *and/or* ordinary food items provided by the facility. For example, the facility may, instead of grapefruit juice, substitute another citrus juice or vitamin C rich juice the resident likes.

PROCEDURES §483.*60*(d)*(4)-(5)*
Observe meal services. If a resident appears to refuse food or drink items, determine if he or she is offered the opportunity to receive substitutes.

PROBES §483.*60*(d)*(4)-(5)*

- Ask residents how the food meets their *preferences, allergies and/or intolerances*.
- *If* residents who refuse food *or drinks, ask them if they are* offered substitutes.
- *Interview residents or staff to determine how alternate food choices are communicated to the residents?*

- *How are food textures, allergies, intolerances, and preferences accommodated per a resident's assessment, care plan and choice and how is this information communicated to staff?*

POTENTIAL TAGS FOR FURTHER INVESTIGATION **§483.*60*(d)*(4)-(5)***
During the investigation of F806, the surveyor may have identified concerns with additional requirements related to outcome, process, and/or structure requirements. The surveyor is advised to investigate these related requirements before determining whether non-compliance may be present at these other tags. Examples of some of the related requirements that may be considered when non-compliance has been identified include, but are not limited to, the following:

- *§483.20(b), F636, Comprehensive Assessments*
  - *Determine if the resident's allergies, intolerances, preferences, or need for a therapeutic diet were comprehensively assessed.*
- *§483.21(b)(1), F656, Comprehensive Care Plans*
  - *Determine if a comprehensive care plan was developed to include the resident's allergies, intolerances, preferences, or need for a therapeutic diet.*
- *§483.21(b)(2), F657, Comprehensive Care Plan Revision*
  - *Determine if the care plan was reviewed and revised by appropriate staff, in conjunction with the interdisciplinary team and with input from the resident or his/her legal representative, to try to address any allergies, intolerances, preferences, or need for a therapeutic diet.*
- *§483.21(b)(3)(i), F658, Care provided by Qualified Persons in Accordance with the Plan of Care*
  - *Determine whether the care plan for a resident with allergies, intolerance, preferences, or a therapeutic diet is adequately and/or correctly implemented.*
- *§§483.25(g)(1)-(3), F692, Nutrition/Hydration*
  - *Determine if the facility has managed the resident's nutritional interventions to meet the resident's nutritional needs, while accommodating the resident's allergies, intolerances, preferences, or need for a therapeutic diet.*

F807
§483.*60*(d) Food *and drink*
Each resident receives and the facility provides—

§483.*60(d)(6) Drinks, including water and other liquids consistent with resident needs and preferences and sufficient to maintain resident hydration.*

GUIDANCE **§483.*60*(d)*(6)***
Proper hydration alone is a critical aspect of nutrition among nursing home residents. Individuals who do not receive adequate fluids are more susceptible to urinary tract infections,

pneumonia, decubitus ulcers, skin infections, confusion and disorientation [35, 36, 37]

Other food items may also include items that become a liquid at room temperature, such as popsicles and ice cream.

If a concern is identified regarding maintaining a resident's hydration status or about a resident's fluid restriction, see §§483.25(g)(1)-(3), F692, Nutrition/Hydration Status.

PROBES* §483.*60*(d)*(6)

- *Are drinks and other fluids provided when the resident requests and consistent with the resident's care plan, preferences and choices?*
- *Does facility staff provide sufficient drinks that the resident prefers to maintain hydration?*
- *Are other liquids, such as broth, popsicles, or ice cream, offered to the resident to encourage fluid intake?*
- *What action does facility staff take to ensure resident hydration is maintained if a resident refuses the fluids offered?*

POTENTIAL TAGS FOR FURTHER INVESTIGATION* §483.*60*(d)*(6)

During the investigation of F807, the surveyor may have identified concerns with additional requirements related to outcome, process, and/or structure requirements. The surveyor is advised to investigate these related requirements before determining whether non-compliance may be present at these other tags. Examples of some of the related requirements that may be considered when non-compliance has been identified include, but are not limited to, the following:

- *§483.10(c), F552, Right to Make Treatment Decisions*
  - *Determine if the facility addressed the resident's right to refuse treatment, including drinks and thickened fluids.*
- *§483.20(b), F636, Comprehensive Assessments*
  - *Determine if the resident's hydration status was comprehensively assessed.*
- *§483.21(b)(1), F656, Comprehensive Care Plans*
  - *Determine if a comprehensive care plan was developed to address a resident's hydration needs and fluid preferences.*
- *§483.21(b)(2), F657, Comprehensive Care Plan Revision*
  - *Determine if the care plan was periodically reviewed and revised by appropriate staff, in conjunction with the practitioner and with input from the resident or his/her legal representative, to address resident hydration needs and preferences.*

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35 Chidester, J.C., and Spangler, A.A, "Fluid Intake in the Institutionalized Elderly," Journal of the American Dietetic Association 97 (1991):23-30.

36 Feinsod, F., Levenson, S., Rapp, K., Rapp, M., Beechinor, E., Liebmann, L. (2004). "Dehydration in frail, older residents in long-term care facilities." Journal of the American Medical Directors Association, 5(2 Suppl), S35-S41.

37 Gasper, P.M. "Water Intake of Nursing Home Resident." Journal of Gerontologic Nursing. 1999; 25(4):22-29.

Effective November 28, 2017

- *§§483.25(g)(1)-(3), F692, Assisted Nutrition and Hydration*
  - *Determine if the facility has managed the resident's hydration needs.*
- *§483.35(a), F725, Sufficient Staffing*
  - *Determine if the concerns related to providing residents with sufficient liquids is related to having sufficient nursing assistant staff to meet these needs.*
- *§483.10(c), F552, Right to Make Treatment Decisions*
  - *Determine if the facility addressed the resident's right to refuse treatment, including drinks and thickened fluids.*
- *§483.20(b), F636, Comprehensive Assessments*
  - *Determine if the resident's hydration status was comprehensively assessed.*
- *§483.21(b)(1), F656, Comprehensive Care Plans*
  - *Determine if a comprehensive care plan was developed to address a resident's hydration needs and fluid preferences.*
- *§483.21(b)(2), F657, Comprehensive Care Plan Revision*
  - *Determine if the care plan was periodically reviewed and revised by appropriate staff, in conjunction with the practitioner and with input from the resident or his/her legal representative, to address resident hydration needs and preferences.*
- *§483.25(g)(1)-(3), F692, Assisted Nutrition and Hydration*
  - *Determine if the facility has managed the resident's hydration needs.*
- *§483.35(a), F725, Sufficient Staffing*
  - *Determine if the concerns related to providing residents with sufficient liquids is related to having sufficient nursing assistant staff to meet these needs.*

F808
§483.*60*(e) Therapeutic Diets
§483.*60*(e)(1) Therapeutic diets must be prescribed by the attending physician.

§483.*60*(e)(2) ***The attending physician may delegate to a registered or licensed dietitian the task of prescribing a resident's diet, including a therapeutic diet, to the extent allowed by State law.***

INTENT §483.*60*(e)(1)-*(2)* - *T*o assure that residents receive and consume foods in the appropriate form and/or the appropriate nutritive content as prescribed by a physician, and/or assessed by the interdisciplinary team to support the *resident's* treatment, plan of care, in accordance with his her goals and preferences.

GUIDANCE* §483.*60*(e)(1)-*(2)
If the residents' attending physician delegates this task he or she must supervise the dietitian and remains responsible for the resident's care even if the task is delegated. The physician would be able to modify a diet order with a subsequent order, if necessary.

NOTE: *The terms "attending physician" or "physician" also includes a non-physician provider (physician assistant, nurse practitioner, or clinical nurse specialist) involved in the management of the resident's care.*

Effective November 28, 2017

DEFINITIONS* §483.*60*(e)(1)-*(2)

"**Therapeutic Diet**" *means* a diet ordered by a physician *or delegated registered or licensed dietitian* as part of treatment for a disease or clinical condition, or to eliminate or decrease specific nutrients in the diet, (e.g., sodium) or to increase specific nutrients in the diet (e.g., potassium), or to provide food the resident is able to eat (e.g., a mechanically altered diet).

"**Mechanically altered diet**" *means* one in which the texture of a diet is altered. When the texture is modified, the type of texture modification must be specific and part of the physicians' *or delegated registered or licensed dietitian* order.

PROBES §483.*60*(e)(1)-*(2)*

- *If a resident is receiving a therapeutic diet, is the diet* prescribed by the attending physician or *delegated registered or licensed dietitian?*
- *If a registered or licensed dietitian has written the order, is this delegation by the physician allowed by State law?*
- If a resident has inadequate nutrition or nutritional deficits that manifest into and/or are a product of weight loss or other medical problems, determine if there is a therapeutic diet that is medically prescribed.

POTENTIAL TAGS FOR FURTHER INVESTIGATION* §483.*60*(e)(1)-*(2)

During the investigation of F808, the surveyor may have identified concerns with additional requirements related to outcome, process, and/or structure requirements. The surveyor is advised to investigate these related requirements before determining whether non-compliance may be present at these other tags. Examples of some of the related requirements that may be considered when non-compliance has been identified include, but are not limited to, the following:

- *§483.30(e)(2), F715, Physician Delegation to Dietitians*
  - *Determine if concerns are identified with the physician delegation/supervision of a registered or licensed dietitian*
- *§§483.25(g)(1)-(3), F692, Assisted Nutrition and Hydration.*
  - *Determine if concerns are identified regarding a resident's nutritional status*

F809

§483.*60*(f) Frequency of Meals

§483.*60*(f)(1) Each resident must receive and the facility must provide at least three meals daily, at regular times comparable to normal mealtimes in the community *or in accordance with resident needs, preferences, requests, and plan of care.*

§483.*60*(f)(2)There must be no more than 14 hours between a substantial evening meal and breakfast the following day, except when a nourishing snack is *served* at bedtime, up to 16 hours may elapse between a substantial evening meal and breakfast the following day if a resident group agrees to this meal span.

§483.*60*(f)*(3) Suitable, nourishing alternative meals and snacks must be provided to residents who want to eat at non-traditional times or outside of scheduled meal service times, consistent with the resident plan of care.*

Effective November 28, 2017

DEFINITIONS* §483.*60*(f)(1)-*(3)
A "**Nourishing snack**" *means* items from the basic food groups*, either singly or in combination with each other.*

"Suitable and nourishing alternative meals and snacks" *means that when an alternate meal or snack is provided, it is of similar nutritive value as the meal or snack offered at the normally scheduled time and consistent with the resident plan of care.*

GUIDANCE* §483.60(f)(1)-*(3)
Facility staff must ensure meals and snacks are served at times in accordance with resident's needs, preferences, and requests. Suitable and nourishing alternative meals and snacks must be provided for residents who want to eat at non-traditional times or outside of scheduled meal times. Adequacy of the "nourishing snack" will be determined both by resident interviews and by evaluation of the overall nutritional status of residents in the facility, (*for example:* Is the offered snack usually satisfying?)

This regulation is not intended to require facilities to provide a 24-hour-a-day full service food operation or an on-site chef. Suitable alternatives may be meals prepared in advance that can be appropriately served by appropriately trained facility staff at non-traditional times.

PROCEDURES §483.60(f)(1)-*(3)*
Observe meal times and schedules and determine if *they are offered at regular times comparable to normal times found in the community*. Interview residents to get their input on meal service schedules to determine if they meet their choices and their input regarding *eating at non-traditional times and the* availability of snacks throughout the day.

PROBES §483.*60*(f)(1)-*(3)*
- *Are three meals offered at regular times?*
- *Are snacks and meals available for residents at non-traditional times or outside of scheduled meal service times, or upon request?*
- *Ask residents if they are offered snacks at bedtime. If snacks are not offered, would they want them?*

F810
§483.*60*(g) Assistive devices
The facility must provide special eating equipment and utensils for residents who need them *and appropriate assistance to ensure that the resident can use the assistive devices when consuming meals and snacks.*

***GUIDANCE* §483.*60*(g)**
The facility must provide *appropriate* assistive devices to residents who need them to maintain or improve their ability to eat *or drink* independently, for example, improving poor grasp by enlarging silverware handles with foam padding, aiding residents with impaired coordination or tremor by installing plate guards, or specialized cups. *The facility must also provide the*

appropriate staff assistance to ensure that these residents can use the assistive devices when eating or drinking.

For concerns regarding the use of other types of assistive devices, such as postural supports for head, trunk and arms, please see guidance under F676 and F677 for ADL care and services.

PROCEDURES §483.*60*(g)
Review sampled residents' comprehensive assessment *and plan of care* for *their capacity/*ability *to eat independently*:

- Determine if recommendations were made for adaptive eating equipment and utensils. If they were, determine if these utensils are available and utilized by residents.
- If recommended but not used, determine if this is by resident's choice.
- If eating equipment and utensils are not being utilized, determine when these were recommended and how their use is being monitored by the facility and if the staff is developing alternative recommendations and monitoring ongoing assessments.
- *Observe whether staff competently assists residents who use assistive devices.*

F811
§483.*60*(h) Paid feeding assistants-
§483.*60*(h)(1) State approved training course. A facility may use a paid feeding assistant, as defined in § 488.301 of this chapter, if—

(i) The feeding assistant has successfully completed a State-approved training course that meets the requirements of §483.160 before feeding residents; and
(ii) The use of feeding assistants is consistent with State law.

§483.*60*(h)(2) Supervision.

(i) A feeding assistant must work under the supervision of a registered nurse (RN) or licensed practical nurse (LPN).
(ii) In an emergency, a feeding assistant must call a supervisory nurse for help.

§483.*60*(h)(3) Resident selection criteria.

(i) A facility must ensure that a feeding assistant *provides dining assistance* only *for* residents who have no complicated feeding problems.
(ii) Complicated feeding problems include, but are not limited to, difficulty swallowing, recurrent lung aspirations, and tube or parenteral/IV feedings.
(iii) The facility must base resident selection on the *interdisciplinary team's* assessment and the resident's latest assessment and plan of care. *Appropriateness for this program should be reflected in the comprehensive care plan.*

NOTE: Paid feeding assistants must complete a training program with the following minimum content as specified at **§**483.160.

a. Minimum training course contents. A State-approved training course for paid feeding assistants must include, at a minimum, 8 hours of training in the following:
   (1) Feeding techniques;
   (2) Assistance with feeding and hydration;
   (3) Communication and interpersonal skills;

(4) Appropriate responses to resident behavior;
(5) Safety and emergency procedures, including the Heimlich maneuver;
(6) Infection control;
(7) Resident rights; and
(8) Recognizing changes in residents that are inconsistent with their normal behavior and the importance of reporting those changes to the supervisory nurse.

b. Maintenance of records. A facility must maintain a record of all individuals, used by the facility as feeding assistants, who have successfully completed the training course for paid feeding assistants.

INTENT §483.*60*(h)(1)-(3) - *To ensure that residents are assessed for appropriateness for a feeding assistant program, receive services as per their plan of care, and feeding assistants are trained and supervised. The use of paid feeding assistants is intended to supplement certified nurse aides, not substitute for nurse aides or licensed nursing staff.*

DEFINITIONS §483.*60*(h)(1)-(3)
"Paid feeding assistant" is defined in the regulation at 42 CFR §488.301 as "an individual who meets the requirements specified at 42 CFR §483.*60*(h)(1)(i) and who is paid *by the facility* to feed residents, or who is used under an arrangement with another agency or organization."

NOTE: The regulation uses the term "paid feeding assistant." While we are not using any other term, facilities and States may use whatever term they prefer, such as dining assistant, meal assistant, resident assistant, nutritional aide, etc. in order to convey more respect for the resident. Facilities may identify this position with other titles; however, the facility must be able to identify those employees who meet the requirements under the paid feeding assistant regulation. *While the facility is still responsible for ensuring the safety and care of all residents, this regulation does not apply to family members or to volunteers.*

***GUIDANCE* §483.*60*(h)(1)-(3)**
NOTE: The regulation *requires* that paid feeding assistant*s* must work under the supervision of an RN or LPN, and they must call the supervisory nurse in case of an emergency. Therefore, a facility that has received a waiver and does not have either an RN or LPN available in the building cannot use paid feeding assistants during those times.

Interdisciplinary Team Assessment of Resident Eligibility for Feeding Assistance
When determining whether a resident may be assisted by a paid feeding assistant facility *staff* must base resident selection on the interdisciplinary team's current assessment of the resident's condition and the resident's latest comprehensive assessment and plan of care. *Appropriateness should be reflected in the resident's comprehensive care plan.*

Paid feeding assistants are *only* permitted to assist residents who have no complicated eating or drinking problems as determined by their comprehensive assessment. *Examples of residents that a paid feeding assistant may assist* include residents who are *in*dependent in eating and/or those who have some degree of *minimal* dependence, such as needing cueing or partial assistance, as long as they do not have complicated eating or drinking problems.

Effective November 28, 2017

Paid feeding assistants are not permitted to assist residents who have complicated eating problems, such as (but not limited to) difficulty swallowing, recurrent lung aspirations, or who receive nutrition through parenteral or enteral means. Nurses or nurse aides must continue to assist residents who require the assistance of staff with more specialized training *to eat or drink*.

*P*aid feeding assistants may assist eligible residents to eat and drink at meal times, snack times, or during activities or social events as needed, whenever the facility can provide the necessary supervision.

Supervision of Paid Feeding Assistants - Paid feeding assistant*s* must work under the supervision of an RN or LPN. While we are not prescribing the exact means by which facility RNs and LPNs assert their supervisory responsibilities, we expect that facilities will do so in a way that avoids negative outcomes for their residents. If a facility chooses to use paid feeding assistants, it is the facility's responsibility to ensure that adequate supervisory nursing staff are available to supervise these assistants.

Adequate supervision by a supervising nurse does not necessarily mean constant visual contact or being physically present during the meal/snack time, especially if a feeding assistant is assisting a resident to eat in his or her room. However, in the event that an emergency should occur, the feeding assistant must be aware of and know how to access the supervisory nurse immediately *and the nurse must be located close enough to the resident that he or she can promptly respond.* Should an emergency arise, a paid feeding assistant must immediately call a supervisory nurse for help.

*S*upervisory nurse*s* should monitor the provision of the assistance provided by paid feeding assistants to evaluate on an ongoing basis:

- Their use of appropriate feeding techniques;
- Whether they are assisting assigned residents according to their *care planned* eating and drinking needs;
- Whether they are providing assistance in recognition of the rights and dignity of the resident; and
- Whether they are adhering to safety and infection control practices.

Use of Existing Staff as Paid Feeding Assistants - Facilities may use existing staff*, i.e., licensed nurses, certified nursing assistants,* to assist residents *in feeding*. *However, other employees for example, administrative, clerical, housekeeping, dietary staff, or activity specialists, etc.* must have successfully completed a State-approved training course for paid feeding assistants, as required in §483.160.

Maintenance of Training Records - The facility must maintain a record of all employees used as paid feeding assistants. The record should include verification that they have successfully completed a State-approved training course as required in §483.160.

INVESTIGATIVE PROTOCOL - Use of Paid Feeding Assistants
Objectives - To determine *if*:

- Individuals used as paid feeding assistants successfully completed a State-approved training course;
- Sampled residents who were selected to receive assistance from paid feeding assistants were assessed and determined to be eligible to receive these services based on the latest assessment and plan of care;
- Paid feeding assistants are supervised by an RN or LPN; *and,*
- *Paid feeding assistants know how to obtain assistance in emergencies.*

Use - When through observation, *record review, or* interview*(s)* with residents, family, or staff, a surveyor identifies concerns *that the facility may not be following the requirements regarding paid feeding assistants, including proper training and supervision, and proper assessment and selection of residents for feeding assistance.*

Procedures - *R*eview the *resident's* comprehensive assessment and interdisciplinary care plan to guide observations *and interviews*.

Observations - If *a* concern was discovered through resident or family interview*(s)*, observe the resident while he *or she is* being assisted to eat and drink by a paid feeding assistant. Determine if the assistant is using proper feeding technique and is providing the type of assistance specified in the resident's care plan. Note the resident's condition and observe for the presence of complicated feeding problems *that may require the assistance of a nurse aide or licensed nursing staff*. *The use of paid feeding assistants is intended to supplement, not substitute for, nursing staff. Also during observation note whether:*

- A paid feeding assistant was observed assisting a resident in a location without a call system available or other means of emergency notification;
- A resident who was assessed as ineligible for services due to complicated eating/drinking problems, or a resident who has not been assessed for eligibility, is being assisted by a paid feeding assistant; *and,*
- RN or LPN staff members assigned to supervise paid feeding assistants were observed to be unavailable (*for example,* not *available in case of emergency*).

If the concern was discovered through observations that were already made, only conduct additional observations if necessary to complete the investigation.

Resident and Family Interviews - If a resident is selected for this protocol through surveyor observation that he *or she is* having difficulties in eating or drinking and he *or she is* being assisted by a paid feeding assistant, interview the resident if the resident is interviewable. Ask questions to gain information about why the resident is receiving these services and the resident's experience with receiving assistance to eat and drink. If concerns are identified, inquire if the *resident has* reported these problems to a nurse. If the resident is not interviewable, ask these questions of a family member or the resident's representative.

If the concern was discovered through resident, resident representative or family interviews already conducted, focus any additional interview on questions specific to *complete* the investigation.

Effective November 28, 2017

Paid Feeding Assistant Interviews - Interview paid feeding assistant*s* assisting the selected resident. Determine whether there are concerns with *their* training, supervision, or the selection of the resident such as:

- What training did you successfully complete in providing feeding assistance?
- What information did you receive about this resident's needs for assistance (type of assistance needed, any precautions)?
- In what manner and by whom are you supervised while assisting residents?
- What issues/problems do you report (such as coughing, choking, changes in the resident's usual responses, or level of alertness) and to whom do you report?
- What would you do if an emergency occurred while you were assisting a resident to eat or drink? Who would you contact and how would you contact them?

***Interdisciplinary Team* Interview -** Interview the nurse or other *member(s) of the interdisciplinary team* responsible for assessing *if the* resident *i*s eligible *and appropriate* to receive assistance by a paid feeding assistant. Ask:

- How they determined that this resident has no complicated feeding problems and is eligible to be assisted by a paid feeding assistant*?*
- *If a resident is appropriate to receive assistance from a paid feeding assistant, how is this resident's needs reflected in his or her comprehensive care plan?*
- How they determine that each eligible resident remains free of emergent complicated feeding problems*?*
- Who supervises paid feeding assistants and how is the supervision accomplished*?*
- Describe the processes in place to handle emergencies when a supervisor is not present in the area where paid feeding assistants are assisting residents.

Review of *Resident* Assessment of Eligibility to Receive Assistance from a Paid Feeding Assistant - Determine whether the resident's assessment regarding his or her ongoing eligibility to be assisted by a paid feeding assistant is based on identification of the current condition of the resident and any additional or new risk factors or condition changes that may impact on the resident's ability to eat or drink. This information may be contained in the RAI or in other supporting documents such as progress notes, etc. The assessment of eligibility to receive assistance from a paid feeding assistant is ongoing and should *be reflected in a resident's comprehensive care plan.*

Requirements for Training of Paid Feeding Assistants - Determine how the facility identifies that paid feeding assistants have successfully completed a State-approved training course that meets the requirements at 42 CFR **§**483.160 before they are allowed to assist eligible residents with eating and drinking. If the facility uses temporary (agency) staff as paid feeding assistants, request documentation that these staff have met the minimum training requirements at *42 CFR **§**483.160*. *Review facility's* records *for* all employees used as paid feeding assistants *to verify their* completion of *a State approved* training course *(it is recommended the survey team coordinator assign one surveyor to obtain and verify these records).*

***NOTE:** If the facility has not ensured any paid feeding assistant has completed a State-approved training course, **do not** cite here. Cite 42 CFR §483.95(h), F948, Required training of feeding assistants.*

Effective November 28, 2017

POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION §483.*60*(h)(1)-(3)

During the investigation of F811, the surveyor may have identified concerns with additional requirements related to outcome, process, and/or structure requirements. The surveyor is cautioned to investigate these related requirements before determining whether non-compliance may be present at these other tags. Examples of some of the related requirements that may be considered when non-compliance has been identified include, but are not limited to, the following:

- §483.*10*, F*550*, *Resident Rights*
  - Determine if staff are attentive and responsive to the resident's requests, and if they provide assistance to eat in a manner that respects the resident's dignity, meets needs in a timely manner, and minimizes potential feelings of embarrassment, humiliation, and/or isolation related to inability to assist themselves with food or fluid intake.
- *§483.10(c), F552 and F578, Planning and Implementing Care*
  - *Determine if the facility addressed the resident's right to choose or refuse treatment, including receiving assistance to eat or drink by a paid feeding assistant.*
- §483.20(b), F*636*, Comprehensive Assessments
  - Review whether facility staff initially and periodically conducted a comprehensive, accurate assessment of the resident's ability to eat and drink with or without assistance and/or identified a condition that makes the resident ineligible for this service.
- §483.*21(b)(1)*, F*656*, Comprehensive Care Plans
  - Review whether facility staff developed *or implemented* a comprehensive care plan that was based on the assessment of the resident's conditions, needs, and behaviors, and was consistent with the resident's goals in order to provide assistance with nutrition and hydration as necessary.
- §483.*21(b)*(2)(iii), F*657,* Comprehensive Care Plan Revision
  - Determine if the care plan was reviewed and revised periodically, as necessary, related to eligibility to eat and drink with assistance of a paid feeding assistant.
- §§483.25*(g)(1)-(3),* F*692*, *Nutrition/Hydration Status*
  - Review if facility staff had identified, evaluated, and responded to a change in nutritional parameters, anorexia, or unplanned weight loss, dysphagia, and/or swallowing disorders in relation to the resident's ability to eat.
  - Review if facility staff had identified, evaluated, and responded to a change in the resident's ability to swallow liquids.
- §483.25 (b)*(4)*, F*676*, ADL Assistance for Dependent Residents
  - Determine if staff identified and implemented appropriate measures to provide food and fluids for the resident who cannot perform relevant activities of daily living.
- §483.*35*(a), F*725*, Sufficient Staff
  - Determine if the facility has qualified staff in sufficient numbers to provide assistance to eat or drink to those residents who require such assistance. For residents who are not eligible to receive assistance from paid feeding assistants, determine if there are sufficient *staff* to provide this assistance to these residents in a timely fashion.
- §483.*70(h),* F*841*, Medical Director
  - Determine whether the medical director collaborates with the facility to help develop, implement, and evaluate resident care policies and procedures based on current

standards of practice, e.g., the use of paid feeding assistants, their supervision, and the criteria for determining which residents are eligible to receive assistance to eat or drink from paid feeding assistants.

- *§483.95(h), F948, Required training of feeding assistants.*
  - *Determine if the facility has ensured the paid feeding assistant(s) has completed a State-approved training course prior to employment.*

KEY ELEMENTS OF NONCOMPLIANCE:

To cite F811, the surveyor's investigation will generally show the facility failed to do any one or more of the following:

- *Prohibit* an employee who did not complete a State-approved training to assist a resident to eat or drink; ***or***
- *Ensure all paid feeding assistants (permanent or temporary) are used consistent with State law;* ***or***
- Maintain documentation of a paid feeding assistant's successful completion of a State-approved paid feeding training course; ***or***
- *Ensure paid feeding assistants were* supervised *by a licensed nurse*; ***or***
- *Ensure a paid feeding assistant called a supervisory nurse in an emergency*; ***or***
- *Ensure paid feeding assistants are a*ssisting only those residents without complicated feeding problems and who have been selected as eligible to receive these services from a paid feeding assistant; ***or***
- *Ensure the interdisciplinary team assessed the resident's appropriateness for paid feeding assistance and this need is reflected in the comprehensive care plan.*

DEFICIENCY CATEGORIZATION

- ***An example of Level 4, immediate jeopardy to resident health and safety, includes, but is not limited to:***
  - A resident is being assisted to eat by a paid feeding assistant *and begins to* experiencing choking. *The assistant was not trained to provide abdominal thrusts or the Heimlich maneuver and* the supervising nurse *or other qualified staff* were not available to assist.

- ***An example of Level 3, Actual harm (physical or psychological) that is not immediate jeopardy, includes, but is not limited to:***
  - A resident who *did not have a complicated feeding problem and who* was assessed to have the potential to improving *his or her* eating ability was assisted to eat by a paid feeding assistant. The assistant provided too much food too quickly and the resident was pocketing the food in *their* cheeks. The *assistant did not notice this was happening and as a result the* resident experienced coughing and subsequently vomited.

- ***Examples of Level.2 - No actual harm with a potential for more than minimal harm (physical or psychological) that is not immediate jeopardy, includes but are not limited to:***
  - Residents are being assisted to eat by individuals who have not successfully completed a State-approved paid feeding assistant training course and who otherwise

by State law would not be allowed to feed residents (note that RNs, LPNs or CNAs **are** permitted to feed residents), and there were no resident negative outcomes.

- Paid feeding assistants are assisting eligible residents; however supervising nurses are not nearby *or immediately available to promptly respond to an emergency*, but there have been no negative resident outcomes.

Level 1 - Severity 1 does not apply for this regulatory requirement.

F812
§483.60(i) ***Food safety requirements.***
The facility must –

§483.*60*(i)(1) - Procure food from sources approved or considered satisfactory by *f*ederal, *s*tate or local authorities.

(i) This may include food items obtained directly from local producers, subject to applicable State and local laws or regulations.
(ii) This provision does not prohibit or prevent facilities from using produce grown in facility gardens, subject to compliance with applicable safe growing and food-handling practices.
(iii) This provision does not preclude residents from consuming foods not procured by the facility.

§483.*60*(i)(2) - Store, prepare, distribute and serve food *in accordance with professional standards for food service safety.*

INTENT §483.*60*(i)(1)-(2) - *T*o ensure that the facility:

- Obtains food for resident consumption from sources approved or considered satisfactory by Federal, State or local authorities;
- Follows proper sanitation and food handling practices to prevent the outbreak of foodborne illness. Safe food handling for the prevention of foodborne illnesses begins when food is received from the vendor and continues throughout the facility's food handling processes*; and,*
- *Ensures food safety is maintained when implementing various culture change initiatives such as when serving buffet style from a portable steam table, or during a potluck*.

OVERVIEW §483.*60*(i)

Nursing home residents risk serious complications from foodborne illness as a result of their compromised health status. Unsafe food handling practices represent a potential source of pathogen exposure for residents. Sanitary conditions must be present in health care food service settings to promote safe food handling. CMS recognizes the U.S. Food and Drug Administration's (FDA) Food Code and the Centers for Disease Control and Prevention's (CDC) food safety guidance as national standards to procure, store, prepare, distribute and serve food in long term care facilities in a safe and sanitary manner.

Effective food safety systems involve identifying hazards at specific points during food handling and preparation, and identifying how the hazards can be prevented, reduced or

eliminated. It is important to focus attention on the risks that are associated with foodborne illness by identifying critical control points (CCPs) in the food preparation processes that, if not controlled, might result in food safety hazards. Some operational steps that are critical to control in facilities to prevent or eliminate food safety hazards are thawing, cooking, cooling, holding, reheating of foods, and employee hygienic practices.

Web sites for additional information regarding safe food handling to minimize the potential for foodborne illness include:

- National Food Safety Information Network's Gateway to Government Food Safety Information at http://www.FoodSafety.gov;
- United States Food & Drug Administration Food Code Web site at http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/

DEFINITIONS §483.*60*(i)-(2)

The following definitions are provided to clarify terms related to *professional standards for food service safety,* sanitary conditions and the prevention of foodborne illness. Foodborne illness refers to illness caused by the ingestion of contaminated food or beverages.

"Critical Control Point" *means a specific point, procedure, or step in food preparation and serving process at which control can be exercised to reduce, eliminate, or prevent the possibility of a food safety hazard.*

"Cross-contamination" *means* the transfer of harmful substances or disease-causing microorganisms to food by hands, food contact surfaces, sponges, cloth towels, or utensils which are not cleaned after touching raw food, and then touch ready-to-eat foods. Cross-contamination can also occur when raw food touches or drips onto cooked or ready-to-eat foods.[38]

"Danger Zone" *means* temperatures above 41 degrees Fahrenheit (F) and below 135 degrees F that allow the rapid growth of pathogenic microorganisms that can cause foodborne illness. Potentially Hazardous Foods (PHF) or Time/Temperature Control for Safety (TCS) Foods held in the danger zone for more than 4 hours (if being prepared from ingredients at ambient temperature) or 6 hours (if cooked and cooled) may cause a foodborne illness outbreak if consumed.

"Dry Storage" *means* storing/maintaining dry foods (canned goods, flour, sugar, etc.) and supplies (disposable dishware, napkins, and kitchen cleaning supplies).

"Food Contamination" *means* the unintended presence of potentially harmful substances, including, but not limited to microorganisms, chemicals, or physical objects in food. [39]

"Food Preparation" *means* the series of operational processes involved in *preparing* foods for serving, such as: washing, thawing, mixing ingredients, cutting, slicing, diluting concentrates, cooking, pureeing, blending, cooling, and reheating.

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38 *Partnership for Food Safety Education. (n.d.). Retrieved from http://www.fightbac.org.*
39 *Partnership for Food Safety Education. (n.d.). Retrieved from http://www.fightbac.org.*

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"Food Service/Distribution" *means* the processes involved in getting food to the resident. This may include holding foods hot on the steam table or under refrigeration for cold temperature control, dispensing food portions for individual residents, family style and dining room service, or delivering trays to residents' rooms or units, etc.

"Potentially Hazardous Food (PHF)" or **"Time/Temperature Control for Safety (TCS) Food"** *means* food that requires time/temperature control for safety to limit the growth of pathogens *(i.e., bacterial or viral organisms capable of causing a disease or toxin formation).*

"Storage" refers to the retention of food (before and after preparation) and associated dry goods.

***GUIDANCE* §483.*60*(i)(1)-(2)**
If there is reason to believe that a potential food borne illness/outbreak has occurred at the facility, surveyors should not attempt to investigate on their own but should consult with their State or local Department of Public Health that handles these types of investigations, i.e., Food & Drug or Infection Control departments. In addition States or local public health agencies may have requirements for reporting a potential food borne illness/outbreak, facilities must follow these requirements as appropriate.

Much of this guidance is referenced from the 2013 Recommendations of the United States Public Health Service Food and Drug Administration Food Code. While we do not expect surveyors to determine compliance with this Food Code we are providing a link for reference and information only.
https://www.fda.gov/downloads/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/UCM374510.pdf

Food contaminants fall into 3 *general* categories:

1. Biological Contamination - are pathogenic bacteria, viruses, toxins, and spores that contaminate food. The two most common types of disease producing organisms are bacteria and viruses. Parasites may also contaminate food, but are less common.

Factors which may influence the growth of bacteria *may* include *but are not limited to:*

- Hazardous nature of the food. Although almost any food can be contaminated, certain foods are considered more hazardous than others and are called "potentially hazardous foods (PHF) or Time/Temperature Controlled for Safety (TCS)" food. Examples of PHF/TCS foods include ground beef, poultry, chicken, seafood (fish or shellfish), cut melon, unpasteurized eggs, milk, yogurt and cottage cheese;
- Acidity (pH) of the food. More acidic food (i.e., pH < 5), such as pineapple, vinegar, and lemon juice, *tends to* inhibit bacterial growth;
- Water percentage of the food. Foods that have a high level of water (e.g., fruits and vegetables) encourage bacterial growth; and
- Time and temperature control of the food. Time in conjunction with temperature controls is critical. The longer food remains in the danger zone, the greater the risks for growth of harmful pathogens. Bacteria multiply rapidly in a moist environment in the danger zone. Freezing does not kill bacteria. Rapid death of most bacteria occurs at 165 degrees F or above.

NOTE: Some foods may be considered a TCS food needing time/temperature control for safety to limit pathogenic microorganism growth or toxin formation. Examples include foods held for later service (e.g., cooked rice, beans, grilled sautéed onions, or baked potatoes).

2. Chemical Contamination - The most common chemicals that can be found in a food system are cleaning agents (such as glass cleaners, soaps, and oven cleaners) and insecticides. Chemicals used by the facility staff, in the course of their duties, may contaminate food (e.g., if a spray cleaner is used on a worktable surface while food is being prepared it becomes exposed to a chemical). An inadequately identified chemical may be mistaken for an ingredient used in food preparation. For example, incorrectly stored (e.g., dishwashing liquid stored in a syrup bottle) or unlabeled (e.g., white granulated cleaner that looks like salt) cleaning products may be inadvertently added to food and cause illness. Chemical products *and* supplies, must be *clearly marked as such and* stored separately from food items.

3. Physical Contamination - Physical contaminants are foreign objects that may inadvertently enter the food. Examples include, but are not limited to, staples, fingernails, jewelry, hair, glass, metal shavings from can openers, and pieces *or fragments* of bones *from fish or chicken for example.*

Potential **Factors Implicated in Foodborne Illnesses -** Many *influences may* contribute to foodborne outbreaks, *such as*:

- **Poor Personal Hygiene** - Employee*s, residents, family or visitor's* health and hygiene are significant factors in preventing foodborne illness. "Infectious" individuals (persons capable of transmitting an infection or communicable disease) are a source of *contaminants such as* Norovirus, *Influenza, etc.* Proper hand washing techniques and exclusion of infectious *individuals* from handling food are critical for prevention of foodborne illness.
- **Inadequate Cooking and Improper Holding Temperatures** - Poorly cooked food *or food that is not held at appropriate temperatures may* promote the growth of pathogens that cause foodborne illness.
- **Contaminated Equipment** - Equipment can become contaminated in various ways including, but not limited to:
  - Poor personal hygiene;
  - Improper sanitation; and
  - Contact with raw food (e.g., poultry, eggs, seafood, and meat).
- **Unsafe Food Sources** - *If surveyors have concerns or questions regarding the origin or processing of meat or other food products served to the facility residents, the surveyor should request that the facility provide documents which indicate the food product is from an approved or satisfactory source, as required by §483.60(i)(1) (F812).*

NOTE: The food procurement requirements for facilities are not intended to restrict resident choice. All residents have the right to accept food brought to them by *family or* visitor(s).

Effective November 28, 2017

Strategies for Control *of Potential Foodborne Illness -* The table below illustrates the more commonly identified ingestible *food* items *and sources of contamination* which have been associated with *food borne illness and possible* strategies *to prevent illness*.

Source of Contamination	Primary Agents of Concern	Primary Control Strategies
A. Hazards that are likely to occur - strategies that must be in place to prevent foodborne illness.		
Eggs - unpasteurized or raw	• Salmonella	• PHF/TCS • Cook until all parts of the egg are completely firm • Prevention of cross-contamination to foods
Poultry, raw	• Campylobacter • Salmonella	• PHF/TCS • Cook to proper temperature • Prevention of cross-contamination to *other* foods
	• Clostridium perfringens	• PHF/TCS • Cook to proper temperature
Meat, raw	• E. coli 0157:H7 • Salmonella • Campylobacter	• PHF/TCS • Cook to proper temperature • Prevention of cross-contamination to foods
	• Clostridium perfringens	• PHF/TCS • Cook to proper temperature
Infectious food workers	• Norovirus • Hepatitis A virus • Shigella • Salmonella	• Exclusion of infectious food workers • Proper hand-washing procedures • Avoid bare-hand contact with *any* foods
	• Staphylococcus aureus	• Proper hand-washing procedures • Avoid bare-hand contact with foods
B. Hazards that may occur as a result of food products being adulterated, and for which good food handling practices are needed to minimize the potential for foodborne illness transmission. *The US Food & Drug Administration (FDA considers food adulteration as the act of intentionally debasing the quality of food offered for sale either by the admixture or substitution of inferior substances or by the removal of some valuable ingredient.*		
Fruits and vegetables, fresh	• E. coli O157:H7 • Salmonella • Norovirus • Hepatitis A virus • Shigella	• Wash *by facility staff* prior to use • Keep cut and raw fruits and vegetables refrigerated
Ready-to-eat meat and poultry products	• Listeria monocytogenes	• Proper refrigeration during storage
Pasteurized dairy products	• Listeria monocytogenes	• Proper refrigeration during storage
Ice	• Norovirus	• Cleaning and sanitizing the internal components of the ice machine *and utensils* according to manufacturers' guidelines

Effective November 28, 2017

Employee Health - Employees who handle food must be free of communicable diseases and infected skin lesions. (See the requirement at 42 CFR §483.*80(a)(2)(v), F880, Infection Control, requiring a facility to have an infection prevention and control program that specifies policies for, among other things, the circumstances under which a facility must prohibit an employee from direct contact with residents or their food).*

Hand Washing, Gloves, and Antimicrobial Gel - *Employees should never use* bare hand contact with *any foods, ready to eat or otherwise*. Since the skin carries microorganisms, it is critical that staff involved in food preparation and services consistently utilize good hygienic practices and techniques. Staff should have access to proper hand washing facilities with available soap (regular or anti-microbial), hot water, and disposable towels and/or heat/air drying methods. Antimicrobial gel (hand hygiene agent that does not require water) cannot be used in place of proper hand washing techniques in a food service setting.

The appropriate use of *items* such as gloves, tongs, deli paper, and spatulas is essential in *minimizing the risk of* foodborne illness. Gloved hands are considered a food contact surface that can get contaminated or soiled. Disposable gloves are a single use item and should be discarded *between and* after each use.

The use of disposable gloves is not a substitute for proper hand washing. *Hands must be washed before putting on gloves and after removing gloves.* Failure to change gloves *and wash hands* between tasks*, such as medical treatments or contact with residents, between handling raw meats and ready to eat foods or between handling soiled and clean dishes,* can contribute to cross-contamination.

Hair Restraints/Jewelry/Nail Polish - Dietary staff must wear hair restraints (e.g., hairnet, hat, and/or beard restraint) to prevent hair from contacting food. Staff should maintain nails that are clean and neat, and wearing intact disposable gloves in good condition that are changed appropriately to reduce the spread of infection. Since jewelry can harbor microorganisms, it is recommended that staff keep jewelry to a minimum and cover hand *or wrist* jewelry with gloves when handling food.

Food Receiving and Storage - When food, food products or beverages are delivered to the nursing home, facility staff must inspect these items for safe transport and quality upon receipt and ensure their proper storage, keeping track of when to discard perishable foods and covering, labeling, and dating all *PHF/TCS* foods stored in the refrigerator *or* freezer as indicated.

When food is brought into the facility from an off-site kitchen (any kitchen that is not *proximate to* the facility), this kitchen must be approved and inspected by the appropriate Federal, State, or local authorities. *This does not include food brought to residents from their family or visitors. Obtain a copy of the last approved inspection of the off-site kitchen to verify it has been approved and inspected by the appropriate Federal, State or local authorities. Do not visit the off-site kitchen. Continue to inspect the facility for safe food handling, storage, and food quality after receiving the food delivery.*

<u>Effective November 28, 2017</u>

Food handling risks associated with food stored on the units may include but are not limited to:

- Food left on trays or countertops beyond safe time and/or temperature requirements;
- Food left in refrigerators beyond safe "use by" dates (including, but not limited to foods that have been opened but were not labeled, etc.);
- Food stored in a manner (open containers, without covers, spillage from one food item onto another, etc.) that allows cross-contamination; and
- Failure to maintain refrigerated food temperatures at safe levels;

Personal Refrigerators – *The specific food storage requirements at F812 are for the nursing home food storage and do not apply to residents' personal refrigerators. However, the nursing home must ensure, under Life Safety Code regulations, that the resident room has an adequate electrical system, such as proper outlets, to allow the connection of a refrigerator without overloading the electrical system. Please see F813 related to nursing facility requirements to have a policy regarding personal food items.*

- **Dry Food Storage -** Dry storage may be in a room or area designated for the storage of dry goods, such as single service items, canned goods, and packaged or containerized bulk food that is not PHF/TCS. The focus of protection for dry storage is to keep non-refrigerated foods, disposable dishware, and napkins in a clean, dry area, which is free from contaminants. Controlling temperature, humidity, *and* rodent and insect infestation helps prevent deterioration or contamination of the food. Dry foods and goods should be handled and stored *in a manner that* maintains the integrity of the packaging until they are ready to use. It is recommended that foods stored in bins (e.g., flour or sugar) be removed from their original packaging. Food and food products should always be kept off the floor and clear of ceiling sprinklers, sewer/waste disposal pipes, and vents to maintain food quality and prevent contamination. Desirable practices include managing the receipt and storage of dry food, removing foods not safe for consumption, keeping dry food products in closed containers, and rotating supplies.
- **Refrigerated Storage -** PHF/TCS foods must be maintained at or below 41 degrees F, unless otherwise specified by law. Frozen foods must be maintained at a temperature to keep the food frozen solid. Refrigeration prevents food from becoming a hazard by significantly slowing the growth of most microorganisms. Inadequate temperature control during refrigeration can promote bacterial growth. Adequate circulation of air around refrigerated products is essential to maintain appropriate food temperatures. Foods in a walk-in unit should be stored off the floor. Practices to maintain safe refrigerated storage include:
    - Monitoring food temperatures and functioning of the refrigeration equipment daily and at routine intervals during all hours of operation;
    - Placing hot food in containers (e.g., shallow pans) that permit the food to cool rapidly;
    - Separating raw foods (e.g., beef, fish, lamb, pork, and poultry) from each other and storing raw meats on shelves below fruits, vegetables or other ready-to-eat foods so that meat juices do not drip onto these foods; and
    - Labeling, dating, and monitoring refrigerated food, including, but not limited to leftovers, so it is used by its use-by date, or frozen (where applicable) or discarded.

Effective November 28, 2017

Safe Food Preparation - Many steps in safe food preparation must be controlled and monitored to prevent foodborne illness. Identification of potential hazards in the food preparation process and adhering to critical control points can reduce the risk of food contamination and thereby *minimize the risk of* foodborne illness. *When verifying food temperatures, staff should use a thermometer which is both clean, sanitized, and calibrated to ensure accuracy.*

- **Cross-Contamination -** Cross-contamination can occur when harmful substances, *i.e., chemical* or disease-causing microorganisms are transferred to food by hands *(including gloved hands),* food contact surfaces, sponges, cloth towels, or utensils that are not adequately cleaned. Cross-contamination can also occur when raw food touches or drips onto cooked or ready-to-eat foods.
  Examples of ways to reduce cross-contamination include, but are not limited to:
  - Store raw meat (e.g., beef, pork, lamb, poultry, and seafood) separately and in drip-proof containers and in a manner that prevents cross-contamination of other food in the refrigerator;
  - Between uses, store towels/cloths used for wiping surfaces during the kitchen's daily operation in containers filled with sanitizing solution at the appropriate concentration per manufacturer's specifications. *Assure that these sanitizing solutions are safe and do not have a risk of chemical contamination when preparing foods.* Periodically testing the sanitizing solution helps assure that it maintains the correct concentration.
  - Clean and sanitize work surfaces, including cutting boards and food-contact equipment (e.g., food processors, blenders, preparation tables, knife blades, can openers, and slicers), between uses *and consistent with applicable code.*
- **Thawing -** Thawing *some* foods at room temperature *may* not *be* acceptable because *it may be* within the danger zone for rapid bacterial proliferation. Recommended methods to safely thaw frozen foods include:
  - Thawing in the refrigerator, in a drip-proof container, and in a manner that prevents cross-contamination;
  - Completely submerging the item under cold water (at a temperature of 70 degrees F or below) that is running fast enough to agitate and float off loose ice particles;
  - Thawing the item in a microwave oven, then cooking and serving it immediately afterward; or
  - Thawing as part of a continuous cooking process**.**
- **Final Cooking Temperatures -** *Temperatures are* critical in preventing foodborne illness. Cooking food to the temperature and for the time specified below will either kill dangerous organisms or inactivate them sufficiently so that there is little risk to the resident if the food is eaten promptly after cooking.
  Monitoring the food's internal temperature *is important and will help ensure n* microorganisms can no longer survive and food is safe for consumption. Foods should reach the following internal temperatures *in these situations*:
  - Poultry and stuffed foods*, i.e., turkeys, pork chops, chickens, etc.* - 165 degrees F;
  - Ground meat (e.g., ground beef, ground pork), ground fish, and eggs held for service - at least 155 degrees F;
  - Fish and other *non-ground* meats - 145 degrees F;
  - *If the facility is using* unpasteurized eggs *these eggs* must be cooked until all parts of the egg are completely firm, *regardless of a resident's request* for *such things as*

"sunny side up". To accommodate residents choice for items such as "sunny side up" the facility must use pasteurized eggs only;

- When cooking raw foods in the microwave, *they* should be rotated and stirred during the cooking process so that all parts are heated to a temperature of at least 165 degrees F, and allowed to stand covered for at least 2 minutes after cooking to obtain temperature equilibrium.

NOTE: Fresh, frozen, or canned fruits and vegetables that are cooked do not require the same level of microorganism destruction as raw *meats/*foods. Cooking to a hot holding temperature (135 degrees F) prevents the growth of pathogenic bacteria that may be present in or on these foods.

- **Reheating Foods -** Reheated cooked foods present a risk because they have passed through the danger zone multiple times during cooking, cooling, and reheating. The PHF/TCS food that is cooked and cooled must be reheated so that all parts of the food reach an internal temperature of 165 degrees F for at least 15 seconds before holding for hot service. Ready-to-eat foods that require heating before consumption are best taken directly from a sealed container (secured against the entry of microorganisms) or an intact package from an approved food processing source and heated to at least 135 degrees F for holding for hot service. Although proper reheating will kill most organisms of concern, some toxins, such as that produced by Staphylococcus aureus, cannot be inactivated by reheating food.

NOTE: Using *a* steam table to reheat food is unacceptable since it does not bring the food to the proper temperature within acceptable timeframes.

- **Cooling -** Improper cooling is a major factor in causing foodborne illness. Taking too long to chill PHF/TCS foods has been consistently identified as one factor contributing to foodborne illness. Foods that have been cooked and held at improper temperatures promote the growth of disease-causing microorganisms that may have survived the cooking process (e.g., spore-formers). Cooled food items can be re-contaminated by unsanitary handling practices or cross-contaminated from other food products, utensils, and equipment.

  Large or dense food items, such as roasts, turkeys, soups, stews, legumes, and chili may require interventions (e.g., placing foods in shallow pans, cutting roasts into smaller portions, utilizing ice water baths, and stirring periodically) in order to be chilled safely within an allowed time period. These foods take a long time to cool because of their volume and density. If the hot food container is tightly covered, the cooling rate may be slowed further, leading to longer cooling times during which the food remains in the danger zone.

  Cooked potentially hazardous foods that are subject to time and temperature control for safety are best cooled rapidly within 2 hours, from 135 to 70 degrees F, and within 4 more hours to the temperature of approximately 41 degrees F. The total time for cooling from 135 to 41 degrees F should not exceed 6 hours.

<u>Effective November 28, 2017</u>

- **Modified Consistency -** Residents who require a modified consistency diet may be at risk for developing foodborne illness because of the increased number of food handling steps required when preparing pureed and other modified consistency foods. When hot pureed, ground, or diced food drop into the danger zone (below 135 degrees F), the mechanically altered food must be reheated to 165 degrees F for 15 seconds *if holding for hot service.*
- ***Eggs –***
  - Pooled eggs are raw eggs that have been cracked and combined together. The facility should crack only enough eggs for immediate service in response to a resident's requests or as an ingredient immediately before baking.
  - *Unpasteurized Eggs-* Salmonella infections *may be prevented by substituting* unpasteurized eggs *with* pasteurized eggs in the preparation of foods that will not be thoroughly cooked, such as, but not limited to, Caesar dressing, Hollandaise or Béarnaise sauce, egg fortified beverages, ice cream, and French toast.
  - Raw eggs with damaged shells are also unsafe because of the potential for contamination.

Food Service and Distribution - Various systems are available for serving and distributing food items to residents. These include but are not limited to tray lines, portable steam tables transported to a unit or dining area, open shelved food transport carts with covered trays, or enclosed carts that have hot and cold compartments. Some systems incorporate a heating element (pellet) under each plate of hot food. The purpose of these systems is to provide safe holding and transport of the food to the resident's location. Food safety requires consistent temperature control from the tray line to transport and distribution to prevent contamination (e.g., covering food items). The length of time needed to transport trays is more critical when the food is simply covered and transported in open or closed carts without a heated and cooled environment.

- **Tray line and Alternative Meal Preparation and Service Area -** The tray line may include, but is not limited to the steam table where hot prepared foods are held and served, and the chilled area where cold foods are held and served. A resident's meal tray may consist of a combination of foods that require different temperatures. Food preparation or service area problems/risks to avoid include, but are not limited to:
  - Holding foods in danger zone temperatures which are between 41 degrees F and 135 degrees F;
  - Using the steam table to heat food;
  - Serving meals on soiled dishware and with soiled utensils; and
  - Handling food with bare hands or improperly handling equipment and utensils.

While PHF/TCS foods are on the tray line, the temperature of the foods should be periodically monitored throughout the meal service to ensure proper hot or cold holding temperatures are maintained. If time is being used in place of temperature as a means of ensuring food safety, the facility must have a system in place to track the amount of time a PHF/TCS is held out of temperature control and dispose of it accordingly.

Effective November 28, 2017

- **Food Distribution -** Dining locations include any area where one or more residents eat their meals. These can be located adjacent to the kitchen or a distance from the kitchen, such as residents' rooms and dining rooms in nursing units on other floors or wings of the building. Potential food handling problems/risks associated with food distribution include:
  - Staff distributing trays without first properly washing their hands; and
  - Serving food to residents after collecting soiled plates and food waste, without proper hand washing.

Snacks - Snacks refer to foods served between meals or at bed time. Temperature control and freedom from contamination are also important when ready-to-eat or prepared food items for snacks are sent to the unit and are held for delivery, stored at the nursing station in a unit refrigerator or unit cupboards*, or stored in personal refrigerators in resident rooms*.

Special Events - Facility-sponsored special events, such as cookouts and picnics where food may not be prepared in the facility's kitchen and is served outdoors or in other locations, require the same food safety considerations.

Potluck Events – *Are generally events where families, volunteers or other non-facility staff may organize to provide enjoyment to nursing home residents and support a person-centered, homelike environment. These are different from a facility's special event.*

Regarding food brought into a nursing home prepared by others, please remember the nursing home is responsible for:

- *Storing visitor food in such a way to clearly distinguish it from food used by or prepared by the facility.*
- *Ensuring safe food handling once the food is brought to the facility, including safe reheating and hot/cold holding, and handling of leftovers.*
- *Preventing contamination of nursing home food, if nursing home equipment and facilities are used to prepare or reheat visitor food.*
- *Clearly identifying what food has been brought in by visitors for residents and guests when served.*

Should a foodborne illness occur as a result of a potluck held at the facility, the nursing home could be held responsible. For example, the facility could be held responsible if the facility failed to ensure the food was protected from contamination while being stored in the refrigerator and became contaminated from raw meat juices or failed to ensure staff involved in food service used appropriate hand hygiene and a foodborne illness resulted.

Nursing Home Gardens – Nursing homes that have their own gardens such as, vegetable, fruit or herbs may be compliant with the food procurement requirements as long as the facility has and follows policies and procedures for maintaining *and harvesting* the gardens*, including ensuring manufacturer's instructions are followed if any pesticide(s), fertilizer, or other topical or root-based plant preparations are applied*.

Effective November 28, 2017

NOTE: Facilities must be in compliance with any State or local requirements that may exist pertaining to food grown on facility grounds for resident consumption.

Transported Foods - If residents take prepared foods with them out of the facility (e.g., bag lunches for residents attending dialysis, clinics, sporting events, or day treatment programs), the foods must be handled and prepared for them with the same safe and sanitary approaches used during primary food preparation in the facility. Appropriate food transport equipment or another approach to maintaining safe temperatures for food at special events can help *minimize the risk of* foodborne illness.

Ice - Appropriate ice and water handling practices prevent contamination and the potential for waterborne illness. Ice must be made from potable water. Ice that is used to cool food items (e.g., ice in a pan used to cool milk cartons) is not to be used for consumption. Keeping the ice machine clean and sanitary will help prevent contamination of the ice. Contamination risks associated with ice and water handling practices may include, but are not limited to:

- Staff, residents, visitors, etc., who fail to wash their hands adequately and *use the scoop in an ice machine,* or handle ice with their bare hands, are not following appropriate infection control practices when dispensing ice; and
- Unclean equipment, including the internal components of ice machines that are not drained, cleaned, and sanitized as needed and according to manufacturer's specifications.
- *Ice chests or coolers used to store and transport ice should be cleaned regularly, especially prior to use and when contaminated or visibly soiled.*

Refrigeration - The *facility's* refrigerator*s* and/or freezers must be in good working condition to keep foods at or below 41 degrees F and the freezer must keep frozen foods frozen solid. The following are methods to determine the proper working order of the refrigerators and freezers:

- Document the temperature of external and internal refrigerator gauges as well as the temperature inside the refrigerator. Measure whether the temperature of a PHF/TCS food is 41 degrees or less;
- To make sure the cooling process is effective, measure the temperature of a PHF/TCS that has a prolonged cooling time (e.g., one in a large, deep, tightly covered container). Determine if it is in the danger zone;
- Check for situations where potential for cross-contamination is high (e.g., raw meat stored over ready-to-eat items);
- Check the firmness of frozen food and inspect the wrapper to determine if it is intact enough to protect the food; and
- Interview food service personnel regarding the operation of the refrigerator and the freezer.

Temperature control and freedom from contamination is also important when food or snacks are sent to a unit and held at the nursing station in a unit refrigerator or unit cupboards*, or stored in personal refrigerators in resident rooms*. Food handling risks associated with food stored on the units may include but are not limited to:

- Food left on trays or countertops beyond safe time and/or temperature requirements;
- Food left in refrigerators beyond safe "use by" dates (including, but not limited to foods that have been opened but were not labeled, etc.);

- Food stored in a manner (open containers, without covers, spillage from one food item onto another, etc.) that allows cross-contamination; and
- Failure to maintain refrigerated food temperatures at safe levels;

Personal Refrigerators – *The specific food storage requirements at F812 are for the nursing home food storage and do not apply to residents' personal refrigerators. However, the nursing home must ensure, under Life Safety Code regulations, that the resident room has an adequate electrical system, such as proper outlets, to allow the connection of a refrigerator without overloading the electrical system. Please see F813 related to nursing facility requirements to have a policy regarding personal food items.*

Equipment and Utensil Cleaning and Sanitization - A potential cause of foodborne outbreaks is improper cleaning (washing and sanitizing) of equipment and protecting equipment from contamination via splash, dust, grease, etc.

Machine Washing and Sanitizing - Dishwashing machines use either heat or chemical sanitization methods. *Manufacturer's instructions must **always** be followed*. The following are *general recommendations* according to the U.S. Department of Health and Human Services, Public Health Services, Food and Drug Administration Food Code for each method.

High Temperature Dishwasher (heat sanitization):

- Wash - 150-165 degrees F;
- Final Rinse - 180 degrees F;
  (160 degrees F at the rack level/dish surface reflects 180 degrees F at the manifold, which is the area just before the final rinse nozzle where the temperature of the dish machine is measured); or 165 degrees F for a stationary rack, single temperature machine.

Low Temperature Dishwasher (chemical sanitization):

- Wash - 120 degrees F; and
- Final Rinse - 50 ppm (parts per million) hypochlorite (chlorine) on dish surface in final rinse.

The chemical solution must be maintained at the correct concentration, based on periodic testing, at least once per shift, and for the effective contact time according to manufacturer's guidelines.

Manual Washing and Sanitizing - A 3-step process is used to manually wash, rinse, and sanitize dishware correctly. The first step is thorough washing using hot water and detergent after food particles have been scraped off. The second is rinsing with hot water to remove all soap residues. The third step is sanitizing with either hot water or a chemical solution maintained at the correct concentration, based on periodic testing, *at least when initially filled and as needed, such as with extended use,* and for the effective contact time according to manufacturer's guidelines. *Facilities must have appropriate and adequate testing equipment, such as test strips and thermometers, to ensure adequate washing and sufficient concentration of sanitizing solution is present to effectively clean and sanitize dishware and kitchen equipment.*

After washing and rinsing, dishes and utensils are sanitized by immersion in either:

- Hot water (at least 171 degrees F) for 30 seconds; or
- A chemical sanitizing solution used according to manufacturer's instructions. Chemical sanitization requires greater controls than hot water sanitization. Manufacturer's instructions must **always** be followed.

A high concentration of sanitation solutions may be potentially hazardous (see manufacturer's instructions) *and may be a chemical contaminant of food*. Improper test strips yield inaccurate results when testing for chemical sanitation.

Drying food preparation equipment and utensils with a towel or cloth may increase risks for cross contamination.

Cleaning Fixed Equipment - When cleaning fixed equipment (e.g., mixers, slicers, and other equipment that cannot readily be immersed in water), the removable parts must be washed and sanitized and non-removable parts cleaned with detergent and hot water, rinsed, air-dried and sprayed with a sanitizing solution (at the effective concentration). Finally, the equipment is reassembled and any food contact surfaces that may have been contaminated during the process are re-sanitized (according to the manufacturer's instructions). Service area wiping cloths are cleaned and dried or placed in a chemical sanitizing solution of appropriate concentration.

***PROCEDURES* §483.*60*(i)(1)-(2)**

Through observation, interviews, and record review, determine:

- *If the facility obtained food safe for consumption from approved sources; If the facility stores, prepares, distributes, and serves food in a sanitary manner to prevent foodborne illness;*
- *If the facility has systems (e.g., policies, procedures, training, and monitoring) in place to prevent the spread of foodborne illness and minimize food storage, preparation and handling practices that could cause food contamination and could compromise food safety; and*
- *If the facility utilizes safe food handling from the time the food is received from the vendor and throughout the food handling processes in the facility.*

Adhere to sanitary requirements (e.g., proper washing hands when entering the kitchen and between tasks, use of hair restraints) when assessing the kitchen and meal service throughout the survey process.

***Observations -** Complete the initial brief kitchen tour upon arrival at the facility, with observations focused on practices that might indicate potential for foodborne illness. Make additional observations throughout the survey process during times when food is being stored, prepared, cooked, plated, transported, and distributed to determine if safe food handling practices are being followed. Corroborate observations through interview, record review, and other appropriate documentation.*

***Food Procurement Procedures:** Determine whether food meets safe and sanitary conditions related to when, where, and how the food was received for residents' consumption. If a concern*

is identified, check invoices from food vendors when necessary to verify the source of food acquisition and the date of delivery.

Storage of Food

- *Observe for food storage practices that may place the food, including ice, at risk for biological, chemical, or physical contamination.*
- *Check dry storage areas for canned goods that have a compromised seal (e.g., punctures);*
- *Check all facility refrigerators, including those on resident units, to ensure foods are held at appropriate temperatures and PHF/TCS foods for labeling and dates (e.g., use by dates);*
- *Check freezers to ensure foods are frozen solid;*
- *Look for evidence of pests, rodents and droppings and other sources of contamination in food storage areas; and*
- *Check resident rooms for safe food storage practices.*

Food Preparation Procedures

- *Observe staff food handling practices, such as proper hand washing, the appropriate use of utensils, gloves, and hairnets;*
- *Observe food handling practices that have potential for cross-contamination (e.g., use of food contact surfaces and equipment to prepare various uncooked and ready-to-eat foods);*
- *Have staff demonstrate the calibration technique to ensure the temperature readings on the thermometers are reliable;*
- *Determine if the dietary staff are ensuring PHF/TCS foods are at approved cold holding, hot holding, and final cook temperatures;*
- *Determine if the dietary staff follow approved cooling and reheating procedures for PHF/TCS foods;*
- *Observe staff preparing modified consistency (e.g., pureed, mechanical soft) PHF/TCS foods to determine whether food safety was compromised;*
- *If the staff is preparing resident requests for undercooked eggs (i.e. sunny side up, soft scrambled, soft boiled), determine if pasteurized shell eggs or liquid pasteurized eggs were used to prevent foodborne illness; and*
- *During meal service, observe whether the staff measure the temperature of all hot and cold menu items.*

Service after Meal Times

- *Observe whether facility personnel are operating the dish washing machine according to the manufacturer's specifications.*
- *Check whether the facility has the appropriate equipment and supplies to verify the safe operation of the dish washing machine and the washing of pots and pans.*
- *Check the sanitizing method used (high temperature or chemical) in dishwashing and for storing sanitizing cloths is adequate for sanitizing of dishware, utensils, pots/pans, and equipment.*

- *Observe stored dishes, utensils, pots/pans, and equipment for evidence of soiling. These items should be stored in a clean dry location and not exposed to splash, dust or other contamination; and*
- *Evaluate whether proper hand washing is occurring between handling soiled and clean dishes to prevent cross-contamination of the clean dishes.*

Interviews - *During the course of the survey, interview the staff who performs the task about the procedures they follow to procure, store, prepare, distribute, and serve food to residents. In addition to food safety practices, determine:*

- *What is the facility's practice for dealing with employees who come to work with symptoms of contagious illness (e.g., coughing, sneezing, diarrhea, vomiting) or open wounds;*
- *Whether the facility has, and follows, a cleaning schedule for the kitchen and food service equipment; and*
- *If there is a problem with equipment, how staff informs maintenance and follows up to see if the problem is corrected.*

Record Review - *In order to investigate identified food safety concerns, review supporting data, as necessary, including but not limited to:*

- *Any facility documentation, such as dietary policies and procedures, related to compliance with food sanitation and safety, including but not limited to policies addressing facility food service, potluck events, food from visitors, facility gardens;*
- *Determine if the food service employees have received training related to such compliance;*
- *Monitoring records, such as temperature logs from the tray line, refrigerators, and freezers, and dishwasher temperature and sanitizing records;*
- *Maintenance records, such as work orders and manufacturer's specifications, related to equipment used to store, prepare, and serve food.*

Review of Facility Practices - *Review of facility practices may include, but is not limited to, review of policies and procedures for sufficient staffing, staff training, and following manufacturer's recommendations as indicated. In order to establish if the facility has a process in place to prevent the spread of foodborne illness, interview the staff to determine how they:*

- *Monitor whether the facility appropriately procures, stores, prepares, distributes, and serves food;*
- *Identify and analyze pertinent issues and underlying causes of a food safety concern;*
- *Implement interventions that are pertinent and timely in relation to the urgency and severity of a concern; and*
- *Monitor the implementation of interventions and determine if additional modification is needed.*

DEFICIENCY CATEGORIZATION

- ***Examples of Level 4, immediate jeopardy to resident health and safety, include, but are not limited to:***
  - *A 10-quart covered stock pot with 8 quarts of cooked beans was in the refrigerator. The internal temperature of the beans at the time of survey was measured at 68*

degrees F. The cook stated these beans had been cooked the day before and were going to be served at the next meal, unaware they had been improperly cooled. Improperly cooled beans are at risk for growing toxin producing bacteria that are not destroyed in the reheating process.

- A roast (raw meat) thawing on a plate in the refrigerator had bloody juices overflowing and dripping onto uncovered salad greens on the shelf below. The contaminated salad greens were used to make salad for the noon meal;
- The facility had a recent outbreak of Norovirus after the facility allowed a food worker who was experiencing vomiting and diarrhea to continue preparing food.

- ***An example of Level 3, Actual harm (physical or psychological) that is not immediate jeopardy, includes, but is not limited to:***
  - *The facility failed to properly cool leftover turkey. The turkey was served to the residents, which resulted in an outbreak of foodborne illness, which, based on the facility population, did not result in or have the potential for causing serious harm to any resident.*

- ***Examples of Level.2 - No actual harm with a potential for more than minimal harm (physical or psychological) that is not immediate jeopardy, include but are not limited to:***
  - Food service workers sliced roast pork on the meat slicer. The meat slicer was not washed, rinsed, and sanitized after use;
  - During the initial tour of the kitchen, two food service workers were observed on the loading dock. One was smoking and the other employee was emptying trash. Upon returning to the kitchen, they proceeded to prepare food without washing their hands;
  - Upon inquiry by the surveyor, the food service workers tested the sanitizer of the dish machine, the chemical rinse of the pot-and-pan sink, and a stationary bucket used for wiping cloths. The facility used chlorine as the sanitizer. The sanitizer tested less than 50 ppm in all three locations. Staff interviewed stated they were unaware of the amount of sanitizer to use and the manufacturer's recommendations to maintain the appropriate ppm of available sanitizer.

Level 1 - Severity 1 does not apply for this regulatory requirement.

***POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION* §483.*60*(i)(1)-(2)**

During the investigation of F812, the surveyor may have identified concerns with additional requirements related to outcome, process, and/or structure requirements. The surveyor is advised to investigate these related requirements before determining whether non-compliance may be present at these other tags. Examples of some of the related requirements that may be considered when non-compliance has been identified include, but are not limited to, the following:

- §§483.25(*g)(1)-(5), F692, Nutrition/Hydration Status and F693, Tube Feeding*
  - Determine if residents have experienced nausea, vomiting, diarrhea, or other gastrointestinal symptoms as a result of the failure to store, handle, administer, or remove and discard tube feeding solutions in a safe and sanitary manner.
- §483.35(a), *F725* Sufficient Staffing

- Determine if the facility has sufficient staffing to meet the needs of the residents.

- §483.60(a)(1)(2), *F801*, Dietary Services - Staffing
  - Determine if the facility employs or consults with a qualified dietitian. If not employed full-time, determine if the director of food service receives scheduled consultation from the dietitian concerning storage, preparation, distribution and service of food under sanitary conditions.
- §483.60(a)(3), *F802*-Standard Sufficient Staff
  - Determine if the facility employs sufficient support personnel competent to carry out the functions of the dietary service.
- §483.60(h), *F811,* Paid Feeding Assistants
  - Determine if the Paid Feeding Assistant(s) has/have successfully completed a State-approved training course that meets Federal requirements and that the Feeding Assistant(s) is/are utilizing proper techniques to prevent foodborne illness.
- §483.80, *F880*, Infection Control
  - Determine if the facility's infection control program includes investigation, control, and prevention of foodborne illness.
  - Determine if the facility has practices in place to prevent the spread of infection, including proper hand washing techniques.
- §483.90(c)(2), *F908*, Maintain All Essential Equipment
  - Determine if the equipment in the kitchen, such as refrigerators, food carts, tray line equipment, freezers, dishwashers, ovens, stoves, and ranges etc. is maintained in safe operating condition and according to manufacturers' specifications.
- §483.90(i)(4), *F925,* Effective Pest Control Program
  - Determine if the facility has maintained an effective pest control program so that it remains free of pests and rodents. Determine whether there is evidence of insect larvae, roaches, ants, flies, mice, etc. in food storage, preparation and service areas.
- §§483.75*(d),(e),and* (g)*(1)*-(2), *F867, F868*, Quality Assessment and Assurance
  - Determine whether the quality assessment and assurance committee seeks and reviews concerns related to foodborne illness, and food safety and sanitation to develop and implement appropriate actions to correct identified quality deficiencies when indicated.

KEY ELEMENTS OF NONCOMPLIANCE:

To cite F812, the surveyor's investigation will generally show the facility failed to do any one or more of the following:

- Procure, store, handle, prepare, distribute, and serve food in accordance with the standards summarized in this guidance; ***or***
- Maintain PHF/TCS foods at safe temperatures, at or below 41 degrees F (for cold foods) or at or above 135 degrees F (for hot foods) except during preparation, cooking, or cooling, and ensure that PHF/TCS food plated for transport was not out of temperature control for more than four hours from the time it is plated; ***or***
- Store raw foods (e.g., meats, fish) in a manner to reduce the risk of contamination of cooked or ready-to-eat foods; ***or***
- Cook food to the appropriate temperature to kill pathogenic microorganisms that may cause foodborne illness; ***or***
- Cool food in a manner that prevents the growth of pathogenic microorganisms; ***or***

- Utilize proper personal hygiene practices (e.g., proper hand washing and the appropriate use of gloves) to prevent contamination of food; and
- Use and maintain equipment and food contact surfaces (e.g., cutting boards, dishes, and utensils) to prevent cross-contamination.

F813
§483.*60*(i) ***Food Safety Requirements***
The facility must –

§483.60(i)(3) Have a policy regarding use and storage of foods brought to residents by family and other visitors to ensure safe and sanitary storage, handling, and consumption.

GUIDANCE **§483.*60*(i)*(3)***
The facility must have a policy regarding food brought to residents by family and other visitors. The policy must also include ensuring facility staff assists the resident in accessing and consuming the food, if the resident is not able to do so on his or her own. The facility also is responsible for storing food brought in by family or visitors in a way that is either separate or easily distinguishable from facility food.

The facility has a responsibility to help family and visitors understand safe food handling practices (such as safe cooling/reheating processes, hot/cold holding temperatures, preventing cross contamination, hand hygiene, etc.). If the facility is assisting family or visitors with reheating or other preparation activities, facility staff must use safe food handling practices.

PROBES **§483.*60*(i)*(3)***
Interview family and/or visitors who bring food in to a resident to determine:
- *If he or she was provided the policy about the use and storage of foods brought in by family or visitors.*
- *If the policy was provided in a language he or she could understand.*
- *If safe food handling practices were explained to him or her.*

Interview facility staff to determine:
- *If they are aware of the facility policy addressing food brought in by residents, family, or visitors and how to apply it.*
- *Who is responsible for sharing the facility policy with residents, families, and visitors?*
- *How the facility ensures the resident, family, and/or visitors understand the policy.*
- *If they are assisting with reheating, preparation, or storage of the food, if they understand safe food handling practices.*

POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION **§483.*60*(i)*(3)***
During the investigation of F813, the surveyor may have identified concerns with additional requirements related to outcome, process, and/or structure requirements. The surveyor is advised to investigate these related requirements before determining whether non-compliance may be present at these other tags. Examples of some of the related requirements that may be considered when non-compliance has been identified include, but are not limited to, the following:

Effective November 28, 2017

- *§483.10(f), F561, Self-determination.*
  - *Determine if the facility allowed residents to choose to accept food from any friends, family, visitors, or other guests.*
- *§483.10(g)(16), F581, Notice of Rights, Rules, and Services.*
  - *Determine if the policy is not provided orally and in writing and in a manner the resident can understand.*
- *§§483.60(i)(1)-(2), F812, Food safety requirements*
  - *Determine if concerns are identified with the safe storage, handling, or service of food.*

F814
§483.*60*(i) *Food Safety Requirements*
The facility must –

§483.*60(i)(4)*- Dispose of garbage and refuse properly.

PROBES §483.*60*(i)(4)

- Are garbage and refuse containers in good condition (no leaks) and is waste properly contained in dumpsters or compactors with lids or otherwise covered?
- Are areas such as loading docks, hallways, and elevators used for both garbage disposal and clean food transport kept clean, free of debris and free of foul odors and waste fat?
- Is the garbage storage area maintained in a *sanitary* condition to prevent the harborage and feeding of pests?
- Are garbage receptacles covered when being removed from the kitchen area to the dumpster?

F825
§483.*65* Specialized rehabilitative services.
§483.*65*(a) Provision of services.
If specialized rehabilitative services such as but not limited to physical therapy, speech-language pathology, occupational therapy, *respiratory therapy,* and rehabilitative services for mental illness and intellectual disabilit*y or services of a lesser intensity as set forth at §483.120(c),* are required in the resident's comprehensive plan of care, the facility must—

§483.*65*(a)(1) Provide the required services; or

§483.*65*(a)(2) *In accordance with §483.70(g),* obtain the required services from an outside resource *that is* a provider of specialized rehabilitative services *and is not excluded from participating in any federal or state health care programs pursuant to section 1128 and 1156 of the Act.*

INTENT §483.*65(a)*(1)-(2)
The intent of this regulation is *to ensure that every resident receives specialized rehabilitative services* as determined by their comprehensive *plan of care to assist them to attain, maintain or restore their highest practicable level of physical, mental, functional and psycho-social well-being. The intent is also to ensure that residents with a Mental Disorder (MD), Intellectual*

Disability (ID) or a related condition receive services as determined by their Preadmission Screening and Resident Review (PASARR).

GUIDANCE §483.65(a)(1)-(2)
Regulations governing PASARR are found at 42 CFR §§483.100-138. For any questions or concerns regarding PASARR do not cite here but refer to §§483.20(e) and (k), F644, 645 and/or 646.

"Specialized Rehabilitative Services" *includes but is not limited to physical therapy, speech-language pathology, occupational therapy, or respiratory therapy and are provided or arranged for by the nursing home. They are "specialized" in that they are provided based on each resident's individual assessed rehabilitative needs based on their comprehensive plan of care and can only be performed by or under the supervision of qualified personnel.*

These services must be provided by the facility or an outside resource and delivered by qualified personnel as defined below in the guidance under tag F826 and who are acting within the State's scope of practice laws and regulations.

The facility must provide or arrange for the provision of specialized rehabilitative services to all residents that require these services for the appropriate length of time as assessed in their comprehensive plan of care. These services are considered a facility service provided to *all* residents who need them *based on their comprehensive plan of care* and are included within the scope of facility services.

Care provided by all facility staff must be coordinated and consistent with the specialized rehabilitative services provided by qualified personnel, which is defined under tag F826.

Restorative services are not considered Specialized Rehabilitative Service - As referenced in Section O of the MDS/RAI manual - Restorative services *refers to nursing interventions that promote the resident's ability to adapt and adjust to living as independently and safely as possible. This concept actively focuses on achieving and maintaining optimal physical, mental, and psychosocial functioning. A resident may be started on a restorative nursing program when he or she is admitted to the facility with restorative needs, but is not a candidate for formalized rehabilitation therapy, or when restorative needs arise during the course of a longer-term stay, or in conjunction with formalized rehabilitation therapy. Generally, restorative nursing programs are initiated when a resident is discharged from formalized physical, occupational, or speech rehabilitation therapy.*

PROBES §483.*65*(a)(1)-(2)
1. *P*hysical *and occupational* therapy*:*
- *How did these services maintain,* improve, *or* restore the *individual's* muscle strength, balance, *range of motion, functional mobility or prevent or slow decline or deterioration in the individual's muscle strength?*
- *How are these services maintaining, improving or restoring* the amount of activity the *individual* could do *to maintain, improve or restore their independence*?

- *Do these services assist an individual in minimizing pain to enhance function and independence?*
- *How are these services maintaining, increasing or* decreas*ing* the amount of assistance needed *by the individual* to perform a task?
- *How are these services maintaining,* improv*ing or restoring* gross and fine motor coordination, including sensory awareness, visual-spatial awareness, and body integration?
- *D*o *these services assist* to *maintain,* improve *or restore* memory, problem solving, attention span, and the ability to recognize safety hazards?

2. Speech-*language* pathology:
- *How are these services maintaining,* improv*ing or restoring* auditory comprehension such as understanding common functional words, concepts of time and place, and conversation?
- *How are these services maintaining,* improv*ing or restoring* the functional abilities of *individuals* with moderate to severe hearing loss? For example, *is the individual* instruct*ed* how to effectively and independently use environmental controls to compensate for hearing loss such as eye contact, preferential seating, *and* use of the better ear *or hearing aid*?
- *How are individuals* who cannot speak *or hear assessed* for *devices such as a* communication board or an alternate means of communication?
- *How are these services maintaining, improving or restoring the functional abilities of individuals with swallowing disorders? For example, are muscle re-education, swallowing, positioning, or food consistency modification techniques being employed to restore, improve, or maintain safe swallowing function?*
- *How are these services maintaining, improving or restoring the functional abilities of individuals with speech disorders? For example, are muscle re-education, positioning, breathing, or other techniques being employed to maintain, improve or restore the individual's ability to communicate verbally?*

3. Respiratory Therapy:
- *How are residents assessed to determine which factor or factors may be involved in their underlying causes for ventilator dependence?*
- *How does the clinical team design and implement an individualized comprehensive pulmonary rehabilitation program to include resident assessment, exercise training, education, and psychosocial support?*
- *Are qualified personnel caring for mechanically ventilated residents aware of risk factors for ventilator-associated pneumonia (VAP) (e.g., nebulizer therapy, manual ventilation, and patient transport) and how do they practice prevention for these factors?*
- *How do facility staff implement practices to prevent VAP and other potential infections for residents on ventilator care? Refer to §483.80 (Infection Control).*
- *What precautions do facility staff take to avoid accidental drainage of condensate into the resident's airway and to avoid contamination of caregivers during ventilator disconnection or during disposal of condensate? Refer to §483.80 (Infection Control).*
- *If the conditions that warranted placing the resident on the ventilator stabilize and begin to resolve, does the clinical team determine the patient's readiness for subsequent*

discontinuation of ventilator support and, ultimately, extubation? Is a gradual process implemented according to the physician's orders to wean the resident from the ventilator?

- *How and to whom do facility staff report ventilator malfunction? Does the facility have a system in place to provide ventilator services for residents in the event of a malfunction of equipment?*
- *Does the facility have back-up power to assure ventilators and other respiratory devices are operable in the event of a power failure? Refer to §483.90 (Physical environment).*

PROCEDURES §483.*65*(a)(1)-(2)

For each of the services noted above, surveyors should determine through information obtained by observations, interviews and record reviews, that the facility not only delivered these services, but that the services and interventions:

(1) Were monitored for their effectiveness; and

(2) Assisted residents to attain or maintain their highest practicable level of physical, mental, functional and psycho-social well-being or to prevent or slow a decline in condition.

If the facility did not provide or obtain the required services, cite that here under tag F825. However, if the services provided were not appropriately assessed or delivered in accordance with a resident's plan of care, do not cite here but refer to the section below, Potential Requirements for Additional Investigation.

POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION §483.65(a)(1)-(2)

For residents with MI or ID, their assessment and comprehensive plan of care must be coordinated with their PASARR. If this coordination is not done, or where it is clear that the resident needs a service according to their comprehensive plan of care and facility staff failed to adequately assess the resident or has failed to care plan for the service, do not cite here but refer to §483.20 Resident Assessment and §483.21 Comprehensive person-centered care planning.

Regulations governing PASARR are found at 42 CFR §§483.100-138. For any questions or concerns regarding PASARR do not cite here but refer to §§483.20(e) and (k), F644, 645 and/or 646.

If noncompliance with F 825, has been identified, the surveyor may have identified concerns with related structure, process, and/or outcome requirements. If an additional concerns have been identified, the surveyor must investigate the identified concern. Do not cite any related or associated requirements before first conducting an investigation to determine compliance or non-compliance with the related or associated requirement.

Other Potential Tags

- *Use of Outside Resources,§483.70(g);*
- *Self-determination, §483.10;*
- *Quality of Life, §483.24;*
- *Quality of Care, §483.25;*
- *Resident Rights, §483.10 (for example if there are concerns regarding charges to the resident for any of these services refer to §483.10(f)(11));*

- *If an assistive device is needed for food and nutrition, refer to §483.60;*
- *Behavioral Health Services,§483.40;*
- *Infection Control,§483.80;*
- *Physical Environmental, §483.90*

KEY ELEMENTS OF NONCOMPLIANCE
To cite deficient practice at F825, the surveyor's investigation will generally show that the facility failed to do any one or more of the following:

- *Provide specialized rehabilitative services based on a resident's comprehensive plan of care;* ***OR***
- *Obtain specialized rehabilitative services from an outside resource that is a provider of specialized rehabilitation services that is NOT excluded from participating in any federal or state health care programs pursuant to section 1128 and 1156 of the Social Security Act.*

F826
§483.65(b) Qualifications
Specialized rehabilitative services must be provided under the written order of a physician by qualified personnel.

DEFINITIONS §483.65(b)
"Qualified Personnel" *means a physical therapist, occupational therapist, respiratory therapist, speech-language pathologist, physician, nurse practitioner, clinical nurse specialist, or physician's assistant, who is licensed or certified by the state to furnish therapy services. Qualified personnel may also include a physical therapist assistant (PTA), or an occupational therapy assistant (OTA) when furnishing services under the supervision of a qualified therapist.*

GUIDANCE §483.65(b)
The facility must employ either directly or contract with an outside resource the appropriate qualified personnel as defined above, and additional support staff to ensure the needs of the residents are met in accordance with their comprehensive plan of care.

In addition to meeting the specific competency requirements as part of their license and certification requirements defined under State law or regulations, these personnel must have the training, competencies and skill sets to care for residents as identified through resident assessments, and described in the plan of care.

NOTE: *For residents receiving physical therapy (PT), occupational therapy (OT) and/or speech-language pathology (SLP) services under the Medicare Part B benefit, an order is not required An order from a physician may substitute for the required plan of care (although orders from therapists are not recognized). Although §483.30(e)(3) allows a resident's attending physician to delegate the task of writing therapy orders to a qualified therapist, Medicare Part B does not currently recognize an order written by a therapist. Under current Part B requirements, when a therapy order is written by a qualified therapist, for that therapy to be covered and paid under the Part B benefit, a physician or recognized non-physician practitioner*

including a nurse practitioner, clinical nurse specialist or physician assistant – not a therapist – must sign and date the PT, OT, or SLP plan of care which may be established by the therapist.

In situations where there are differences between federal and state supervision requirements, the requirement with the greater level of supervision will apply. Only physical therapists may supervise physical therapy assistants, and only occupational therapists may supervise occupational therapy assistants. All speech-language pathology services must be provided by a licensed speech-language pathologist, or by a physician, nurse practitioner, clinical nurse specialist, or physician's assistant, who is licensed or certified by the state to furnish therapy services.

PROCEDURES §483.*65*(b)
*During the record review, d*etermine that *these* services are provided under the written order of a physician *(or therapist as delegated by the physician in accordance with §483.30(e)(3))* and *provided* by qualified personnel.

If individuals providing specialized rehabilitative services, i.e., physical, occupational, speech or respiratory therapy are not qualified cite here. If a problem in a resident's care or services is related to the qualifications, competencies or training, of personnel (i.e., facility staff, contractors, temporary staff, etc.), also refer to:

- *Nursing services not related to behavioral health care or dementia care, tag F725 or 726, §483.35(a),(c);*
- *Any staff caring for residents with dementia or a history of trauma and/or post-traumatic stress disorder, tag F741, §483.40;*
- *Administration, tag F839, §483.70(f).*

If there are any problems in quality of care related to *restoring,* maintaining or improving a *resident's* functional abilities, *d*etermine if these problems are attributable in part to the qualifications*, competencies or training* of specialized rehabilitative services staff. *Also refer to §483.25 (Quality of Care) and §483.24 (Quality of Life).*

KEY ELEMENTS OF NONCOMPLIANCE
To cite deficient practice at F826, the surveyor's investigation will generally show that the facility failed to do any one or more of the following:

- *Obtain a written order from a physician (or therapist as delegated by the physician in accordance with §483.30(e)(3)), except as otherwise permitted with regard to residents receiving these services under the Medicare Part B benefit (as explained above);* ***OR****,*
- *Ensure that services were provided by qualified personnel.*

F835
§483.*70* Administration.
A facility must be administered in a manner that enables it to use its resources effectively and efficiently to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident.

Effective November 28, 2017

GUIDANCE §483.*70*
Resources include but are not limited to a facility's operating budget, staff, supplies, or other services necessary to provide for the needs of residents.

PROCEDURES* §483.*70
Cite this tag if the actions, inactions, or decisions in administering the facility contributed to deficient practice(s). The facility's administration is not limited to the administrator and may also include the facility's governing body, management company, and/or others identified by the facility as part of the facility administration.

The investigation must demonstrate how the administration knew or should have known of the deficient practice and how the lack of administration involvement contributed to the deficient practice found. When citing this F835, it is not acceptable to simply reiterate the non-compliance from any other associated tags and then refer to this tag. Surveyors must document how the administration knew or should have known of the deficient practice and taken action(s) as appropriate.

F836
§483.*70*(a) Licensure.
A facility must be licensed under applicable State and local law.

§483.*70*(b) Compliance with Federal, State, and Local Laws and Professional Standards.
The facility must operate and provide services in compliance with all applicable Federal, State, and local laws, regulations, and codes, and with accepted professional standards and principles that apply to professionals providing services in such a facility.

§483.*70*(c) Relationship to Other HHS Regulations.
In addition to compliance with the regulations set forth in this subpart, facilities are obliged to meet the applicable provisions of other HHS regulations, including but not limited to those pertaining to nondiscrimination on the basis of race, color, or national origin (45 CFR part 80); nondiscrimination on the basis of *disability* (45 CFR part 84); nondiscrimination on the basis of age (45 CFR part 91); *nondiscrimination on the basis of race, color, national origin, sex, age, or disability (45 CFR part 92);* protection of human subjects of research (45 CFR part 46); and fraud and abuse (42 CFR part 455) *and protection of individually identifiable health information (45 CFR parts 160 and 164).* Violation*s of such other provisions* may result in *a finding of non-compliance with this paragraph.*

DEFINITIONS §483.*70*(a)-(c)
"Accepted professional standards and principles" *means Federal*, State *and local laws or* professional licensure standards.

An "**authority having jurisdiction"** is *the public agency, i.e.,* Federal, State or local, or *official(s) having the authority to make a determination of noncompliance, and is responsible for providing and signing official correspondence notifying the facility or professional of their final adverse action.*

Effective November 28, 2017

GUIDANCE §483.*70*(a)-(c)
This regulation and guidance only applies to actions taken under State licensure authority or other Federal HHS agencies as defined in the regulation, it does NOT include any federal CMS enforcement actions as required at 42 CFR Part 488.

PROCEDURES: §483.70(a)-(c)
*Facility l*icenses, permits, and approvals must be *provided* upon request *if necessary to determine compliance with these requirements*. *Surveyors may not interpret or enforce another agency's requirements.* If *surveyors* identify a situation indicating that the facility or *any* professional providing services may not be in compliance with a State or local law, regulation, Code and/or standard, refer that information to the authority having jurisdiction for their follow-up action. *The Centers for Medicare & Medicaid Services (CMS), Regional Office* (RO) *will* assist you to contact the appropriate Federal agency to refer your concern*s*. Do not delay a survey waiting for confirmation *of receipt* from *another agency or* authority *having jurisdiction.*

*If surveyors determined **and** received confirmation from the authority having jurisdiction that a final adverse action has been taken, then the facility could be found to not meet the requirements at* §§483.*70(b) or (c) and a deficiency may be cited here. A final* adverse action *includes* an action imposed by the authority having jurisdiction and is *not* under appeal or litigation by the facility or the professional providing services in the facility.

Do not cite *this tag*:

- When the authority having jurisdiction ***has not*** *taken a* final adverse action;
- To simply cite non-compliance with State or local licensure requirements *unless final adverse action from the authority having jurisdiction has been confirmed*; or
- As past non-compliance if, at the time of the *current* survey, the facility or professional is in compliance with the Federal, State or local law, regulation, code and /or standard but was found not to be in compliance with those requirements during a time before the *current* survey. If there is a question, confirm the facility's current compliance status with the authority having jurisdiction.

KEY ELEMENTS OF NONCOMPLIANCE
To cite deficient practice at F836, the surveyor's investigation will generally show that the facility failed to do any one of the following:

- *Hold a current license from the State or other applicable authority to operate as a nursing home and this information has been verified with the appropriate authority;* ***or***
- *Provide services in compliance with all applicable Federal, State, and local laws, regulations, and codes, and with accepted professional standards and principles that apply to any professional providing services in the facility, whether temporary or permanent.*

Effective November 28, 2017

F837
§483.*70*(d) Governing body.
§483.*70*(d)(1) The facility must have a governing body, or designated persons functioning as a governing body, that is legally responsible for establishing and implementing policies regarding the management and operation of the facility; and

§483.*70*(d)(2) The governing body appoints the administrator who is—
(i) Licensed by the State, where licensing is required;
(ii) Responsible for management of the facility; *and*
(iii) Reports to and is accountable to the governing body.

§483.*70*(d)*(3) The governing body is responsible and accountable for the QAPI program, in accordance with §483.75(f). [§483.70(d)(3) Governing body responsibility of QAPI program will be implemented beginning November 28, 2019 (Phase 3).]*

INTENT §483.*70*(d)
This regulation is intended to ensure that the facility has an active (engaged and involved) governing body that is responsible for establishing and implementing policies regarding the management of the facility.

DEFINITIONS §483.*70*(d)
***"Governing body"** refers to individuals such as facility owner(s), Chief Executive Officer(s), or other individuals who are legally responsible to establish and implement policies regarding the management and operations of the facility.*

GUIDANCE §483.*70*(d)
The facility must determine:

- *A process and frequency by which the administrator reports to the governing body, the method of communication between the administrator and the governing body including, how the governing body responds back to the administrator and what specific types of problems and information (i.e., survey results, allegations of abuse or neglect, complaints, etc.) are reported or not reported directly to the governing body;*
- *How the administrator is held accountable and reports information about the facility's management and operation (i.e., audits, budgets, staffing, supplies, etc.).; and*
- *How the administrator and the governing body are involved with the facility wide assessment in §483.70(e) Facility assessment at F838.*

PROCEDURES §483.70(d)
Request the names and contact information of the members of the governing body at the Entrance Conference. If there are concerns, conduct an interview with the administrator and if possible with one or more members of the governing body or designated person(s) functioning as the governing body.

Effective November 28, 2017

F838

§483.70(e) Facility assessment.

The facility must conduct and document a facility-wide assessment to determine what resources are necessary to care for its residents competently during both day-to-day operations and emergencies. The facility must review and update that assessment, as necessary, and at least annually. The facility must also review and update this assessment whenever there is, or the facility plans for, any change that would require a substantial modification to any part of this assessment. The facility assessment must address or include:

§483.70(e)(1) The facility's resident population, including, but not limited to,

- ***(i) Both the number of residents and the facility's resident capacity;***
- ***(ii) The care required by the resident population considering the types of diseases, conditions, physical and cognitive disabilities, overall acuity, and other pertinent facts that are present within that population;***
- ***(iii) The staff competencies that are necessary to provide the level and types of care needed for the resident population;***
- ***(iv) The physical environment, equipment, services, and other physical plant considerations that are necessary to care for this population; and***
- ***(v) Any ethnic, cultural, or religious factors that may potentially affect the care provided by the facility, including, but not limited to, activities and food and nutrition services.***

§483.70(e)(2) The facility's resources, including but not limited to,

- ***(i) All buildings and/or other physical structures and vehicles;***
- ***(ii) Equipment (medical and non- medical);***
- ***(iii) Services provided, such as physical therapy, pharmacy, and specific rehabilitation therapies;***
- ***(iv) All personnel, including managers, staff (both employees and those who provide services under contract), and volunteers, as well as their education and/or training and any competencies related to resident care;***
- ***(v) Contracts, memorandums of understanding, or other agreements with third parties to provide services or equipment to the facility during both normal operations and emergencies; and***
- ***(vi) Health information technology resources, such as systems for electronically managing patient records and electronically sharing information with other organizations.***

§483.70(e)(3) A facility-based and community-based risk assessment, utilizing an all-hazards approach.

INTENT* §483.*70(e)

The intent of the facility assessment is for the facility to evaluate its resident population and identify the resources needed to provide the necessary care and services the residents require.

Effective November 28, 2017

DEFINITIONS* §483.*70(e)
"Competency" *is a measurable pattern of knowledge, skills, abilities, behaviors, and other characteristics in performing that an individual needs to perform work roles or occupational functions successfully.*

GUIDANCE* §483.*70(e)
A facility assessment may be similar to common business practices for strategic and capital budget planning. Strategic planning is an organization's process of defining its strategy, or direction, and making decisions on allocating its resources to pursue this strategy. However, while a facility may include input from its corporate organization, the facility assessment must be conducted at the facility level.

The facility assessment will enable each nursing home to thoroughly assess the needs of its resident population and the required resources to provide the care and services the residents need. It should serve as a record for staff and management to understand the reasoning for decisions made regarding staffing and other resources, and may include the operating budget necessary to carry out facility functions.

To ensure the required thoroughness, individuals involved in the facility assessment should, at a minimum, include the administrator, a representative of the governing body, the medical director, and the director of nursing. The environmental operations manager, and other department heads (for example, the dietary manager, director of rehabilitation services, or other individuals including direct care staff should be involved as needed.

Although not required, facility staff are strongly encouraged to seek input from the resident/family council, residents, their representative(s), or families and incorporate that information as appropriate when formulating their assessment.

An assessment of the resident population is the foundation of the facility assessment. It must include an evaluation of diseases, conditions, physical, functional or cognitive status, acuity of the resident population, and any other pertinent information about the residents that may affect and plan for the services the facility must provide (e.g., MDS data, Facility Characteristics report form CMS 672). The assessment of the resident population will also contribute to identifying the physical space, equipment, assisted technology, individual communication devices, or other material resources that are needed to provide the required care and services to residents.

The regulation outlines that the individualized approach of the facility assessment is the foundation to determine staffing levels and competencies. Therefore, the facility assessment must include an evaluation of the overall number of facility staff needed to ensure sufficient number of qualified staff are available to meet each resident's needs. Furthermore, the assessment must include a competency-based approach to determine the knowledge and skills required among staff to ensure residents are able to maintain or attain their highest practicable physical, functional, mental, and psychosocial well-being and meet current professional standards of practice. This also includes any ethnic, cultural, or religious factors that may need to be considered to meet resident needs, such as activities, food preferences, and any other

aspect of care identified. Finally, the assessment should consider a review of individual staff assignments and systems for coordination and continuity of care for residents within and across these staff assignments. Also refer to F553, §483.10 Resident Rights for more information and guidance on cultural competence.

The facility must review and update this assessment annually or whenever there is, or the facility plans for, any change that would require a modification to any part of this assessment. For example, if the facility decides to admit residents with care needs who were previously not admitted, such as residents on ventilators or dialysis, the facility assessment must be reviewed and updated to address how the facility staff, resources, physical environment, etc., meet the needs of those residents and any areas requiring attention, such as any training or supplies required to provide care.

The assessment must include or address the facility's resources which include but are not limited to a facility's operating budget, supplies, equipment or other services necessary to provide for the needs of residents.

The assessment must include or address an evaluation of the facility's training program to ensure any training needs are met for all new and existing staff, individuals providing services under a contractual arrangement, and volunteers, consistent with their expected roles. The assessment should also include an evaluation of what policies and procedures may be required in the provision of care and that these meet current professional standards of practice. If there are any concerns regarding training refer to §483.95 Training.

The facility assessment must include an evaluation of any contracts, memorandums of understanding including third party agreements for the provision of goods, services or equipment to the facility during both normal operations and emergencies. The facility assessment must address their process for overseeing these services and how those services will meet resident needs and regulatory, operational, maintenance, and staff training requirements. For example, if the facility contracts for language translation, the assessment must address how those contractors will ensure services are provided both during normal operational hours and during emergencies.

The facility assessment must consider health information technology resources, such as managing resident records and electronically sharing information with other organizations. For example, the assessment should address how the facility will securely transfer health information to a hospital, home health agency, or other providers for any resident transferred or discharged from the facility.

The facility assessment must include an evaluation of the physical environment necessary to meet the needs of the residents. This must include an evaluation of how the facility needs to be equipped and maintained to protect and promote the health and safety of residents. This should also include an evaluation of building maintenance capital improvements, or structures, vehicles, or medical and non-medical equipment and supplies.

Effective November 28, 2017

The facility based and community-based risk assessment, utilizing an all-hazards approach must evaluate the facility's ability to maintain continuity of operations and its ability to secure required supplies and resources during an emergency or natural disaster. For example, if the facility is located in a flood zone, the risk assessment must include an evaluation of how residents will be kept safe and needs met during a flood affecting the facility. Facility staff should consider involving their local/county Office of Emergency Preparedness when conducting this community based risk assessment. The facility's emergency preparedness plans as required under §483.73 should be integrated and compatible with the facility assessment. As one is updated, so should the other.

Risk Assessment is general terminology that is within the emergency preparedness regulations and preamble to the Final Rule (81 Fed. Reg. 63860, Sept. 16, 2016) which describes a process facilities are to use to assess and document potential hazards within their areas and the vulnerabilities and challenges which may impact the facility. Additional terms currently used by the industry are all-hazards risk assessments, also referred to as Hazard Vulnerability Assessments (HVAs) , or all-hazards self-assessments. For the purposes of these guidelines, we are using the term "risk assessment," which may include a variety of current industry practices used to assess and document potential hazards and their impacts.

Hazard Vulnerability Assessments (HVAs) are systematic approaches to identifying hazards or risks that are most likely to have an impact on a healthcare facility and the surrounding community. The HVA describes the process by which a provider or supplier will assess and identify potential gaps in its emergency plan(s).

Potential loss scenarios should be identified first during the risk assessment. Once a risk assessment has been conducted and an facility has identified the potential hazards/risks they may face, the organization can use those hazards/risks to conduct a Business Impact Analysis.

This guidance is not specifying which type of generally accepted emergency preparedness risk assessment facilities should have, as the language used in defining risk assessment activities is meant to be easily understood by all providers and suppliers that are affected by this final rule and is aligned with the national preparedness system and terminology (81 Fed. Reg. 63860, at 63875). However, facilities are expected to conduct a full assessment of hazards based on geographical location and the individual facility dynamics, such as patient population.

PROCEDURES* §483.*70(e)

If systemic care concerns are identified that are related to the facility's planning, review the facility assessment to determine if these concerns were considered as part of the facility's assessment process. For example, if a facility recently started accepting bariatric residents, and concerns are identified related to providing bariatric services, did facility staff update its assessment before accepting residents with these needs to identify the necessary equipment, staffing, etc., needed to provide care that is effective and safe for the residents and staff? Questions surveyors should consider include, but are not limited to, the following:

- *How did the facility assess the resident population? Does this reflect the population observed?*
- *How did the facility determine the acuity of the resident population?*

- *How did the facility determine the staffing level?*
- *How did the facility determine what skills and competencies would be required by those providing care?*
- *Who was involved in conducting the facility assessment?*
- *How did the facility determine what equipment, supplies, and physical environment would be required to meet all resident needs?*
- *How did the facility develop its emergency plan?*
- *If a deficient practice is systemic and is observed at another tag, was this related to an incomplete facility assessment? How?*

KEY ELEMENTS OF NONCOMPLIANCE

To cite deficient practice at F838, the surveyor's investigation will generally show that the facility failed to do any one of the following:

- *Annually and as necessary, conduct, document, review and update a facility-wide assessment;* ***or***
- *Address or include in the facility assessment the minimum requirements as described in sections (1)(i-v), (2)(i-vi), and (3) above.*

DEFICIENCY CATEGORIZATION

- ***An example of Level 4, immediate jeopardy to resident health and safety, includes, but is not limited to:***
  - *When conducting dining observations, each surveyor noted concerns regarding lack of staff availability to assist residents during meals. Interviews with residents and families indicated that often they had to wait for staff to assist the resident and the food was often cold by the time someone came to help. In addition, a record review of several of these residents noted that they each had a significant unplanned weight loss in the past two months and one of these residents had been recently hospitalized with a diagnosis of malnutrition and dehydration. A review of the facility's most current Facility Assessment did not include an evaluation of the care required by the resident population considering the types of diseases, conditions, physical and cognitive disabilities, overall acuity, and other pertinent facts that are present within that population (e.g., assistance with eating).*

- ***An example of Level 3, Actual harm (physical or psychological) that is not immediate jeopardy, includes, but is not limited to:***
- *One of the sampled residents had experienced a fall while staff were transferring them bed to a chair. The resident's care plan indicates requiring a two-person assist using a mechanical lift. After the fall, the resident was evaluated and although he did not suffer any physical harm, upon interview he did express psychological harm and stated he was afraid of using these lifts and would prefer to remain in bed. Interviews with nursing staff indicated that many of the lifts are old, in frequent need of repair and often malfunction when used. They also stated that they have brought this matter to the attention of management many times. A review of the most recent Facility Assessment did not include or address equipment necessary to provide for the needs of residents.*

- ***An example of Level 2 - No actual harm with a potential for more than minimal harm (physical or psychological) that is not immediate jeopardy, includes but is not limited to:***
  - *The facility recently admitted several individuals, some that follow a vegan diet and others that follow the Judaism faith, both of which include dietary restrictions. Although these residents still consumed the food offered by the facility, they expressed concerns that they are not always able to choose foods that are consistent with their cultural beliefs. Upon review of the facility assessment, the facility had not addressed the cultural dietary needs of these residents, and how they would be met.*

- ***Examples of Level 1 - No actual harm with a potential for minimal harm include but are not limited to:***
  - *When reviewing the Facility Assessment, the survey team identified that while the assessment included all the required components, it had not been reviewed for any potential updates in the last 15 months. Facilities are required to review and update the assessment at least annually. The facility's failure to review the assessment within 12 months may result in the facility failing to identify a factor that would require a change to the assessment, thereby potentially placing the residents at risk for at least minimal harm.*

POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION
If the survey investigation reveals that there are not sufficient or competent staff refer to:

- *F639, §483.21(b)(3), Comprehensive Person-Centered Care Planning;*
- *F725 or 726, §§483.35(a),(c) for any nursing services not related to behavioral health care or dementia care;*
- *F741, §483.40 for any staff caring for residents with dementia or a history of trauma and/or post-traumatic stress disorder;*
- *F801, §483.60(a) for Food and Nutrition staff;*
- *F826, §483.65(b), Specialized rehabilitative services;*
- *F839, §483.70(f), Staff qualifications;*
- *F837, §483.70(d), Governing Body*
- *F865, §483.75, QAPI/QA&A*

F839
§483.7*0(f)* Staff qualifications.
§483.*70(f)*(1) The facility must employ on a full-time, part-time or consultant basis those professionals necessary to carry out the provisions of these requirements.

§483.*70(f)*(2) Professional staff must be licensed, certified, or registered in accordance with applicable State laws.

***DEFINITIONS* §483.*70*(f)**
"Licensed health professional" *as defined at §483.5 is a physician; physician assistant; nurse practitioner; physical, speech, or occupational therapist; physical or occupational therapy assistant; registered professional nurse; licensed practical nurse; or licensed or certified social worker; or registered respiratory therapist or certified respiratory therapy technician.*

Effective November 28, 2017

PROCEDURES §483.*70*(f)
If there is reason to doubt the qualifications *or competencies* of ***any personnel***, *including* temporary, agency *and contracted individuals, verify qualifications* with the appropriate *State* registry *or practitioner professional licensing body.*

If the survey investigation reveals that there are concerns with the qualifications or competencies of:

- *Activities professionals refer to F679, §483.24(c)(2);*
- *Nursing Staff refer to F726, §483.35;*
- *Any staff caring for residents with dementia or a history of trauma and/or post-traumatic stress disorder refer to F741, §483.40;*
- *Food and Nutrition staff refer to F801, §483.60(a);*
- *Individuals providing Specialized rehabilitative services refer to F826, §483.65(b),;*
- *Social Workers refer to F850, §483.70(p);*

NOTE: Only cite F839 for any staff not referenced above or if any professional staff is not licensed, certified, or registered in accordance with applicable State laws. This includes any physician or practitioner including the Medical director that does not hold a valid license to practice in the State where the Nursing Home is located.

If a facility has not designated a physician to serve as a Medical Director refer that citation under F841.

F840
§483.*70*(g) Use of outside resources.
If the facility does not employ a qualified professional person to furnish a specific service to be provided by the facility, the facility must have that service furnished to residents by a person or agency outside the facility under an arrangement described in section 1861(w) of the Act or (with respect to services furnished to NF residents and dental services furnished to SNF residents) an agreement described in paragraph (*g*)(2) of this section.

§483.*70*(g)(2) Arrangements as described in section 1861(w) of the Act or agreements pertaining to services furnished by outside resources must specify in writing that the facility assumes responsibility for—

(i) Obtaining services that meet professional standards and principles that apply to professionals providing services in such a facility; and
(ii) The timeliness of the services.

***DEFINITIONS* §483.*70*(g)**
"Timeliness" *means that services are completed and results are provided within the timeframe(s) specified in accordance with facility policies and procedures, the medical orders, or professional standards of practice; and that facility staff notifies the resident's physician, dentist, physician assistant, nurse practitioner or clinical nurse specialist as directed in the medical order.*

Effective November 28, 2017

F841
§483.*70(h)* Medical director.
§483.*70(h)*(1) The facility must designate a physician to serve as medical director.

§483.*70(h)*(2) The medical director is responsible for—
(i) Implementation of resident care policies; and
(ii) The coordination of medical care in the facility.

DEFINITIONS §483.*70*(h)
"Medical director" *means* a physician who oversees the medical care and other designated care and services in a health care organization or facility. Under these regulations, the medical director is responsible for coordinating medical care and helping to implement and evaluate resident care policies that reflect current *professional* standards of practice.

"Physician*/practitioner" (physician assistant, nurse practitioner, clinical nurse specialist)* means the *individual* who has responsibility for the medical care of a resident.

"Current *professional* standards of practice" refers to approaches to care, procedures, techniques, treatments, etc., that are based on research and/or expert consensus and that are contained in current manuals, textbooks, or publications, or that are accepted, adopted or promulgated by recognized professional organizations or national accrediting bodies.

"Resident care policies" *refers to* the facility's overall goals, directives, and governing statements that direct the delivery of care and services to residents consistent with current *professional* standards of practice.

GUIDANCE §483.*70*(h)
If the medical director does not hold a valid license to practice in the State where the nursing home is located refer to F839 - §483.70(f) Staff qualifications. The facility must designate a physician to serve as medical director (unless waived per §488.56(b) by CMS).

The facility must identify how the medical director will fulfill his/her responsibilities to effectively implement resident care policies and coordinate medical care for residents in the facility. This may be included in the medical director's job description or through a separate facility policy. Facilities and medical directors have flexibility on how all the duties will be performed. However, the facility must ensure all responsibilities of the medical director are effectively performed, regardless of how the task is accomplished or the technology used, to ensure residents attain or maintain their highest practicable physical, mental, and psychosocial well-being. For example, some, but not all, duties may be conducted remotely using various technologies (e.g., phone, email, fax, telehealth, etc., that is compliant with all confidentiality and privacy requirements).

It is important that the medical director's responsibilities require *that he/she* be knowledgeable about current *professional* standards of practice in caring for long term care residents, and about how to coordinate and oversee *other* practitioners.

If the medical director is also an attending physician, there should be a process to ensure there are no concerns with the individual's performance as a physician (i.e., otherwise, the medical director is monitoring his/her own performance). If there are concerns regarding his/her performance, the facility's administration should have a process for how to address these situations.

While medical directors who work for multi-facility organizations, *such as* corporate or regional offices, may *be involved in* policy development, the *facility's individual policies must be based on the facility's unique environment and its resident's needs, and not based on a broad, multi-facility structure.*

Although the medical director is not required to sign policies, the facility must be able to show that the development, review, and approval of resident care policies included his/her input.

Medical director responsibilities must include their participation in:

- *Administrative decisions including recommending, developing and approving facility policies related to residents care. Resident care includes the resident's physical, mental and psychosocial well-being;*
- *Issues related to the coordination of medical care identified through the facility's quality assessment and assurance committee and other activities related to the coordination of care;*
- *Organizing and coordinating physician services and services provided by other professionals as they relate to resident care;*
- *Participate in the Quality Assessment and Assurance (QAA) committee or assign a designee to represent him/her. (Refer to F865).*

Note: Having a designee does not change or absolve the Medical Director's responsibility to fulfill his or her role as a member of the QAA committee, or his or her responsibility for overall medical care in the facility.

In addition, the medical director responsibilities should include, but are not limited to:

- *Ensuring the appropriateness and quality of medical care and medically related care;*
- *Assisting in the development of educational programs for facility staff and other professionals;*
- *Working with the facility's clinical team to provide surveillance and develop policies to prevent the potential infection of residents. Refer to Infection Control requirement at §483.80;*
- *Cooperating with facility staff to establish policies for assuring that the rights of individuals (residents, staff members, and community members) are respected;*
- *Supporting and promoting person-directed care such as the formation* of advance directives, end-of-life care, and provisions that enhance resident decision making, including choice regarding medical care options*;*
- Identifying performance expectation*s* and facilitating feedback to physicians and other health care practitioners regarding their performance and practices;

- Discussing and intervening (as appropriate) with a health care practitioner regarding medical care that is inconsistent with current standards of care; and
- *Assisting in developing* systems to monitor the performance of the health care practitioners *including* mechanisms for communicating and resolving issues related to medical care *and* ensuring that other licensed practitioners (e.g., nurse practitioners) who may perform physician-delegated tasks act within the regulatory requirements and within the scope of practice as defined by State law.

PROCEDURES §483.*70*(h)

If a deficiency has been identified regarding a resident's care, also determine if the medical director had knowledge or should have had knowledge of a problem with care, or physician services, or lack of resident care policies and practices that meet current professional standards of practice and failed:

- *To get involved or to intercede with other physicians or practitioners in order to facilitate and/or coordinate medical care; and/or*
- *To provide guidance for resident care policies.*

Interview the medical director about his/her:

- *Involvement in assisting facility staff with resident care policies, medical care, and physician issues;*
- Understanding of *his/her* roles, *responsibilities* and functions and the extent *to which he/she receives support from facility management* for these roles and functions;
- *Process for providing feedback to physicians and other health care practitioners regarding their performance and practices, including discussing and intervening (as appropriate) with a health care practitioner regarding medical care that is inconsistent with current professional standards of care;*
- Input into the facility's scope of services including the capacity to care for residents with complex or special care needs, such as dialysis, hospice or end-of-life care, respiratory support with ventilators, intravenous medications/fluids, dementia and/or related conditions, or problematic behaviors or complex mood disorders;
- *His/her participation or involvement in conducting the Facility Assessment and the Quality Assessment and Assurance (QAA) Committee.*

Interview facility leadership (e.g., Administrator, Director of Nursing, and others as appropriate) about how *they interact* with the medical director related to the coordination of medical care, the facility's clinical practices *and concerns or issues with other physicians or practitioners.*

Also, refer to §483.30 Physician Services for more information.

KEY ELEMENTS OF NONCOMPLIANCE

To cite deficient practice at F841, the surveyor's investigation will generally show that the facility failed to do any of the following:

- *Designate a physician to serve as medical director;* ***or***
- *Ensure the medical director fulfilled his/her responsibility for the implementation of resident care policies or the coordination of medical care in the facility.*

Effective November 28, 2017

DEFICIENCY CATEGORIZATION

- ***An example of Level 4, immediate jeopardy to resident health and safety, includes, but is not limited to:***
  - *The facility's medical director was aware of and did not intervene when a health care practitioner continued over several months to provide inappropriate medical care for infection prevention to a resident that was inconsistent with current professional standards of care. As a result this resident's health continued to decline, and was hospitalized with a severe infection.*

- ***An example of Level 3, Actual harm (physical or psychological) that is not immediate jeopardy, includes, but is not limited to:***
  - *The Director of Nursing repeatedly requested the medical director's assistance in coordinating medical care with attending physicians for residents receiving psychotropic medications. In particular there were several physicians who had a known history of failing to provide justification for continued use of these medications and not attempting a gradual dose reduction for the residents under his/her care. As a result of the medical director's failure to intervene, several residents continued to receive these medications without medical/clinical justification. Based on record review and interviews with residents, their representative's and staff, there was no supporting evidence to indicate that an Immediate Jeopardy situation existed. However, due to the continuation of the use of these psychotropic medications, the residents withdrew from activities and from eating in the dining room. This caused decreased appetite and substantial weight loss for several residents. Actual harm, both physical and psychosocial was indicated. Unnecessary Medications, was also cited for not ensuring the residents were receiving the lowest dose possible.*

- ***An example of Level 2 - No actual harm with a potential for more than minimal harm that is not immediate jeopardy, includes but is not limited to:***
  - *The administrator had made multiple requests for the medical director to meet with physicians to ensure that they were familiar with the facility's resident care policies. At the time of the survey the medical director was interviewed and stated that she had not yet had an opportunity to introduce herself to or meet with physicians. Although no actual harm occurred, due the medical director's failure to ensure implementation of resident care policies, the potential for more than minimal harm existed.*

Level 1 - Severity 1 does not apply for this regulatory requirement

F842
§483.20(f)(5) Resident-identifiable information.
(i) A facility may not release information that is resident-identifiable to the public.
(ii) The facility may release information that is resident-identifiable to an agent only in accordance with a contract under which the agent agrees not to use or disclose the information except to the extent the facility itself is permitted to do so.

§483.*70(i)* Medical records.

Effective November 28, 2017

§483.*70(i)*(1) In accordance with accepted professional standards and practices, the facility must maintain *medical* records on each resident that are—

(i) Complete;
(ii) Accurately documented;
(iii) Readily accessible; and
(iv) Systematically organized

§483.*70(i)(2)* The facility must keep confidential all information contained in the resident's records, regardless of the form or storage method of the records, except when release is—

(i) *To the individual, or their resident representative where permitted by applicable law;*
(ii) *Required by* Law*;*
(iii) *For treatment,* payment*, or health care operations, as permitted by and in compliance with 45 CFR 164.506;*
(iv) For public health activities, reporting of abuse, neglect, or domestic violence, health oversight activities, judicial and administrative proceedings, law enforcement purposes, organ donation purposes, research purposes, or to coroners, medical examiners, funeral directors, and to avert a serious threat to health or safety as permitted by and in compliance with 45 CFR 164.512.

§483.*70(i)*(3) The facility must safeguard *medical* record information against loss, destruction, or unauthorized use.

§483.7*0(i)*(4) *Medical* records must be retained for—

(i) The period of time required by State law; or
(ii) Five years from the date of discharge when there is no requirement in State law; or
(iii) For a minor, *3* years after a resident reaches legal age under State law.

§483.7*0(i)*(5) The *medical* record must contain—

(i) Sufficient information to identify the resident;
(ii) A record of the resident's assessments;
(iii) The *comprehensive* plan of care and services provided;
(iv) The results of any preadmission screening *and resident review evaluations and determinations* conducted by the State;
(v) Physician, nurse, and other licensed professionals* progress notes*; and
(vi) Laboratory, radiology and other diagnostic services reports as required under §483.50.

GUIDANCE §483.*70*(i)

The medical record shall reflect a resident's progress toward achieving their person-centered plan of care objectives and goals and the improvement and maintenance of their clinical, functional, mental and psychosocial status. Staff must document a resident's medical and non-medical status when any positive or negative condition change occurs, at a periodic reassessment and during the annual comprehensive assessment. The medical record must also reflect the resident's condition and the care and services provided across all disciplines to ensure information is available to facilitate communication among the interdisciplinary team.

Effective November 28, 2017

The medical record *must* contain an accurate representation of the actual experience*s* of the *resident and include* enough information to provide a picture of the resident's progress, including *his/her* response to treatment*s and/or services*, and changes in *his/her condition, plan of care goals, objectives and/or interventions.*

Except for the annual comprehensive assessment, periodic reassessments when a significant change in status occurs, and quarterly monitoring assessments, regulations do not define the documentation frequency of a resident's progress. Professional standards of practice however suggests documentation include a resident's care plan implementation progress.

Resident Assessment Instrument (RAI) data is part of a resident's *medical* record and is protected from improper disclosure by facilities under current *Federal* law. Facilities are required by §§1819(c)(1)(A)(iv) and 1919(c)(1)(A)(iv) of the Act and §483.70(l)(2) and (l)(3) to keep confidential all information contained in the resident's medical record and to maintain safeguards against the unauthorized use of a resident's information, regardless of the storage method of the records.

At §483.20(f)(5), Resident-identifiable information, it requires that a facility may not release information that is resident-identifiable to the public and that the facility may release information that is resident-identifiable to an agent only in accordance with a contract under which the agent agrees not to use or disclose the information except to the extent the facility itself is permitted to do so. If a deficiency is identified related to this regulation cite the deficient practice here at F842.

Electronic Health Records (EHR) - *Facilities using an electronic format for medical or other resident documentation* (*for example, documenting progress notes, medication administration,* electronic claims filing, etc.) must comply with the *Health Insurance Portability and Accountability Act (HIPAA) privacy and security rules 45 CFR Parts 160 and 164*. Surveyors are not responsible for assessing compliance with *these rules.* The Department of Health and Human Services' Office for Civil Rights has primary responsibility for enforcing the HIPAA Privacy and Security Rules. The surveyors' responsibility is to assess compliance with the *regulatory requirement* for maintaining the content and confidentiality of the medical record. *If there are concerns that the facility's practice may constitute violations of the HIPAA privacy or security rules, refer these concerns to HHS' Office for Civil Rights.*

The facility is responsible for ensuring the backup of data and security of information. CMS encourages the development of systems that permit appropriate sharing of clinical information across providers, if the development of such systems is fully consistent with the requirement for protecting the confidentiality of the medical record.

Surveyors should not evaluate the features of the EHR system. Instead focus on how the EHR system is being used in the facility.

Use of Electronic Signatures – Electronic signatures are acceptable whether or not the record is entirely electronic. If a facility uses these signatures, they must have policies that identify those individuals who are authorized to sign electronically and describe the security safeguards to

prevent unauthorized use of these signatures. Such security safeguards include, but are not limited to, the following:

- Built-in safeguards to minimize the possibility of fraud;
- That each staff responsible for an attestation has an individualized identifier;
- The date and time is recorded from the computer's internal clock at the time of entry;
- An entry is not to be changed after it has been recorded, and;
- The computer program controls what sections/areas any individual can access or enter data, based on the individual's personal identifier (and, therefore his/her level of professional qualifications).

When rubber stamp signatures are authorized by the facility's management, the individual whose signature the stamp represents shall place in the administrative offices of the facility a signed statement to the effect that he/she is the only one who has the stamp and uses it. A list of computer codes and written signatures must be readily available and maintained under adequate safeguards. *Refer to §483.30(b) Physician Visits, for additional guidance.*

INVESTIGATIVE PROCEDURES* §483.*70(i)

When reviewing a resident's medical record, *determine if the record, including any archived information, is accessible to and* provide*s* sufficient information for *appropriate* staff to respond to the changing status and needs of the resident. *For example:*

- *Does the medical record provide sufficient information for staff to respond to the changing status and needs of the resident?*
- *How does the facility ensure medical records are accessible to staff?*
- *How does the facility handle the archiving of documentation?*

Interview facility staff to determine the facility's policies and practice for maintaining confidentiality of resident's records. Concerns regarding medical record confidentially, storage (including archiving) should be reviewed under this tag.

Determine through observations, record review and interviews:

- How facility *staff* ensure confidentiality of resident records?
- If there is a problem with confidentiality, is it systematic, that is, does the problem lie in the recordkeeping system, or with a staff person's use of records, e.g., leaving records in a place easily accessible to residents, visitors, or other unauthorized persons?
- Are computer screens showing information left unattended and readily observable or accessible by others not authorized to view this information?
- Are there documents publicly posted such as passwords or other information, which could be evidence of noncompliance with confidentiality?

Use of Electronic Records in the Survey Process

*T*here are no requirements *for* the use of Electronic Health Record (EHR) system*s, however if a* facility *uses an EHR system,* it must grant *access to the survey team timely (i.e., before the end of the first day of the survey)*. If access to an EHR is *required* by the surveyor, the facility will:

(a) provide the surveyor with *instructions, guidance, or information* on how to use its *EHR* system; and,

(b) designate an individual who will, when requested by the surveyor, access the system, respond to any questions or assist the surveyor as needed in a timely fashion.

*T*he facility must make available *to surveyors upon their request,* a printout of any record or part of a record. *Surveyors should only request printed copies when needed to support a potential deficient practice or if additional information is needed that is not contained in the EHR*.

If facility staff impedes the survey process by *purposefully and/or* unnecessarily delaying or restricting access to records *this* may lead to noncompliance and *potential* enforcement actions. *If this situation occurs surveyors should contact their supervisors and if needed they would then contact the CMS Regional Office for assistance.*

KEY ELEMENTS OF NONCOMPLIANCE

To cite deficient practice at F842, the surveyor's investigation will generally show that the facility failed to do any of the following:

- *Ensure resident-identifiable information was not released to the public or any unauthorized entity as stated in §483.20(f)(5)(ii); or*
- *Ensure that any resident-identifiable information released to an agent, was to an agent in accordance with a contract under which the agent agreed not to disclose any information the facility would not also be able to release publicly; or*
- *Maintain medical records on each resident in accordance with accepted professional standards and practices that are:*
  - *Complete;*
  - *Accurately documented;*
  - *Readily accessible; and*
  - *Systematically organized.*
- *Keep all information in the resident's records confidential, except when release is:*
  - *To the resident, or resident representative where permitted by applicable law; or*
  - *Required by law; or*
  - *For treatment, payment, or health care operations permitted and in compliance with 45 CFR §164.512; or*
  - *Allowed under the conditions of 483.70(i)(2)(iv).*
- *Safeguard medical record information against loss, destruction, or unauthorized use; or*
- *Retain medical records for:*
  - *The period of time required by State law; or*
  - *Five years from the date of discharge when there is no requirement in State law; or*
  - *Three years after a minor resident reaches legal age under State law; or*
- *Ensure the medical record contained:*
  - *Sufficient information to identify the resident;*
  - *A record of the resident's assessments;*
  - *The comprehensive plan of care and services provided;*
  - *The results of the pre admission PASARR Level 1 screening and subsequent evaluations and determinations;*
  - *Physicians, nurses, and other licensed professionals progress notes; or*
  - *Laboratory, radiology, and other diagnostic service reports.*

Effective November 28, 2017

F843
§483.*70(j)* Transfer agreement.
§483.*70(j)(*1) In accordance with section 1861(l) of the Act, the facility (other than a nursing facility which is located in a State on an Indian reservation) must have in effect a written transfer agreement with one or more hospitals approved for participation under the Medicare and Medicaid programs that reasonably assures that—

- **(i) Residents will be transferred from the facility to the hospital, and ensured of timely admission to the hospital when transfer is medically appropriate as determined by the attending physician *or, in an emergency situation, by another practitioner in accordance with facility policy and consistent with State law;* and**
- **(ii) Medical and other information needed for care and treatment of residents and, when the transferring facility deems it appropriate, for determining whether such residents can *receive appropriate services or receive services* in a less *restrictive* setting than either the facility or the hospital, *or reintegrated into the community* will be exchanged between the *providers, including but not limited to the information required under §483.15(c)(2)(iii).***

§483.*70(j)*(2) The facility is considered to have a transfer agreement in effect if the facility has attempted in good faith to enter into an agreement with a hospital sufficiently close to the facility to make transfer feasible.

***GUIDANCE* §483.*70*(j)**
A facility must demonstrate its good faith effort to secure a transfer agreement with a hospital. If a hospital that the facility reached out to refuses to accept a transfer agreement, determine if the facility reached out to any other hospitals.

A good faith effort is considered to have been made if the nursing home has exhausted all reasonable means and taken every necessary and appropriate step to enter into an agreement with a hospital sufficiently close to the facility to make the transfer of residents safe and orderly.

Also refer to §483.15 - Admission, transfer and discharge rights. Information in the transfer agreement should support the requirements in §483.15(c), F622 and the facility's efforts to ensure safe and orderly transfers. In addition, the agreement should include the information in §483.15(c)(2)(iii), and consider other information that may be necessary for the safe and orderly transfer of the resident, and care and treatment of the resident at the receiving setting.

KEY ELEMENTS OF NONCOMPLIANCE
To cite deficient practice at F843, the surveyor's investigation will generally show that the facility failed to do any one of the following:

- *Have a written transfer agreement in effect with one or more hospitals approved for participation in Medicare/Medicaid programs; or*
- *Ensure the transfer agreement(s) reasonably assured:*
  - *Residents will be transferred for timely admission to the hospital when medically appropriate; or*
  - *Medical or other information will be exchanged between the facility and the hospital:*
    - *Including, but not limited to the information required under §483.15(c)(2)(iii); or*

- *Information needed for resident care/treatment; or*
- *To determine whether the resident can be cared for in a less restrictive setting than either the facility or the hospital; or*

- *Attempt good faith efforts to enter into an agreement with a hospital sufficiently close to the facility to make the transfer safely and orderly.*

F844
§483.*70(k)* Disclosure of ownership.
§483.*70(k)*(1) The facility must comply with the disclosure requirements of §420.206 and 455.104 of this chapter.

§483.*70(k)*(2) The facility must provide written notice to the State Agency responsible for licensing the facility at the time of change, if a change occurs in—

(i) Persons with an ownership or control interest, as defined in §§420.201 and 455.101 of this chapter;
(ii) The officers, directors, agents, or managing employees;
(iii) The corporation, association, or other company responsible for the management of the facility; or
(iv) The facility's administrator or director of nursing.

§483.*70(k)*(3) The notice specified in paragraph (k)(2) of this section must include the identity of each new individual or company.

The following hyperlinks are included for surveyor reference only.
42 CFR §420.201 Disclosure of Ownership and Control: Definitions
42 CFR §420.206 Disclosure of Persons Having Ownership, Financial, or Control Interest
42 CFR §455.101 Disclosure of Information by Providers and Fiscal Agents: Definitions
42 CFR §455.104 Disclosure by Medicaid Providers and Fiscal Agents: Information on Ownership and Control

F845
§483.7*0(l)* Facility closure-Administrator.
Any individual who is the administrator of the facility must:

§483.*70(l)*(1) Submit to the State Survey Agency, the State LTC ombudsman, residents of the facility, and the legal representatives of such residents or other responsible parties, written notification of an impending closure:

(i) At least 60 days prior to the date of closure; or
(ii) In the case of a facility where the Secretary or a State terminates the facility's participation in the Medicare and/or Medicaid programs, not later than the date that the Secretary determines appropriate;

§483.*70(l)*(2) Ensure that the facility does not admit any new residents on or after the date on which such written notification is submitted; and

Effective November 28, 2017

§483.*70(l)*(3) Include in the notice the plan, that has been approved by the State, for the transfer and adequate relocation of the residents of the facility by a date that would be specified by the State prior to closure, including assurances that the residents would be transferred to the most appropriate facility or other setting in terms of quality, services, and location, taking into consideration the needs, choice, and best interests of each resident.

***GUIDANCE* §483.*70*(l)**

The closure plan is developed when a facility knows it is closing or upon involuntary termination of the Medicare/Medicaid provider agreement. The closure plan should be based on policies and procedures as required by §483.70(m).

An individual serving as the administrator of a skilled nursing facility (SNF), nursing facility (NF) or dually participating facility (SNF/NF) must provide written notification of an impending closure of a facility which also includes the plan for relocation of residents at least 60 days prior to the impending closure; or, if the Secretary terminates the facility's participation in Medicare or Medicaid, not later than the date the Secretary determines appropriate. Notice must be provided to the State Survey Agency, the State Long Term Care Ombudsman (State LTC), all the residents of the facility, and the legal representatives of residents or other responsible parties. An impending closure does not include events that may result in a temporary closure resulting from a local, regional, State or national emergency situation such as a fire, hurricane, or tornado.

In some cases, an administrator may not have direct control over an impending closure and implementing the facility's written notice and closure plans and procedures. For example, an administrator may be hired to oversee the facility's impending closure and he/she was not present when the decision was made to close the facility, or the administrator was employed less than 60 days prior to impending closure. However, this does not relieve the current administrator from implementing or developing the plans, procedures, and providing notifications as required. In this example, the administrator must provide the closure notice and plan as soon as possible and begin implementing the plans for closure working with the State Survey Agency for the orderly and safe transfer, discharge and relocation of all residents. The new administrator or other temporary manager hired to assist with the facility closure must develop and/or implement the closure plans and work closely with the State Survey Agency and CMS Regional Office (CMS RO) to ensure that appropriate procedures are implemented.

In a situation in which notice requirements were not met by the previous or current administrator, the State Survey Agency and the CMS RO may take action against the administrator as permitted under §488.446. Refer to Chapter 7 of the State Operations Manual for more information on enforcement actions in these situations.

For all impending closures, the facility needs to submit its closure plan to the State Survey Agency for review and approval. The closure plan must contain the information necessary to identify the steps for a safe and orderly facility closure, including the transfer, discharge or relocation of all residents and identify the individual(s) responsible for ensuring the plans and procedures are successfully carried out.

Effective November 28, 2017

If CMS or the State Medicaid Agency involuntarily terminates the facility's participation in the Medicare and/or Medicaid programs, the facility's notifications must be no later than the date specified by CMS or the State Medicaid Agency. Notice must still be given if the facility remains open but CMS or the State Medicaid Agency involuntarily terminates the facility's participation in the Medicare and/or Medicaid programs.

In addition, the administrator or someone acting on behalf of the administrator should notify in writing, prior to the impending closure of the facility, the:

- *Facility's Medical Director;*
- *Residents' primary physician;*
- *CMS Regional Office (RO); and*
- *State Medicaid Agency.*

Although not required, facilities are encouraged to provide notice to other entities that are impacted, such as employees, union representatives, vendors, community partners, hospitals, home health agencies, dialysis facilities and other providers as early as possible.

The facility's notifications should be developed with input from the facility's medical director and other management staff, and include details from the closure plan for the safe and orderly transfer, discharge or adequate relocation of all residents.

In addition to written notification, facility staff should discuss this information with residents, their families and/or legal representatives in order to provide a better understanding of the closure and their rights. Notice of facility closure to residents and their legal or other responsible parties must be provided in a language and manner they understand.

Facility staff should make every possible effort to lessen transfer trauma for residents, which may include:

- *Reviewing the resident's care routines, needs, and preferences with staff at the receiving facility who will be caring for the resident, and*
- *Assisting residents and or their representatives with obtaining information required to make an informed decision about facility relocation.*

Also refer to §483.15(c) Transfer and discharge requirements.

The notice must include:

- *The name, address, and telephone number of the State LTC ombudsman;*
- *For residents with developmental disabilities, the mailing address and telephone number of the agency responsible for the protection and advocacy of developmentally disabled individuals established under Part C of the Developmental Disabilities Assistance and Bill of Rights Act; and*
- *For residents with mental illness, the mailing address and telephone number of the agency responsible for the protection and advocacy of individuals with mental illness established under the Protection and Advocacy for Mentally Ill Individuals Act.*

In addition, the notice should include contact information for the primary facility contact(s) responsible for the daily operation and management of the facility during the facility's closure process.

KEY ELEMENTS OF NONCOMPLIANCE

To cite deficient practice at F845, the surveyor's investigation will generally show that the facility failed to do any one of the following:

- *Provide prior notice of an impending closure to the appropriate parties as required;* ***or***
- *Ensure no new residents continued to be admitted to the facility on or after the date of the notice of impending closure was submitted;* ***or***
- *Ensure residents were transferred, discharged or relocated to the most appropriate and available facility or other setting in terms of quality, services, and location, taking into consideration the needs, choice, and best interests of each resident.*

F846

§483.*70(m)* Facility closure.

The facility must have in place policies and procedures to ensure that the administrator's duties and responsibilities involve providing the appropriate notices in the event of a facility closure, as required at paragraph (l) of this section.

***GUIDANCE* §483.*70*(m)**

Policies and procedures must be in place at all times in order to be used in the case of a facility closure or in case of termination of a facility's Medicare and/or Medicaid Provider Agreement, in order to meet the requirements of §483.70(l) The policies and procedures must address:

- *The administrator's duties and responsibilities as required per §483.70(l) for submitting a closure plan and providing timely written notice to the State Survey Agency, the State LTC Ombudsman, residents of the facility, and the legal representatives of residents or other responsible parties, including the CMS Regional Office (RO), the State Medicaid Agency, and staff responsible for providing care and services to residents;*
- *How facility staff will identify available settings in terms of quality, services, and location, by taking into consideration each resident's individual needs, choices, and best interests. The facility may not close until all residents are transferred, relocated or discharged in a safe and orderly manner to the most appropriate setting; and*
- *Assurance that no new residents will be admitted to the facility on or after the date that the written notice of impending closure was provided to the State Survey Agency;*

To ensure resident safety during a facility closure or termination of a facility's Medicare and/or Medicaid Provider Agreement, the policies and procedures should also address:

- *How facility staff will ensure that all pertinent information about each resident is communicated to the receiving provider in accordance with §483.15(c)(2)(iii), and each resident's complete medical record information including archived files, Minimum Data Set (MDS) assessments, and all orders, recommendations or guidelines from the resident's attending physician;*
- *In addition to the administrator, the primary contact(s) responsible for the daily operation and management of the facility during the facility's closure process;*

- *The roles and responsibilities of the facility's owners, administrator, or their replacement(s) or temporary managers/monitors during the closure process, and their contact information;*
- *Provisions for ongoing operations and management of the facility and its residents and staff during the closure process that include:*
  - *Payment of salaries and expenses to staff, vendors, contractors, etc.;*
  - *Continuation of appropriate staffing and resources to meet the needs of each resident, including the provision of medications, services, supplies, and treatments as ordered by the resident's physician/practitioner;*
  - *Ongoing accounting, maintenance, and reporting of resident personal funds; and*
  - *Labeling, safekeeping and appropriate transfer of resident's personal belongings, such as clothing, medications, furnishings, etc. at the time of transfer or relocation, including contact information for missing items after the facility has closed.*

The facility's policies and procedures should also consider certain provisions to prepare residents to ensure a safe and orderly transfer from the facility. These provisions include, but are not limited to:

- *Interviewing residents and their legal or other responsible parties, to determine each resident's goals, preferences, and needs in planning for the services, location, and setting to which they will be moved;*
- *Offering each resident (in a manner and language understood by the resident) the opportunity to obtain information regarding their community options, including setting and location;*
- *Providing residents with information or access to information pertaining to the quality of the providers and/or services they are considering; psychological preparation or counseling of each resident as necessary; and*
- *Making every reasonable effort to accommodate each resident's goals, preferences and needs regarding receipt of services, location, and setting.*

PROCEDURES* §483.*70(m)

Once notified of a facility's impending closure, if a copy of the facility's plan for the transfer and relocation of the residents was not included with the notice, the State Survey Agency should immediately request a copy of the facility's closure plan for their review and approval. In addition, the State Survey Agency should request the facility's admissions records to verify that no new residents have been admitted on or after the date that the notice of closure was provided.

A resident who had been temporarily transferred to an acute care setting, is on bed hold, or is on a temporary leave would not be considered to be a new admission upon return to the facility. However, each of these situations may need to be evaluated on a case by case basis in order to determine if the clinical care or social needs of the resident may continue to be met by the facility if transferred back to the facility in closure. If it is determined that the clinical care or social needs of the resident cannot be met by the closing facility and the resident is not transferred back to the closing facility, the same notice requirements specified above apply to the resident and the resident's legal representatives, other responsible parties, and other parties as if the resident was still living in the facility.

Interview the administrator and other individual(s) responsible for managing, overseeing, coordinating and implementing the plan to evaluate how each component of the plan is being operationalized.

NOTE: The review of certain components such as an evaluation of the facility's closure plan, policies and procedures may be conducted off-site by the State Survey Agency and may include assistance from the State LTC Ombudsman as the State Survey Agency deems suitable and necessary.

When conducting an onsite survey prior to the impending closure, tour the facility and interview staff including the medical director, residents, and family. Determine their involvement in and/or knowledge of the facility closure plans and the resident transfer procedures. Determine through observation, interview, and record review, as applicable:

- *That the delivery of resident care and services are continuing to be provided, monitored and supervised based upon the assessed needs and choices of each resident. If problems are noted it may be necessary to further investigate and review other quality of care regulations as appropriate. Do not cite quality of care issues under the Facility Closure regulations;*
- *Whether written notices were provided timely and that the notice included the expected date of the resident's transfer to another facility or other setting; and*
- *How the facility involved the resident, his/her legal representative or other responsible party, and the resident's primary physician to determine the resident's goals, preferences and needs in planning for the services, location and setting to which they will be moved.*

NOTE: Refer to §483.15 for guidance for the post-discharge plan of care for an anticipated discharge which applies to a resident whom the facility discharges to a private residence or other home and community based setting, to another nursing home, or to another type of residential facility such as a board and care home or an intermediate care facility for individuals with intellectual disabilities or mental illness.

NOTE: §§488.426(a)(1) and(2) - Transfer of residents, or closure of the facility and transfer of residents, gives authority to the State for temporary facility closure in emergency situations. If the State Survey Agency approves a facility's temporary relocation of residents during an emergency with the expectation that the residents will return to the facility, this would not be regarded as a facility closure under these requirements and the notification requirements would not be applicable. However, if a facility ultimately closes permanently due to an emergency, the administrator is required to provide proper notifications and follow the procedures outlined in this guidance.

F849

§483.70(o) Hospice services.

§483.70(o)(1) A long-term care (LTC) facility may do either of the following:

- ***(i) Arrange for the provision of hospice services through an agreement with one or more Medicare-certified hospices.***
- ***(ii) Not arrange for the provision of hospice services at the facility through an agreement with a Medicare-certified hospice and assist the resident in transferring to a facility***

that will arrange for the provision of hospice services when a resident requests a transfer.

§483.70(o)(2) If hospice care is furnished in an LTC facility through an agreement as specified in paragraph (o)(1)(i) of this section with a hospice, the LTC facility must meet the following requirements:

- *(i) Ensure that the hospice services meet professional standards and principles that apply to individuals providing services in the facility, and to the timeliness of the services.*
- *(ii) Have a written agreement with the hospice that is signed by an authorized representative of the hospice and an authorized representative of the LTC facility before hospice care is furnished to any resident. The written agreement must set out at least the following:*
  - *(A) The services the hospice will provide.*
  - *(B) The hospice's responsibilities for determining the appropriate hospice plan of care as specified in §418.112 (d) of this chapter.*
  - *(C) The services the LTC facility will continue to provide based on each resident's plan of care.*
  - *(D) A communication process, including how the communication will be documented between the LTC facility and the hospice provider, to ensure that the needs of the resident are addressed and met 24 hours per day.*
  - *(E) A provision that the LTC facility immediately notifies the hospice about the following:*
    - *(1) A significant change in the resident's physical, mental, social, or emotional status.*
    - *(2) Clinical complications that suggest a need to alter the plan of care.*
    - *(3) A need to transfer the resident from the facility for any condition.*
    - *(4) The resident's death.*
  - *(F) A provision stating that the hospice assumes responsibility for determining the appropriate course of hospice care, including the determination to change the level of services provided.*
  - *(G) An agreement that it is the LTC facility's responsibility to furnish 24-hour room and board care, meet the resident's personal care and nursing needs in coordination with the hospice representative, and ensure that the level of care provided is appropriately based on the individual resident's needs.*
  - *(H) A delineation of the hospice's responsibilities, including but not limited to, providing medical direction and management of the patient; nursing; counseling (including spiritual, dietary, and bereavement); social work; providing medical supplies, durable medical equipment, and drugs necessary for the palliation of pain and symptoms associated with the terminal illness and related conditions; and all other hospice services that are necessary for the care of the resident's terminal illness and related conditions.*
  - *(I) A provision that when the LTC facility personnel are responsible for the administration of prescribed therapies, including those therapies determined appropriate by the hospice and delineated in the hospice plan of care, the LTC facility personnel may administer the therapies where permitted by State law and as specified by the LTC facility.*

(J) A provision stating that the LTC facility must report all alleged violations involving mistreatment, neglect, or verbal, mental, sexual, and physical abuse, including injuries of unknown source, and misappropriation of patient property by hospice personnel, to the hospice administrator immediately when the LTC facility becomes aware of the alleged violation.

(K) A delineation of the responsibilities of the hospice and the LTC facility to provide bereavement services to LTC facility staff.

§483.70(o)(3) Each LTC facility arranging for the provision of hospice care under a written agreement must designate a member of the facility's interdisciplinary team who is responsible for working with hospice representatives to coordinate care to the resident provided by the LTC facility staff and hospice staff. The interdisciplinary team member must have a clinical background, function within their State scope of practice act, and have the ability to assess the resident or have access to someone that has the skills and capabilities to assess the resident. The designated interdisciplinary team member is responsible for the following:

(i) Collaborating with hospice representatives and coordinating LTC facility staff participation in the hospice care planning process for those residents receiving these services.

(ii) Communicating with hospice representatives and other healthcare providers participating in the provision of care for the terminal illness, related conditions, and other conditions, to ensure quality of care for the patient and family.

(iii) Ensuring that the LTC facility communicates with the hospice medical director, the patient's attending physician, and other practitioners participating in the provision of care to the patient as needed to coordinate the hospice care with the medical care provided by other physicians.

(iv) Obtaining the following information from the hospice:

(A) The most recent hospice plan of care specific to each patient.

(B) Hospice election form.

(C) Physician certification and recertification of the terminal illness specific to each patient.

(D) Names and contact information for hospice personnel involved in hospice care of each patient.

(E) Instructions on how to access the hospice's 24-hour on-call system.

(F) Hospice medication information specific to each patient.

(G) Hospice physician and attending physician (if any) orders specific to each patient.

(v) Ensuring that the LTC facility staff provides orientation in the policies and procedures of the facility, including patient rights, appropriate forms, and record keeping requirements, to hospice staff furnishing care to LTC residents.

§483.70(o)(4) Each LTC facility providing hospice care under a written agreement must ensure that each resident's written plan of care includes both the most recent hospice plan of care and a description of the services furnished by the LTC facility to attain or maintain the resident's highest practicable physical, mental, and psychosocial well-being, as required at §483.24.

Effective November 28, 2017

DEFINITIONS **§483.*70(o)***

"Hospice care" *means a comprehensive set of services described in Section 1861(dd)(1) of the Social Security Act, identified and coordinated by an interdisciplinary group (IDG) to provide for the physical, psychosocial, spiritual, and emotional needs of a terminally ill patient and/or family members, as delineated in a specific patient plan of care. (42 CFR §418.3) Note: These services are provided by a Medicare-certified hospice.*

"Hospice Attending Physician" *- This clarifies that a doctor of medicine, osteopathy or nurse practitioner, if meeting the listed requirements, may function as the "attending physician" in a hospice. The hospice regulations do not provide for a physician assistant to function as the hospice attending physician. §418.3 Definitions. For the purposes of this part — "Attending physician" means a —*

(1)(i) Doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he or she performs that function or action; or

(ii) Nurse practitioner who meets the training, education, and experience requirements as described in §410.75 (b) of this chapter.

(2) Is identified by the individual, at the time he or she elects to receive hospice care, as having the most significant role in the determination and delivery of the individual's medical care.

In a nursing home, a physician's assistant may not act as the hospice attending physician, however, the resident's attending physician at the nursing home may delegate tasks to a physician's assistant per F714 - §483.30(e)(1).

"Palliative care" *- means patient and family-centered care that optimizes quality of life by anticipating, preventing, and treating suffering. Palliative care throughout the continuum of illness involves addressing physical, intellectual, emotional, social, and spiritual needs and to facilitate patient autonomy, access to information, and choice. (§418.3)*

"Terminally ill" *- means that the individual has a medical prognosis that his or her life expectancy is 6 months or less if the illness runs its normal course. (§418.3)*

"Bereavement counseling" *- means emotional, psychosocial, and spiritual support and services provided before and after the death of the patient to assist with issues related to grief, loss, and adjustment. (§418.3)*

GUIDANCE **§483.*70(o)***

Provision Of Hospice Services In A Nursing Home

As described in §§483.70(o)(1)(i),(ii),there is no requirement that a nursing home allow a hospice to provide hospice care and services in the facility. If a nursing home has made arrangements with one or more hospices to provide services in the nursing home, there must be a written agreement describing the responsibilities between each hospice and the nursing home prior to the hospice initiating care for a resident who has elected the hospice benefit. The written agreement applies to the provision of all hospice services for any nursing home resident receiving services from the specific hospice and does not need to be rewritten for each resident.

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If the nursing home has a written agreement(s) with one or more hospice provider(s), it must, in accordance with F581-§483.10(g)(16), inform each resident before, or at the time of admission, and periodically during the resident's stay, of hospice, among other services, available in the nursing home. If the nursing home has an agreement with more than one hospice, this information must be provided to the resident/designated representative in order to allow choice of the hospice provider he/she prefers.

If a resident chooses a hospice that does not have an agreement with the nursing home:

- *The nursing home may establish a written agreement with the hospice and allow the hospice provider to provide hospice services in the nursing home; or*
- *The nursing home must assist the resident, when the resident requests, in transferring to a nursing home of his/her choice that has an agreement or will arrange for the provision of hospice services with a hospice; or in relocating to a non-nursing home setting (e.g. inpatient hospice unit, private home, or residential/assisted living facility) that uses the hospice of his/her choice; or*
- *The resident may choose not to elect the hospice benefit and continue to reside in the nursing home with the attending physician/practitioner of their choice and receive nursing home care and services.*

If the nursing home or the hospice terminates the written agreement, the nursing home:

- *Must provide assistance to affected residents in contacting or selecting another hospice provider(s) with which the nursing home has or will enter into a written agreement; or*
- *When the resident requests, assist the resident in transferring to a nursing home of his/her choice that has an agreement or will enter into an agreement for the provision of hospice services; or in relocating to a non-nursing home setting (e.g. inpatient hospice unit, private home, or residential/assisted living facility) that uses the hospice of his/her choice; or*
- *The resident may choose to revoke the hospice benefit and continue to reside in the nursing home with the attending physician/practitioner of their choice and receive nursing home care and services.*

NOTE: When a resident/designated representative requests and/or initiates a discharge to another facility or location, the nursing home is not required to provide a notice of discharge and/or transfer as it is not a nursing home initiated transfer/discharge. This applies in the situation, in which there is no written agreement for hospice services, and/or the resident chooses a hospice with which the nursing home does not have a written agreement, and the nursing home chooses not to establish such an agreement.

Nursing Home Ensures Professional Standards and Timeliness of Services

As described in §483.70(o)(2)(i) the nursing home must ensure that services provided by the hospice (including the individuals providing the services) meet professional standards and principles, that the services and care meet the assessed needs of each resident, and that the hospice is certified for participation in the Medicare program. (Refer to F675 and F658.) The nursing home and hospice must assure that all physician/practitioners meet State licensure requirements and are working within their scope of practice and professional State licensure requirements.

The nursing home staff must monitor the delivery of care in order to assure that the hospice provides services to the resident in a way that meets his/her needs in a timely manner including:

- *Observation of interactions and care provided by the hospice staff sufficient to assure that the hospice services meet the professional standards of care;*
- *Interviews with the resident/designated representative regarding hospice care and services; and*
- *Review of the resident's record for pertinent documentation regarding the delivery of hospice care.*

For example, if a resident has an increase in pain that is not being managed by the current interventions, or if current interventions may be causing adverse consequences that are distressing to the resident, the requirement that the nursing home ensure the provision of timely hospice services would include notifying the hospice of the resident's change in condition so that the hospice, in consultation with the nursing home and the resident's attending physician/practitioner, can reassess the resident and with input from the resident/designated representative, change the plan of care, as indicated, to assure the resident receives the treatment necessary to achieve his/her optimal comfort level.

Signed Written Agreement with Hospice Prior to Provision of Care

As described in §483.70(o)(2)(ii)(A), the written agreement must be signed by authorized representatives of the hospice and the nursing home prior to the provision of hospice services.

The hospice retains primary responsibility for the provision of hospice care and services, based upon the resident's assessments and choices. According to hospice regulations at §418.100(c)(2) - "Nursing services, physician services, and drugs and biologicals (as specified in §418.106) must be made routinely available on a 24-hour basis 7 days a week. Other covered services must be available on a 24-hour basis when reasonable and necessary to meet the needs of the patient and family." Other covered services include counseling (including spiritual, dietary and bereavement), social work, hospice aide, volunteer, and homemaker services, physical therapy, occupational therapy, and speech-language pathology services, short-term inpatient care, drugs, biologicals, and medical appliances related to the palliation and management of the terminal illness and related conditions. (§418.112(c)(6))

Hospice Plan of Care

As described in §483.70(o)(2)(ii)(B), when a hospice patient is a resident of a nursing home, the hospice must establish the hospice plan of care in coordination with the nursing home, the resident's nursing home attending physician/practitioner, and to the extent possible, the resident/designated representative.

In order to provide continuity of care, the hospice and the nursing home must collaborate in the development of a coordinated plan of care for each resident receiving hospice services. The structure of the plan of care is established by the nursing home and the hospice. The coordinated plan of care must identify the provider responsible for performing each or any specific services/functions that have been agreed upon. The plan of care may be divided into two portions, one maintained by the nursing home and the other maintained by the hospice. The

nursing home and the hospice must be aware of the location and content of the coordinated plan of care (which includes the nursing home portion and the hospice portion) and the plan must be current and internally consistent in order to assure that the needs of the resident for both hospice care and nursing home care are met at all times.

The nursing home must designate a member of the nursing home's interdisciplinary team who is responsible for working with hospice to coordinate care for the resident. (See §483.70(o)(3)(i) below.) In addition, different nursing home staff, who are knowledgeable regarding the resident's care, may also work with hospice staff in the development of the plan of care. The hospice coordinator must provide ongoing coordination and collaboration with the nursing home coordinator, the resident's attending physician/practitioner and the resident/designated representative regarding changes to the resident's plan(s) of care.

Based on the shared communication between the hospice and the nursing home, the coordinated plan(s) of care should reflect the identification of:

- *Diagnoses;*
- *A common problem list;*
- *Palliative interventions;*
- *Palliative goals/objectives;*
- *Responsible discipline(s);*
- *Responsible provider(s); and*
- *Resident/designated representative choices regarding care and goals.*

Nursing Home Responsibilities

As described in §483.70(o)(2)(ii)(C), the nursing home retains primary responsibility for implementing those aspects of care that are not related to the duties of the hospice. The nursing home's services must be consistent with the plan of care developed in coordination with the hospice, and the nursing home must offer the same services to its residents who have elected the hospice benefit as it furnishes to its residents who have not elected the hospice benefit. Therefore, the hospice patient residing in a nursing home should not experience any lack of services or personal care because of his or her status as a hospice patient. This includes what would normally be provided to a resident in the nursing home, including but not limited to the following: conducting the comprehensive assessments which includes the Resident Assessment Instrument (RAI), providing personal care, activities, medication administration, required physician visits, monthly medication regimen review, support for activities of daily living, social services as appropriate, nutritional support and services, and monitoring the condition of the resident. The nursing home must maintain an environment in which there are no inappropriate signs posted in residents' rooms or in staff work areas visible by other residents and/or visitors that include confidential clinical or personal information, such as information about hospice services. (Refer to F550, Dignity.)

Communication Process Between Nursing Home and Hospice

As described in §483.70(o)(2)(ii)(D), the written agreement must specify a process for communicating necessary information regarding the resident's care between the nursing home

and the hospice 24-hours a day, 7-days a week including how these communications will be documented.

Both the hospice and the nursing home may document physician orders in the resident's nursing home record. Orders are to be dated and signed in accordance with Federal requirements (Refer to F711 – physician orders) and any applicable State laws. There is no Federal regulation that prohibits nursing home staff from taking orders for care from the hospice physician. Any changes to orders initiated by the hospice should be communicated to the resident's attending physician/practitioner in a timely manner. The nursing home must communicate with the hospice regarding orders provided by the resident's attending physician/practitioner in the nursing home, if he/she is not the resident's designated physician on the hospice team. Prior to plan of care or order changes the hospice physician and the resident's attending physician/practitioner may need to collaborate to address an emergent change in the resident's condition and to assure the resident's needs are met. If there is a conflict between orders given by hospice and the resident's attending physician/practitioner, there must be communication between the nursing home and the hospice regarding the issue. This communication should include the nursing home medical director and the hospice medical director as well as other pertinent staff as needed.

Notifying Hospice Regarding Clinical Changes

As described in §483.70(o)(2)(ii)(E), the written agreement must include a provision that the nursing home will immediately contact and communicate with the hospice staff regarding any significant changes in the resident's status, clinical complications or emergent situations. Situations include, but are not limited to, changes in cognition or sudden unexpected decline in condition, a fall with a suspected fracture or adverse consequences related to a medication or therapy, or other situations requiring a revision to the plan of care. The immediate notification to hospice does not change the requirement that a nursing home must also immediately notify the resident's attending physician/practitioner. Prior to plan of care or order changes, the hospice and the resident's attending physician/practitioner may need to collaborate to address this change and to assure that the resident's immediate and ongoing treatment and care needs are met in accordance with the resident's decisions and advance directives regarding end of life care are met, including situations which could require a potential transfer to an acute care setting. This decision making must be consistent with the resident's wishes and most current version of advance directive, if any. (Refer to F578) If there is a conflict between the nursing home and the hospice regarding the course of hospice care or level of service, there must be communication between the nursing home and the hospice regarding the issue. This communication should include the nursing home medical director and the hospice medical director as well as other pertinent staff, as needed.

Hospice Determines Level of Hospice Services

As described in §483.70(o)(2)(ii)(F), the written agreement must state that the hospice assumes responsibility for professional management of the resident's hospice services provided, in accordance with the hospice plan of care and the hospice conditions of participation, and make any arrangements necessary for hospice-related inpatient care in a participating Medicare/Medicaid facility (§418.112(b)).

The agreement must also include language that the hospice assumes the responsibility for determining the level of hospice services. Any substantive changes in the level of hospice services must be developed by the hospice and these changes must be reflected in the coordinated plan of care. These changes should be made in collaboration with the resident/designated representative, the resident's attending physician/practitioner, and nursing home staff.

Nursing Home Responsibilities for Personal Care and Nursing Needs in Coordination with Hospice

As described in §483.70(o)(2)(ii)(G), the provisions of the written agreement must delineate how the care and needs will be provided based upon the resident's identified needs.

It is the nursing home's responsibility to continue to furnish 24-hour room and board care, meeting the resident's personal care and nursing needs. Services provided must be consistent with the plan of care developed in coordination with the hospice Interdisciplinary Group (IDG).

Delineation of Hospice Responsibilities

As described in §483.70(o)(2)(ii)(H), to comply with this requirement, the written agreement must contain a clear statement that the hospice assumes responsibility for determining the appropriate course of hospice care to be provided and delineate the services that the hospice is required to provide to the resident (not already covered by the nursing home through the provision of room and board and services to meet the resident's personal care and nursing needs as required by §483.70(o)(2)(ii)(G)).

When the resident elects the hospice benefit, the resident may choose to specify his/her nursing home attending physician/practitioner as the hospice attending physician. If the resident does not choose his/her nursing home attending physician, he/she may select another physician/practitioner as the hospice attending physician.

The hospice IDG in collaboration with the resident's nursing home attending physician/practitioner is responsible for the palliation and management of specified aspects of care, based on the agreement. The agreement identifies the process for developing the plan of care in collaboration with the resident's attending physician/practitioner and includes the process to be followed to reconcile disagreements between the resident's attending physician/practitioner and hospice physician.

NOTE: *The nursing home regulations at F710 - Physician Supervision), requires that "The facility must ensure that another physician supervises the medical care of residents when their attending physician is unavailable." According to the hospice CoPs at §418.64(a) and (a)(3) - Standard: Physician services, "The hospice medical director, physician employees, and contracted physician(s) of the hospice, in conjunction with the patient's attending physician, are responsible for the palliation and management of the terminal illness and conditions related to the terminal illness…(3) If the attending physician is unavailable, the medical director, contracted physician, and/or hospice physician employee is responsible for meeting the medical needs of the patient."*

The written agreement must identify how the nursing home will obtain information regarding the provision of medical care including medication information from the hospice, and should include the identification of hospice non-physician practitioners who, according to State law, may provide orders for medical care of the resident.

Nursing Home Responsibilities for Administration of Prescribed Therapies
As described in §483.70(o)(2)(ii)(I), the written agreement must include the provision that the LTC facility personnel may administer therapies where permitted by State law and as specified by the LTC facility as noted in the coordinated plan of care.

Report to Hospice any Alleged Violations of Mistreatment, Neglect, Verbal, Mental, Sexual, and Physical Abuse Including Injuries of Unknown Source and/or Misappropriation of Property by Hospice Personnel
As described in §483.70(o)(2)(ii)(J), the nursing home must follow all of the requirements within §483.12(a)(b) and (c), Free From Abuse…(F600-610) for the prevention, identification, protection, reporting and investigation of allegations of abuse, neglect, verbal, mental, sexual abuse, mistreatment and injuries of unknown source. This also includes prohibiting taking and/or posting photos or recordings that are demeaning and or humiliating to a nursing home resident or the use of an authorized photo or recording in a demeaning/humiliating manner. The privacy and confidentiality of the resident's care and records must be maintained. (Refer to F583 - Privacy and Confidentiality).

The nursing home must also notify the hospice administrator of any such allegations involving hospice employees and contractors and anyone else providing services on behalf of the hospice and the outcome of its investigation.

NOTE: *The hospice must follow the requirements as indicated in the Federal regulations at §418.52(b)(4)(i-iv) for reporting, investigating and taking appropriate corrective actions.*

Responsibilities for Bereavement Services for Nursing Home Staff
As described in §483.70(o)(2)(ii)(K), the death of the resident may have a direct impact on identified nursing home staff. The written agreement should specify when the nursing home should provide information to the hospice regarding nursing home staff that may benefit from bereavement services. The written agreement between the hospice and the nursing home should specify how bereavement services will be coordinated and operationalized by the hospice provider for nursing home staff. The written agreement must include a description of the nursing home's role in providing such services. These services should be individualized based on the resident involved and the staff involvement in their care. In the case of several hospices offering services in a nursing home, each hospice's written agreement must include the provision regarding bereavement services for staff as noted above.

NOTE: *According to the hospice CoPs at §418.64(d) - Counseling services must include, but are not limited to, the following: (1) - Bereavement counseling. The hospice must: (ii) "Make bereavement services available to the family and other individuals in the bereavement plan of care up to 1 year following the death of the patient. Bereavement counseling also extends to*

residents of a SNF/NF or ICF/MR when appropriate and identified in the bereavement plan of care."

Nursing Home Designee(s) Responsibilities

As described in §483.70(o)(3)(i)-(v), the nursing home must identify and designate, in writing, an employee of the nursing home to assume the responsibilities for collaborating and coordinating activities between the nursing home and the hospice. The nursing home employee must have a clinical background, function within their State scope of practice act, and have the ability to assess the resident or have access to someone that has the skills and capabilities to assess the resident. The designated nursing home coordinator should be familiar with hospice philosophy and practices. The nursing home should provide the name of the designated nursing home staff member to the resident/representative for ongoing communication regarding care or concerns. If the designated employee is not available, the nursing home may delegate this function to another nursing home employee who meets the requirements identified above. It should be noted that in nursing homes contracting with more than one hospice, the nursing home may designate more than one/different employees to serve as coordinator with the respective hospice(s). Due to the complex clinical needs of a resident who is in the terminal stages of life, the interdisciplinary team member must have the ability to assess the resident or have access to someone who has the ability to assess the resident.

The communication process established should include a system for the designated interdisciplinary team member to obtain the information as identified at §483.70(o)(3) (iv) A-G. The resident's nursing home record must have evidence of this information.

The designated employee is responsible for assuring that orientation is provided to hospice staff.

This orientation is meant to address the overall facility environment including policies, rights, record keeping and forms requirements. It is important for the nursing home to document and have available information regarding hospice staff orientation.

NOTE: *Refer to § 418.112(f). In addition to the orientation that nursing homes must provide to hospice staff, hospices must provide orientation to nursing home staff providing care for hospice patients. The orientation requirements while separate regulations for both the nursing home and hospice, should be a collaborative effort to assure that the hospice employees provide services and care effectively in the nursing home and that the hospice ensures that the nursing home staff understands the basic philosophy and principles of hospice care. If a nursing home has written agreements with multiple hospice providers, the nursing home should collaborate with each hospice to assure that the nursing home staff are familiar with specific policies and procedures for each individual hospice. It may not be necessary for each hospice to provide information to nursing home staff regarding the hospice philosophy and principles of care if the nursing home staff has received this information and are aware of the philosophy and principles of care.*

Provision of Current, Coordinated Plan of Care

As described in §483.70(o)(4), the intent of this regulation is to ensure coordination of care between the nursing home and the hospice in order to assure that the most current plans of care

for each resident have been coordinated, individualized and identify what each entity will provide.

KEY ELEMENTS OF NONCOMPLIANCE

To cite deficient practice at F849, the surveyor's investigation will generally show that the facility failed to do any one of the following:

- *Develop a written agreement with the Medicare-certified hospice prior to hospice services being provided to a resident;* ***or***
- *Establish a communication process, including how the communication will be documented between the LTC facility and the hospice provider, to ensure that the needs of the resident are addressed and met 24 hours per day;* ***or***
- *In accordance with the written agreement to immediately notify the hospice about a significant change in the resident's condition, or the presence of clinical complications that suggest a need to alter the plan of care, or a need to transfer the resident from the facility or of the resident's death;* ***or***
- *To designate a member of the facility's interdisciplinary team who is responsible for working with hospice representatives to coordinate care to the resident provided by the LTC facility staff and hospice staff;* ***or***
- *Ensure that each resident's written plan of care includes both the most recent hospice plan of care and a description of the services furnished by the LTC facility to attain or maintain the resident's highest practicable physical, mental, and psychosocial well-being;* ***or***
- *Delineate the responsibilities of the hospice and the LTC facility to provide bereavement services to LTC facility staff.*

If there are concerns with the implementation of care or services by the hospice provider, then the survey team must refer the complaint to the State agency responsible for oversight of hospice, identifying the specific resident(s) involved and the concerns identified.

INVESTIGATIVE SUMMARY

Use the Hospice and End of Life Care and Services Critical Element (CE) Pathway, along with the interpretive guidelines when determining if the facility meets the requirements for providing care and services for a resident receiving hospice services, in accordance with professional standards of practice, the coordinated person-centered care plan. In addition, the services must be and based upon the requirements included in the written agreement between the nursing home and hospice.

Summary of Investigative Procedure

Briefly review the most recent comprehensive assessments, coordinated care plan and orders to identify whether the facility has recognized, assessed, provided interventions and implemented care and services according to professional standards of practice, in order to meet the resident's hospice care needs. This information will guide observations and interviews to be made in order to corroborate concerns identified. In addition, investigate to assure that there are sufficient numbers of trained, qualified and competent staff to provide the interventions identified for a resident receiving hospice care and services. If concerns are identified, review the appropriate sections of the written agreement above.

If the resident has been in the facility for less than 14 days (before completion of all the Resident Assessment Instrument (RAI) is required), review the baseline care plan which must be completed within 48 hours to determine if the facility is providing appropriate care and services based on information available at the time of admission. In addition, review to determine whether the comprehensive care plan is evaluated and revised based on the resident's response to interventions.

NOTE: Always observe for visual cues of psychosocial distress and harm (see Appendix P, Guidance on Severity and Scope Levels and Psychosocial Outcome Severity Guide).

If a concern is identified during the survey regarding hospice care and/or the timeliness of the hospice services, the survey team should review how the nursing home's QAA committee is monitoring the provision of hospice services, such as monitoring the response by the hospice for the timely provision of care, including onsite visits by hospice staff during a crisis or change in the resident's condition.

If noncompliance is identified related to the written agreement, cite at F849. If noncompliance is identified related to quality of care, cite at F685, Quality of Care.

DEFICIENCY CATEGORIZATION

- ***Examples of Level 4, immediate jeopardy to resident health and safety, include, but are not limited to:***
  - *The failure of the facility to assure that the resident received hospice care and services based upon a written agreement with a Medicare-certified hospice. For example, a deficiency was cited at Severity Level 4, at F697, when the resident has severe uncontrolled pain, or F675, acute respiratory distress and at F849, the facility fails to contact and consult with the hospice as per the written agreement for a change in condition.*
  - *The facility failed to establish a written agreement with a Medicare-certified hospice that was allowed to provide hospice services in the nursing home. In this example, a deficiency was cited at Severity Level 4, at F697, when the resident was administered medication for pain management by the hospice, and due to lack of coordination, the nursing home, unaware of the administration of the medication, also administered pain medication resulting in an overdose of opioids and hospitalization due to acute respiratory failure, and at F849, the facility failed to establish a written agreement with a Medicare-certified hospice that was allowed to provide hospice services in the nursing home, resulting in the lack of coordination.*

- ***Examples of Level 3 - Actual harm (physical or psychological) that is not immediate jeopardy include but are not limited to:***
  - *The failure of the facility to assure that the resident received hospice care and services based upon a written agreement with a Medicare-certified hospice. For example, a deficiency was cited at Severity Level 3, at F697, when the resident has experienced pain that compromised his/her function (physical and/or psychosocial) and/or ability to reach his/her highest practicable well-being as a result of the*

facility's failure to recognize or address the situation, or failure to develop, implement, monitor, or modify a pain management plan to try to meet the resident's needs. For example, the pain was intense enough that the resident experienced recurrent insomnia, or reduced ability to move and perform ADLs, or a decline in mood or reduced ability to communicate/socialize with family and/ or participation in activities; and at F849, the facility failed to contact and consult with the hospice as per the written agreement for reviewing the resident's care plan for pain management.

- *At F849, the facility failed to establish a written agreement with a Medicare-certified hospice that was allowed to provide hospice services in the nursing home. In addition, the facility failed to contact and consult with the hospice for concerns related to significant changes in the resident's physical condition or need to alter the plan of care which is a component of the written agreement regulation. For example, a deficiency was cited at Severity Level 3, at F697, when a resident experienced significant episodic pain (that was not all-consuming or overwhelming but was greater than minimal discomfort to the resident) related to care/treatment such as prior to wound care, exercise or physical therapy. The facility failed to involve the hospice and failed to develop, implement, monitor, or modify pain management interventions.*

- ***Examples of Level 2 - No actual harm with a potential for more than minimal harm that is not immediate jeopardy include but are not limited to:***
  - *The failure of the facility to assure that the resident received hospice care and services based upon a written agreement with a Medicare-certified hospice. For example, a deficiency was cited at Severity Level 2, at F697, when the resident was on a pain management program utilizing opioids. The resident was experiencing episodic minimal discomfort and the facility failed to consult with the hospice regarding the bowel management plan as identified in the coordinated plan of care. The facility was cited at F849 for failure to contact and consult with the hospice as per the written agreement for communicating with the hospice for review and possible revision of the resident's care plan.*
  - *At F849, the facility failed to establish a written agreement with a Medicare-certified hospice that was allowed to provide hospice services in the nursing home. In addition, the facility failed to contact and consult with the hospice for concerns related to a need to alter the plan of care which is a component of the written agreement regulation. For example, a deficiency was cited at Severity Level 2, at F697, when a resident experienced daily or less than daily discomfort with no compromise in physical, mental, or psychosocial functioning as a result of the facility's failure to adequately recognize or address the pain management. The resident was able to participate in ADL's and/or activities of choice. The facility failed to involve the hospice in developing, implementing, monitoring, or modifying pain management interventions.*
  - *The facility failed to assure that the written agreement met one or more of the regulatory specifications resulting in the potential for negative resident outcomes.*

- ***An example of Level 1 - No actual harm with a potential for minimal harm includes but is not limited to:***
  - *There are components of the written agreement that were not met but they may have minimal impact to the resident. Failure to meet these elements will be cited at severity level 1. For example: The facility failed to implement provisions of the agreement regarding bereavement services for the LTC.*

POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION* §483.*70(o) - Hospice Services
If an additional concern has been identified, the surveyor must investigate the identified concern. Do not cite any related or associated requirements before first conducting an investigation to determine compliance or non-compliance with the related or associated requirement. Some examples include, but are not limited to, the following:

- *42 CFR § 483.21(b)(1), F656, Comprehensive Care Plans;*
- *42 CFR § 483.21(b)(2), F657, Comprehensive Care Plan Revision;*
- *42 CFR § 483.25, F685, Quality of Care;*
- *42 CFR § 483.40(d), F745, Medically Related Social Services;*
- *42 CFR § 483.70(h), F841, Medical Director;*
- *42 CFR §483.70(i)(5), F842, Resident Records; and*
- *42 CFR §483.75(c)(h)(i), F866, §483.75(d)(e)(g)(2)(ii)-(iii) F867 Quality Assessment and Assurance.*

F850
§483.*70(p)* Social worker.
***Any* facility with more than 120 beds must employ a qualified social worker on a full-time basis. A qualified social worker is:**

§483.*70(p)(1)* An individual with *a minimum of* a bachelor's degree in social work or a bachelor's degree in a human services field including, but not limited to, sociology, *gerontology,* special education, rehabilitation counseling, and psychology; and

§483.*70(p)(2)* One year of supervised social work experience in a health care setting working directly with individuals.

GUIDANCE* §483.*70(p)
The regulations do not require a Social Worker when a facility has equal to or less than 120 beds.

If the facility has more than 120 beds and its full-time social worker does not provide on-site coverage on a full-time basis determine how these services are provided to meet the individual needs of the resident whenever needed. If social services deficiencies are identified refer to §483.40(d), F745, regardless of the number of beds.

KEY ELEMENTS OF NONCOMPLIANCE
To cite deficient practice at F850, the surveyor's investigation will generally show that the facility failed to do any one of the following:

Effective November 28, 2017

- *A facility with more than 120 beds did not employ a qualified social worker on a full-time basis;* ***or***
- *The individual functioning as the social worker did not meet the qualifications specified in this regulation.*

F851

§483.70(q) Mandatory submission of staffing information based on payroll data in a uniform format.

Long-term care facilities must electronically submit to CMS complete and accurate direct care staffing information, including information for agency and contract staff, based on payroll and other verifiable and auditable data in a uniform format according to specifications established by CMS.

§483.*70(q)(1) Direct Care Staff.*

Direct Care Staff are those individuals who, through interpersonal contact with residents or resident care management, provide care and services to allow residents to attain or maintain the highest practicable physical, mental, and psychosocial well-being. Direct care staff does not include individuals whose primary duty is maintaining the physical environment of the long term care facility (for example, housekeeping).

§483.*70(q)(2) Submission requirements.*

The facility must electronically submit to CMS complete and accurate direct care staffing information, including the following:

- ***(i) The category of work for each person on direct care staff (including, but not limited to, whether the individual is a registered nurse, licensed practical nurse, licensed vocational nurse, certified nursing assistant, therapist, or other type of medical personnel as specified by CMS);***
- ***(ii) Resident census data; and***
- ***(iii) Information on direct care staff turnover and tenure, and on the hours of care provided by each category of staff per resident per day (including, but not limited to, start date, end date (as applicable), and hours worked for each individual).***

§483.70(q)(3) Distinguishing employee from agency and contract staff.

When reporting information about direct care staff, the facility must specify whether the individual is an employee of the facility, or is engaged by the facility under contract or through an agency.

§483.*70(q)(4) Data format.*

The facility must submit direct care staffing information in the uniform format specified by CMS.

§483.70(q)(5) Submission schedule.

The facility must submit direct care staffing information on the schedule specified by CMS, but no less frequently than quarterly.

Effective November 28, 2017

INTENT* §483.*70(q)
To ensure that long-term care facilities are electronically submitting direct care staffing information (including agency and contract staff) per day, based on payroll and other verifiable and auditable data. The staffing hours, when combined with census information, can then be used to not only report on the level of staff in each nursing home, but also to report on employee turnover and tenure.

GUIDANCE* §483.*70(q)
The facility is responsible for ensuring all staffing data entered in the Payroll-Based Journal (PBJ) system is auditable and able to be verified through either payroll, invoices, and/or tied back to a contract.

Refer to the CMS Electronic Staffing Data Submission Payroll-Based Journal Policy Manual for submission guidelines. Please see the following link for more information: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Staffing-Data-Submission-PBJ.html

For questions related to F851, surveyors, providers, or other stakeholders should email NHStaffing@cms.hhs.gov.

KEY ELEMENTS OF NONCOMPLIANCE
To cite deficient practice at F851, the investigation the surveyor's investigation will generally show that the facility failed to do any one of the following:

- *Complete data for the entire reporting period, such as hours paid for all required staff, each day;* ***or***
- *Provide accurate data;* ***or***
- *Provide data by the required deadline.*

F865
§483.75(a) Quality assurance and performance improvement (QAPI) program.
[§483.75 and all subparts will be implemented beginning November 28, 2019 (Phase 3), unless otherwise specified]
Each LTC facility, including a facility that is part of a multiunit chain, must develop, implement, and maintain an effective, comprehensive, data-driven QAPI program that focuses on indicators of the outcomes of care and quality of life. The facility must:

§483.75(a)(1) Maintain documentation and demonstrate evidence of its ongoing QAPI program that meets the requirements of this section. This may include but is not limited to systems and reports demonstrating systematic identification, reporting, investigation, analysis, and prevention of adverse events; and documentation demonstrating the development, implementation, and evaluation of corrective actions or performance improvement activities;

§483.75(a)(2) Present its QAPI plan to the State Survey Agency no later than 1 year after the promulgation of this regulation; [§483.75(a)(2) implemented November 28, 2017 (Phase 2)]

Effective November 28, 2017

§483.75(a)(3) Present its QAPI plan to a State Survey Agency or Federal surveyor at each annual recertification survey and upon request during any other survey and to CMS upon request; and

§483.75(a)(4) Present documentation and evidence of its ongoing QAPI program's implementation and the facility's compliance with requirements to a State Survey Agency, Federal surveyor or CMS upon request.

§483.75(b) Program design and scope.
A facility must design its QAPI program to be ongoing, comprehensive, and to address the full range of care and services provided by the facility. It must:

§483.75(b)(1) Address all systems of care and management practices;

§483.75(b)(2) Include clinical care, quality of life, and resident choice;

§483.75(b)(3) Utilize the best available evidence to define and measure indicators of quality and facility goals that reflect processes of care and facility operations that have been shown to be predictive of desired outcomes for residents of a SNF or NF.

§483.75(b (4) Reflect the complexities, unique care, and services that the facility provides.

§483.75(f) Governance and leadership.
The governing body and/or executive leadership (or organized group or individual who assumes full legal authority and responsibility for operation of the facility) is responsible and accountable for ensuring that:

§483.75(f)(1) An ongoing QAPI program is defined, implemented, and maintained and addresses identified priorities.

§483.75(f)(2) The QAPI program is sustained during transitions in leadership and staffing;

§483.75(f)(3) The QAPI program is adequately resourced, including ensuring staff time, equipment, and technical training as needed;

§483.75(f)(4) The QAPI program identifies and prioritizes problems and opportunities that reflect organizational process, functions, and services provided to residents based on performance indicator data, and resident and staff input, and other information.

§483.75(f)(5) Corrective actions address gaps in systems, and are evaluated for effectiveness; and

§483.75(f)(6) Clear expectations are set around safety, quality, rights, choice, and respect.

§483.75(h) Disclosure of information.

A **State or the Secretary may not require disclosure of the records of such committee except in so far as such disclosure is related to the compliance of such committee with the requirements of this section.** ***[§483.75(h) will be implemented November 28, 2016 (Phase 1)]***

§483.75(i) Sanctions.
Good faith attempts by the committee to identify and correct quality deficiencies will not be used as a basis for sanctions. ***[§483.75(i) implemented November 28, 2016 (Phase 1)]***

INTENT
These requirements are intended to ensure facilities develop a plan that describes the process for conducting QAPI/QAA activities, such as identifying and correcting quality deficiencies as well as opportunities for improvement, which will lead to improvement in the lives of nursing home residents, through continuous attention to quality of care, quality of life, and resident safety.

GUIDANCE §483.75(a)(2)-(3), and (h)-(i)
QAPI Plan
A QAPI plan is the written plan containing the process that will guide the nursing home's efforts in assuring care and services are maintained at acceptable levels of performance and continually improved. The plan describes how the facility will conduct its required QAPI and QAA committee functions. The facility is required to develop a QAPI plan and present its plan to federal and state surveyors at each annual recertification survey and upon request during any other survey, and to CMS upon request.

The QAPI plan must describe in detail the scope of the QAA committee's responsibilities and activities, and the process addressing how the committee will conduct the activities necessary to identify and correct quality deficiencies. Each nursing home, including facilities which are a part of a multi-chain organization, should tailor its QAPI plan to reflect the specific units, programs, departments, and unique population it serves, as identified in its facility assessment.

The QAPI plan must describe how the facility will ensure care and services delivered meet accepted standards of quality, identify problems and opportunities for improvement, and ensure progress toward correction or improvement is achieved and sustained.

The QAPI plan must describe the process for identifying and correcting quality deficiencies. Key components of the process include:

- *Tracking and measure performance;*
- *Establishing goals and thresholds for performance measurement;*
- *Identifying and prioritizing quality deficiencies;*
- *Systematically analyzing underlying causes of systemic quality deficiencies;*
- *Developing and implementing corrective action or performance improvement activities; and*
- *Monitoring or evaluating the effectiveness of corrective action/performance improvement activities, and revising as needed.*

Disclosure of Information and Good Faith Attempts

The survey process is intended to be an objective assessment of facility compliance with the requirements of participation. This assessment is guided by facility performance and outcomes as reported by Quality Measures (QMs) and Minimum Data Set (MDS) data, as well as complaints and surveyor observations, interviews, and record reviews. The surveyor task to review the QAPI Plan/QAA is intended to occur at the end of the survey, after completion of investigation into all other requirements to ensure that concerns are identified by the survey team independent of the QAPI Plan/QAA review. Surveyors must use critical thinking and investigatory skills to identify noncompliance, rather than using information provided during the QAA review as a source to identify deficiencies. The intent of §483.75(h), (i) is to:

- *Ensure information obtained from QAA committee documents that is related to the committee's good faith attempt to identify and correct quality deficiencies are not used by surveyors to identify additional concerns not previously identified during the survey; and*
- *Foster a culture where nursing homes can openly conduct their internal QAA investigations and performance improvement efforts.*

Surveyors may only require facilities to disclose QAA committee records if they are used to determine the extent to which facilities are compliant with the provisions for QAA.

Protection from disclosure is generally afforded documents generated by the QAA committee, such as minutes, internal papers, or conclusions. However, if those documents contain the evidence necessary to determine compliance with QAPI/QAA regulations, the facility must allow the surveyor to review and copy them. The ***key point*** *is that the facility must provide satisfactory evidence that it has, through its QAA committee, identified its own high risk, high volume, and problem-prone quality deficiencies, and are making a "good faith attempt" to correct them.*

Information gleaned from disclosure of QAA committee documents will not be used to cite new issues (not already identified by the survey team) or to expand the scope or severity of concerns identified on the current survey.

NOTE: *Prior to conducting the QAA review, the survey team must conduct a thorough investigation of all issues identified, including expanding the sample as necessary to determine the scope of the issue.*

Reports and Logs

Incident and accident reports, wound logs, or other reports or records used to track adverse events are not protected from disclosure. Surveyors may request these documents as part of their normal investigation of other areas of concern throughout the survey to support their findings.

Surveyor Access to QAA Material and Confidentiality of Patient Safety Work Products

CMS supports and encourages nursing homes to work on a confidential basis with an Agency for Healthcare Research and Quality (AHRQ) approved Patient Safety Organization (PSO) to obtain technical assistance in identifying, analyzing and preventing quality deficiencies and adverse events. The Federal Patient Safety and Quality Improvement Act of 2005 (PSQIA), Public Law 109-41, established a voluntary reporting system designed to enhance the data

available to assess and resolve patient safety and health care quality issues. PSQIA has afforded privileged and confidential status to "patient safety work product" (PSWP). PSWP includes data, reports, records, memoranda, analysis, or written and oral statements assembled and developed for reporting to a PSO and have been submitted to a PSO approved and listed by the Department of Health and Human Services (HHS) AHRQ.

PSQIA and the Patient Safety Rule only limit the disclosure of PSWP. Neither PSQIA nor the Patient Safety Rule limit the disclosure of non-PSWP, including its disclosure to a Federal, state or local government for public health surveillance, investigation or health oversight. The preamble to the final Patient Safety Rule states:

> *"Information is not patient safety work product if it is collected to comply with external reporting, such as…certification or licensing records for compliance with health oversight agency requirements;…complying with required disclosures by particular providers or suppliers pursuant to Medicare's Conditions of participation or conditions of coverage…" (73 FR 70742-70743, November 21, 2008).*

Ultimately, it is the nursing home's final decision as to whether to enter into a relationship with a PSO and to create a patient safety evaluation system (PSES) which is the collection, management, or analysis of information for reporting to or by a PSO. Additionally, the nursing home must determine what information to place within the PSES, considering a number of factors, including how they will demonstrate compliance with the Long-term Care Requirements for Participation, in particular, the QAA requirements. A nursing home must be prepared to meet its obligation to provide surveyors access to QAA program information to demonstrate compliance without disclosing PSWP as that term is defined in 42 CFR Part 3, the regulation implementing the Federal PSQIA. There is no barrier under the PSQIA for nursing homes to maintain duplicate systems, one consisting of patient safety work product within a protected patient safety evaluation system, and another to demonstrate compliance with local, State or Federal requirements.

Surveyors should consider the following key points:

- *Surveyors assessing QAA compliance must ask nursing homes to provide evidence of QAA compliance.*
- *Surveyors must **never** ask or demand that a nursing home show them "patient safety work product." If a nursing home states that all relevant QAA material has been placed in its PSES, or is protected PSWP, surveyors must ask to see the agreement the nursing home has with an AHRQ-approved PSO, to confirm that it has an approved protected PSES.*
- *If a nursing home has placed all evidence related to QAA compliance in its PSES as patient safety work product and does not also maintain a separate non-confidential system to provide evidence of compliance, or is unable to remove evidence of such compliance from its PSES, it may not be able to demonstrate its compliance to the surveyor.*

Good Faith Attempts

If the facility, through its QAA committee, has identified and made a good faith attempt to correct the same issue identified by the survey team during the current survey, the facility will

not be cited for QAA (it may however, still be cited with deficiencies related to actual or potential issues at other relevant tags).

A good faith attempt to correct an identified quality deficiency involves determining where a facility is within the process of identifying and correcting a problem (or problems). Surveyors will have to determine if the facility became aware of the issue as soon as it should have – was the issue a high-risk, high-volume, or problem-prone issue they should have been tracking? Was there a negative outcome to a resident which should have alerted them to the issue? What steps did the facility take when they became aware of the issue? Has there been enough time to implement changes and to evaluate the effectiveness of those changes? Do their efforts demonstrate diligence and an honest attempt to correct the issue?

Identifying and correcting problems requires facilities to:

- *Collect data from various sources related to high risk, high volume, and problem-prone issues such as medical errors and adverse events;*
- *Analyze the data collected to identify performance indicators signaling deviation from expected performance;*
- *Study the issue to determine underlying causes and contributing factors;*
- *Develop and implement corrective actions; and*
- *Monitor data related to the issue to determine if they are sustaining corrections, or if revisions are necessary.*

If the survey team has identified a current issue which will be cited at S/S level of E or above, or has identified substandard quality of care, the surveyor conducting the QAPI/QAA Review should consider if the facility's monitoring systems should also have identified the same issue. The surveyor must take into consideration whether the QAA committee has had sufficient time through its monitoring systems to identify the issue, if it was a high risk, problem-prone issue they should have been monitoring, and whether there has been a reasonable amount of time to respond to the issue. Issues which are likely to cause serious harm, impairment, or death must be responded to immediately. If the facility has identified the issue through its QAA committee, the surveyor must then evaluate the extent to which their actions or plans to correct the issue demonstrate a "good faith attempt."

Surveyors must not use documentation provided by the facility during the QAA review to identify additional concerns not previously identified by the survey team during the current survey, nor can they expand the scope or the severity of the problem based on information gleaned from this disclosure.

Facility Refusal to Provide Evidence of Compliance

Refusal by a facility to produce evidence of compliance with QAA will lead to citation of noncompliance with F865, requiring a plan of correction, and possible imposition of enforcement remedies up to and including termination of the facility's provider agreement. In the event of a facility refusal to produce evidence of compliance, the team coordinator should contact their State Agency supervisor.

The Code of Federal Regulations (CFR) 42 CFR, 489.53(a)(1), (3) and (4) stipulates the following:

*"**(a) Basis for termination of agreement with any provider.** CMS may terminate the agreement with any provider if CMS finds that any of the following failings is attributable to that provider:*

(1) It is not complying with the provisions of title XVIII and the applicable regulations of this chapter or with the provision of the agreement…

(3) It no longer meets the appropriate conditions of participation or requirements (for SNFs or NFs) set forth elsewhere in this chapter…

(4) It fails to furnish information that CMS finds necessary for a determination as to whether payments are or were due under Medicare and the amounts due."

Thus, since access to QAA committee records may be necessary to determine whether a facility meets the Medicare requirements at 483.75, denial of such access risks termination of the provider agreement.

KEY ELEMENTS OF NONCOMPLIANCE

To cite deficient practice at F865, the surveyor's investigation must generally show that the facility failed to develop a QAPI plan and/or make the plan available to federal and/or state surveyors.

INVESTIGATIVE SUMMARY

Use the Facility Task Pathway for Quality Assurance and Performance Improvement (QAPI) Plan and Quality Assessment and Assurance (QAA) Review, as appropriate, along with the above interpretive guidelines when determining if the facility meets the requirements for, or investigating concerns related to the QAPI plan.

Summary of Investigative Procedure

Prior to conducting the QAPI Plan/QAA review, the survey team should identify and validate systemic problems in the facility. This includes concerns identified from offsite preparation that represent repeat deficient practice, and concerns or issues identified throughout the survey that will potentially be cited at a S/S of E or above.

F866

§483.75(c) Program feedback, data systems and monitoring.

(§483.75(c) will be implemented during Phase 3)

A facility must establish and implement written policies and procedures for feedback, data collections systems, and monitoring, including adverse event monitoring. The policies and procedures must include, at a minimum, the following:

§483.75(c)(1) Facility maintenance of effective systems to obtain and use of feedback and input from direct care staff, other staff, residents, and resident representatives, including how such information will be used to identify problems that are high risk, high volume, or problem-prone, and opportunities for improvement.

Effective November 28, 2017

§483.75(c)(2) Facility maintenance of effective systems to identify, collect, and use data and information from all departments, including but not limited to the facility assessment required at §483.70(e) and including how such information will be used to develop and monitor performance indicators.

§483.75(c)(3) Facility development, monitoring, and evaluation of performance indicators, including the methodology and frequency for such development, monitoring, and evaluation.

§483.75(c)(4) Facility adverse event monitoring, including the methods by which the facility will systematically identify, report, track, investigate, analyze and use data and information relating to adverse events in the facility, including how the facility will use the data to develop activities to prevent adverse events.

F867
§483.75(d) Program systematic analysis and systemic action.
(§483.75(d) will be implemented during Phase 3)

§483.75(d)(1) The facility must take actions aimed at performance improvement and, after implementing those actions, measure its success, and track performance to ensure that improvements are realized and sustained.

§483.75(d)(2) The facility will develop and implement policies addressing:
- ***(i) How they will use a systematic approach to determine underlying causes of problems impacting larger systems;***
- ***(ii) How they will develop corrective actions that will be designed to effect change at the systems level to prevent quality of care, quality of life, or safety problems; and***
- ***(iii) How the facility will monitor the effectiveness of its performance improvement activities to ensure that improvements are sustained.***

§483.75(e) Program activities.
(§483.75(e) will be implemented during Phase 3)

§483.75(e)(1) The facility must set priorities for its performance improvement activities that focus on high-risk, high-volume, or problem-prone areas; consider the incidence, prevalence, and severity of problems in those areas; and affect health outcomes, resident safety, resident autonomy, resident choice, and quality of care.

§483.75(e)(2) Performance improvement activities must track medical errors and adverse resident events, analyze their causes, and implement preventive actions and mechanisms that include feedback and learning throughout the facility.

§483.75(e)(3) As part of their performance improvement activities, the facility must conduct distinct performance improvement projects. The number and frequency of improvement projects conducted by the facility must reflect the scope and complexity of the facility's services and available resources, as reflected in the facility assessment required at §483.70(e). Improvement projects must include at least annually a project that focuses on high risk or

Effective November 28, 2017

problem-prone areas identified through the data collection and analysis described in paragraphs (c) and (d) of this section

§483.75(g) **Quality assessment and assurance.**
§483.75(g)**(2) The quality assessment and assurance committee** ***reports to the facility's governing body, or designated person(s) functioning as a governing body regarding its activities, including implementation of the QAPI program required under paragraphs (a) through (e) of this section. The committee must:***

- ***(ii)*** **Develop and implement appropriate plans of action to correct identified quality deficiencies;**
- ***(iii) Regularly review and analyze data, including data collected under the QAPI program and data resulting from drug regimen reviews, and act on available data to make improvements.***

[§483.75(g)(2)(ii) implemented November 28, 2016 (Phase 1) except as related to implementation of the QAPI program, which will be implemented November 28, 2019 (Phase 3)]

DEFINITIONS §483.75(g)(2)(ii)-(iii)
"Adverse Events": *An adverse event is defined as an untoward, undesirable, and usually unanticipated event that causes death or serious injury, or the risk thereof, which includes near misses.*

"Corrective Action"*: A written and implemented plan of action for correcting or improving performance in response to an identified quality deficiency. Use of the term corrective action in this guidance is not synonymous with a Plan of Correction (formal response to cited deficiencies). This is also separate from the written QAPI plan.*

"High Risk, High Volume, Problem-Prone":
"High risk": *Refers to care or service areas associated with significant risk to the health or safety of residents, e.g., tracheostomy care; pressure injury prevention; administration of high risk medications such as warfarin, insulin, and opioids.*

"High Volume": *Refers to care or service areas performed frequently or affecting a large population, thus increasing the scope of the problem, e.g., transcription of orders; medication administration; laboratory testing.*

"Problem-prone"*: Refers to care or service areas that have historically had repeated problems, e.g., call bell response times; staff turnover; lost laundry.*

"Near Miss": *A potential harm event that did not reach a resident.*

"Plan Do Study Act (PDSA) Cycle": *An iterative four-step improvement method used to quickly test change in a process, resulting in continuous improvement. Also known as a Deming cycle, rapid-cycle improvement, or Plan Do Check Act (PDCA) cycle.*

Effective November 28, 2017

"Quality Assurance and Performance Improvement (QAPI)": *Nursing home QAPI is the coordinated application of two mutually-reinforcing aspects of a quality management system: Quality Assurance (QA) and Performance Improvement (PI). QAPI takes a systematic, interdisciplinary, comprehensive, and data-driven approach to maintaining and improving safety and quality in nursing homes while involving residents and families, and all nursing home caregivers in practical and creative problem solving.*

- ***Quality Assurance (QA):*** *QA is the specification of standards for quality of care, service and outcomes, and systems throughout the facility for assuring that care is maintained at acceptable levels in relation to those standards. QA is on-going and both anticipatory and retrospective in its efforts to identify how the organization is performing, including where and why facility performance is at risk or has failed to meet standards.*
- ***Performance Improvement (PI):*** *PI (also called Quality Improvement - QI) is the continuous study and improvement of processes with the intent to improve services or outcomes, and prevent or decrease the likelihood of problems, by identifying opportunities for improvement, and testing new approaches to fix underlying causes of persistent/systemic problems or barriers to improvement. PI in nursing homes aims to improve facility processes involved in care delivery and enhanced resident quality of life. PI can make good quality even better.*

"Quality Deficiency (or Opportunity for Improvement)": *A deviation in performance resulting in an actual or potential undesirable outcome, or an opportunity for improvement. A quality deficiency is anything the facility considers to be in need of further investigation and correction or improvement. Examples include problems such as medical errors and accidents, as well as improvement opportunities such as responses to questionnaires showing decreased satisfaction. This term is not necessarily synonymous with a deficiency cited by surveyors, but may include issues related to deficiencies cited on annual or complaint surveys.*

GUIDANCE §483.75(g)(2)(ii)
Identifying Quality Deficiencies
The QAA committee's responsibility to identify quality deficiencies requires facilities to have a system for monitoring departmental performance data routinely in order to identify deviations in performance and adverse events. Issues identified must be prioritized to determine which concerns pose a high risk to resident safety, health, and well-being, those which are problem-prone, and those which are high volume (occur with frequency). Adverse events, such as the elopement without injury of a cognitively-impaired resident, should be considered a high risk problem for which corrective action is required.

Adverse Events
An adverse event is defined as an untoward, undesirable, and usually unanticipated event that causes death or serious injury, or the risk thereof, which includes near misses. Facilities must have mechanisms or systems in place to ensure the QAA Committee takes necessary steps to identify the cause and correct the issue.

In 2014, the Department of Health and Human Services, Office of Inspector General (OIG) released its report "Adverse Events in Skilled Nursing Facilities (SNFs): National Incidence Among Medicare Beneficiaries," which found that one in three Medicare beneficiaries were

harmed by an adverse event or temporary harm event within their first 35 days while residing in a SNF. The OIG determined that nearly sixty percent of the events were potentially preventable. The OIG classified the events into three categories: medication, care, and infection related adverse events.

CMS collaborated with the Agency for Healthcare Research and Quality (AHRQ) to develop a listing of common potentially preventable events that occur in nursing homes – this list is not all-inclusive of potentially preventable events. This list is subject to change as technology and research redefine what is preventable.

Potentially Preventable Events Related to:		
Medication	***Care***	***Infection***
Change in mental status/delirium related to use of opiates and psychotropic medication	*Falls, abrasions/skin tears, or other trauma related to care*	*Respiratory infections:* • *Pneumonia* • *Influenza*
Hypoglycemia related to use of antidiabetic medication	*Electrolyte imbalance (including dehydration and acute kidney injury/insufficiency) associated with inadequate fluid maintenance*	*Skin and wound infections:* • *Surgical Site Infections (SSIs)* • *Soft tissue and non-surgical wound infections*
Ketoacidosis related to use of antidiabetic medication	*Thromboembolic events related to inadequate resident monitoring and provision of care*	*Urinary tract infections (UTIs)* • *Catheter Associated UTIs (CAUTIs)* • *UTIs (non-catheter associated)*
Bleeding related to use of antithrombotic medication	*Respiratory distress related to inadequate monitoring and provision of tracheostomy/ventilator care*	*Infectious diarrhea* • *Clostridium difficile* • *Norovirus*
Thromboembolism related to use of antithrombotic medication	*Exacerbations of preexisting conditions related to inadequate or omitted care*	
Prolonged constipation/ileus/ impaction related to use of opiates	*Feeding tube complications (aspiration, leakage, displacement) related to inadequate monitoring and provision of care*	
Electrolyte imbalance (including dehydration and acute kidney injury) related to use of diuretic medication	*In-house acquired/worsened stage pressure injuries, and unstageable/suspected deep tissue injuries*	
Drug toxicities including: acetaminophen, digoxin;	*Elopement*	

Effective November 28, 2017

Potentially Preventable Events Related to:		
levothyroxine; ACE inhibitors; phenytoin; lithium; valproic acid; antibiotics		
Altered cardiac output related to use of cardiac/blood pressure medication		

According to the OIG report, preventable adverse events were generally caused by:

- *Appropriate treatment provided in a substandard way (56%)*
- *Resident's progress not adequately monitored (37%)*
- *Necessary treatment not provided (25%)*
- *Inadequate resident assessment and care planning (22%)*

Corrective Action

Once a quality deficiency is identified, the QAA committee has a responsibility to oversee development of "appropriate" corrective action. An appropriate corrective action is one that appears to address the underlying cause of the issue comprehensively, at the systems level.

There are many different methodologies available to facilities for developing corrective action. CMS has not prescribed a particular method that must be used. Corrective action generally involves a written plan that includes:

- *A definition of the problem – which, depending on the severity and extent of the problem, may require further study by the committee to determine contributing causes of the problem (Root Cause Analysis);*
- *Measurable goals or targets;*
- *Step-by-step interventions to correct the problem and achieve established goals; and*
- *A description of how the QAA committee will monitor to ensure changes yield the expected results.*

Corrective actions may take the form of one or more tests of change, or PDSA cycles until the desired performance goals have been met, or facilities may convene a Performance Improvement Project (PIP).

While facilities are not yet required to perform them, PIPs are a type of corrective action that generally involves a team making a concentrated effort over time to improve a systemic problem. It often requires a systematic investigation, such as a Root Cause Analysis (RCA) to identify underlying causes or factors which have contributed to, or caused the problem. Interventions are designed to address the underlying causes. Once each intervention is implemented, the team closely monitors results to determine if changes are yielding the expected improvement or if the interventions should be revised.

NOTE: *The requirement for facilities to conduct PIPs will be implemented in Phase 3, beginning on November 28, 2019.*

Effective November 28, 2017

KEY ELEMENTS OF NON-COMPLIANCE

To cite deficient practice at F867, the surveyor's investigation must generally show that the facility failed to:

- *Identify quality deficiencies; and*
- *Develop and implement action plans to correct identified quality deficiencies.*

INVESTIGATIVE SUMMARY

Use the Facility Task Pathway for Quality Assurance and Performance Improvement (QAPI) Plan and Quality Assessment and Assurance (QAA) Review, as appropriate, along with the above interpretive guidelines when determining if the facility meets the requirements for, or investigating concerns related to QAA Committee identification and correction of quality deficiencies.

Summary of Investigative Procedure

Prior to conducting the QAPI Plan/QAA review, the survey team should identify and validate systemic problems in the facility. This includes concerns identified from offsite preparation that represent repeat deficient practice, and concerns or issues identified throughout the survey that will potentially be cited at a S/S of E or above.

DEFICIENCY CATEGORIZATION

Examples of Severity Level 4 Non-compliance Immediate Jeopardy to Resident Health or Safety include but are not limited to:

- *Evidence showing one or more residents received third degree burns from hot water temperatures in the month prior to the survey. QAA review showed there was no system in place for routine monitoring of hot water temperatures throughout the facility, yet no action had been taken to correct the systemic, high risk issue. (Cross-referenced at F689, Accidents)*
- *Evidence showing the facility failed to monitor their system for communicating each residents' code status. This resulted in staff having inaccurate and inconsistent information to use in emergency situations. QAA review showed the QAA committee was not aware of this systemic issue, and the QAA committee was not monitoring facility practices related to accurate and consistent communication of residents' advance directives and code status.*

Examples of Severity Level 3 Non-compliance Actual Harm that is Not Immediate Jeopardy include, but are not limited to:

- *Evidence showing the facility had no system for conducting infection surveillance, with accompanying evidence that several residents on one unit had Clostridium difficile, one of whom had a resultant decline in their ability to perform ADLs. QAA review showed the QAA committee had identified the issue, put a corrective action in place, but failed to monitor to ensure the corrective action was achieving the intended results. (Cross-reference and also cited at Infection Control).*
- *Evidence showing the facility had repeat deficiencies for the past two surveys related to their failure to ensure residents' post discharge needs were care planned and met upon discharge. During the current survey it was determined that a resident was discharged with no education about how to manage his new onset diabetes, resulting in his*

rehospitalization. The QAA review showed the QAA committee was not aware of the issue, and was not monitoring its practices around discharge. (Cross-referenced and also cited at Discharge Planning.

Example of Severity Level 2 Considerations: No Actual Harm with Potential for More Than Minimal Harm that is Not Immediate Jeopardy includes, but is not limited to:

- *Facility failed to identify an unresolved quality deficiency involving inaccurate weights, which was previously cited on the last annual survey. This issue has the potential to cause more than minimal harm.*

Example of a Severity Level 1: No actual harm with potential for minimal harm includes but is not limited to:

- *Facility failed to ensure that monitoring occurred as planned for an identified quality deficiency. On interview it was determined that the facility's corrective action involved monitoring monthly for three months to ensure the issue was corrected, however, documentation showed that for the second month, there was no evidence that monitoring had occurred. The QAA coordinator explained that she was out of the facility during that period.*

F868
§483.75(g) **Quality assessment and assurance.**
§483.75(g)**(1) A facility must maintain a quality assessment and assurance committee** ***consisting at a minimum of:***

(i) The director of nursing services;
(ii) The Medical Director or his/her designee;
(iii) At least ***three*** **other members of the facility's staff,** ***at least one of who must be the administrator, owner, a board member or other individual in a leadership role; and***
(iv) The infection preventionist.
[483.75(g)(1)(iv) Implemented beginning November 28, 2019(Phase 3)]

§483.75(g)**(2) The quality assessment and assurance committee** ***reports to the facility's governing body, or designated person(s) functioning as a governing body regarding its activities, including implementation of the QAPI program required under paragraphs (a) through (e) of this section. The committee must:***

(i) Meet at least quarterly ***and as needed to coordinate and evaluate activities under the QAPI program, such as identifying*** **issues with respect to which quality assessment and assurance activities*****, including performance improvement projects required under the QAPI program,*** **are necessary.**

DEFINITIONS §483.75(g)(1)-(2)
"Non-physician practitioner (NPP)": *A nurse practitioner (NP), clinical nurse specialist (CNS), or physician assistant (PA).*

GUIDANCE §483.75(g)(1)-(2)
QAA Committee
QAA committee responsibilities include identifying and responding to quality deficiencies

throughout the facility, and oversight of the QAPI program when fully implemented. Additionally, the committee must develop and implement corrective action, and monitor to ensure performance goals or targets are achieved, and revising corrective action when necessary.

The committee should be composed of staff who understand the characteristics and complexities of the care and services delivered by each unit, and/or department. The QAA Committee must be composed of, at a minimum:

- *The director of nursing (DON),*
- *The Medical Director or his/her designee, and*
- *At least three other staff, one of whom must be the facility's administrator, owner, board member, or other individual in a leadership role who has knowledge of facility systems and the authority to change those systems.*

Facilities may have a larger committee than required by the regulation. *Residents and families may provide a valuable perspective to committee efforts, although their participation is not required. Representation by staff with responsibility for direct care and services provides perspectives that are valuable in identifying, analyzing and correcting problems in resident care areas. Additionally, departments such as maintenance, housekeeping, laundry services, and other service areas such as the business office should be provided opportunities to participate in the committee, when relevant performance data is discussed.* Consideration should be given as to how committee information is provided to and from staff who may not be members of the committee, but whose responsibilities include oversight of departments or services.

As noted above, the Medical Director is a required member of the QAA committee. This requirement stems from the Medical Director's responsibility for the overall medical care provided and the implementation of all resident care policies in the facility. There should be evidence of meaningful participation by the Medical Director in the QAPI program, such as reporting on trends identified during oversight and review of reports such as the report of irregularities from the medication regimen review, and other oversight activities. For additional guidance related to the Medical Director's role, see 483.70(h), Medical Director, F841.

The Medical Director's designee must not be another required member, such as the DON, but may be a NPP. The designee must have knowledge of the facility's policies, procedures and practices so that he/she can fully participate and can add value to the QAA committee comparable to the medical director. Having a designee for the QAA committee, does not change or absolve the Medical Director's responsibility to fulfill his or her role as a member of the QAA committee, or his or her responsibility for overall medical care in the facility. In addition, there must be evidence of communication of the content of the meeting to the Medical Director, with his/her acknowledgement of this information. The Medical Director, in conjunction with the QAA committee, may arrange for real-time alternative methods of participation, such as videoconferencing and teleconference calls. For additional guidance related to the Medical Director's responsibilities, see 483.70(h) Medical Director, F841.

Frequency of Meetings

QAA committee meetings must be held at least quarterly or more often as necessary to fulfill the

committee's *responsibilities to identify and correct quality deficiencies* effectively. *The QAA committee determines what performance data will be monitored and the schedule or frequency for monitoring this data. There is no expectation that all performance data will be monitored at each committee meeting, however, the data must be reviewed with enough frequency to enable the committee to know if improvement is needed or if improvement is occurring (for current corrective actions).*

KEY ELEMENTS OF NONCOMPLIANCE

To cite deficient practice at F868, the surveyor's investigation must generally show that the facility failed to meet any one of the following:

- *Establish and maintain a QAA committee;*
- *Ensure the QAA committee is composed of the required committee members;*
- *Meet at least quarterly, and with enough frequency to conduct required QAPI/QAA activities.*

INVESTIGATIVE SUMMARY

Use the Facility Task Pathway for Quality Assurance and Performance Improvement (QAPI) Plan and Quality Assessment and Assurance (QAA) Review, as appropriate, along with the above interpretive guidelines when determining if the facility meets the requirements for, or investigating concerns related to the QAA Committee and QAPI program.

Summary of Investigative Procedure

Prior to conducting the QAPI Plan/QAA review, the survey team should identify and validate systemic problems in the facility. This includes concerns identified from offsite preparation that represent repeat deficient practice, and concerns or issues identified throughout the survey that will potentially be cited at a S/S of E or above.

F880

§483.*80* Infection Control

The facility must establish and maintain an infection *prevention and* control program designed to provide a safe, sanitary and comfortable environment and to help prevent the development and transmission of *communicable* disease*s* and infection*s*.

§483.*80(a)* Infection *prevention and* control program.

The facility must establish an infection *prevention and* control program *(IPCP) that must include, at a minimum, the following elements:*

§483.*80(a)(1) A system for preventing, identifying, reporting, investigating, and controlling infections and communicable diseases for all residents, staff, volunteers, visitors, and other individuals providing services under a contractual arrangement based upon the facility assessment conducted according to §483.70(e) and following accepted national standards;*

§483.*80(a)(2) Written standards, policies, and procedures for the program, which must include, but are not limited to:*

(i) A system of surveillance designed to identify possible communicable diseases or infections before they can spread to other persons in the facility;

(ii) When and to whom possible incidents of communicable disease or infections should be reported;
(iii) Standard and transmission-based precautions to be followed to prevent spread of infections;
(iv) When and how isolation should be used for a resident; including but not limited to:
(A) The type and duration of the isolation, depending upon the infectious agent or organism involved, and
(B) A requirement that the isolation should be the least restrictive possible for the resident under the circumstances.
(v) The circumstances under which **the facility must prohibit employees with a communicable disease or infected skin lesions from direct contact with residents or their food, if direct contact will transmit the disease***; and*
(vi) The hand hygiene procedures to be followed by staff involved in direct resident contact.

§483.*80(a)(4) A system for recording incidents identified under the facility's IPCP and the corrective actions taken by the facility.*

§483.*80(e)* **Linens.**
Personnel must handle, store, process, and transport linens so as to prevent the spread of infection.

§483.*80(f) Annual review.*
The facility will conduct an annual review of its IPCP and update their program, as necessary.

INTENT 483.80(a),(e),(f)
The intent of this regulation is to ensure that the facility:

- *Develops and implements an ongoing infection prevention and control program (IPCP) to prevent, recognize, and control the onset and spread of infection to the extent possible and reviews and updates the IPCP annually and as necessary. This would include revision of the IPCP as national standards change;*
- *Establishes facility-wide systems for the prevention, identification, investigation and control of infections of residents, staff, and visitors. It must include an ongoing system of surveillance designed to identify possible communicable diseases or infections before they can spread to other persons in the facility and procedures for reporting possible incidents of communicable disease or infections;* ***NOTE****: For purposes of this guidance, "staff" includes employees, consultants, contractors, volunteers, caregivers who provide care and services to residents on behalf of the facility, and students in the facility's nurse aide training programs or from affiliated academic institutions.*
- *Develops and implements written policies and procedures for infection control that, at a minimum:*
  - *Explain how standard precautions and when transmission-based precautions should be utilized, including but not limited to the type and duration of precautions for particular infections or organisms involved and that the precautions should be the least restrictive possible for the resident given the circumstances and the resident's ability to follow the precautions;*

- *Prohibit staff with a communicable disease or infected skin lesions from direct contact with residents or their food, if direct contact will transmit the disease; and*
- *Require staff follow hand hygiene practices consistent with accepted standards of practice.*

- *Requires staff handle, store, process, and transport all linens and laundry in accordance with accepted national standards in order to produce hygienically clean laundry and prevent the spread of infection to the extent possible.*

DEFINITIONS

"Airborne precautions": actions taken to prevent or minimize the transmission of infectious agents/organisms that remain infectious over long distances when suspended in the air. These infectious particles can remain suspended in the air for prolonged periods of time and can be carried on normal air currents in a room or beyond, to adjacent spaces or areas receiving exhaust air.[40]

"Alcohol-based handrub (ABHR)": a 60-95 percent ethanol or isopropyl alcohol- containing preparation base designed for application to the hands to reduce the number of viable microorganisms.

"Cleaning"*: removal of visible soil (e.g., organic and inorganic material) from objects and surfaces and is normally accomplished manually or mechanically using water with detergents or enzymatic products.*

"Cohorting": the practice of grouping residents infected or colonized with the same infectious agent together to confine their care to one area and prevent contact with susceptible residents (cohorting residents).[40] During outbreaks, healthcare *staff* may be assigned to a *specific* cohort of residents to further limit opportunities for transmission (cohorting staff). *The terms "cohort or cohorting" is standardized language used in the practice of infection prevention and control; the use of this terminology is not intended to offend residents or staff.*

"Colonization": the presence of microorganisms on or within body sites without detectable host immune response, cellular damage, or clinical expression.[40]

"Communicable disease" (also known as [a.k.a.] "contagious disease"): an infection transmissible (*e.g.,* from person-to-person) by direct contact with an affected individual or the individual's body fluids or by indirect means (e.g., contaminated object).

"Community-*acquired* infections" *(a.k.a. "present on admission")***:** infections that are present or incubating at the time of admission and *which* generally develop within 72 hours of admission.

"Contact precautions": measures that are intended to prevent transmission of infectious agents which are spread by direct or indirect contact with the resident or the resident's environment.[40]

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40 Siegel, J.D., Rhinehart, E., Jackson, M., Chiarello, L., & the Healthcare Infection Control Practices Advisory Committee. (2007). *2007 Guideline for isolation precautions: Preventing transmission of infectious agents in healthcare settings.* Accessed on June 9, 2017 from https://www.cdc.gov/infectioncontrol/guidelines/isolation/index.html

"Contaminated laundry": *laundry which has been soiled with blood/body fluids or other potentially infectious materials or may contain sharps.*

"Decontamination": *the use of physical or chemical means to remove, inactivate, or destroy pathogenic organisms on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal.*

"Disinfectant"*: usually a chemical agent (but sometimes a physical agent) that destroys disease-causing pathogens or other harmful microorganisms but might not kill bacterial spores. It refers to substances applied to inanimate objects.* [41]

"Disinfection": *thermal or chemical destruction of pathogenic and other types of microorganisms. Disinfection is less lethal than sterilization because it destroys most recognized pathogenic microorganisms but not necessarily all microbial forms (e.g., bacterial spores).* [41]

"Droplet precautions": actions designed to reduce/prevent the transmission of pathogens spread through close respiratory or mucous membrane contact with respiratory secretions.

"Hand hygiene": a general term that applies to *hand washing,* antiseptic *hand wash, and alcohol-based hand rub.*[42]

"Hand washing": *the vigorous, brief rubbing together of all surfaces of hands with plain (i.e., nonantimicrobial) soap and water, followed by rinsing under a stream of water.*[43]

"Healthcare-associated infection (HAI)": an infection that *residents acquire, that is associated with a medical or surgical intervention (e.g., podiatry, wound care debridement) within a nursing home and was not present or incubating at the time of admission.*

"Hygienically clean": being free of pathogens in sufficient numbers to cause human illness.[44]

"Infection": the establishment of an infective agent in or on a suitable host, producing clinical signs and symptoms (e.g., fever, redness, heat, purulent exudates, etc.).

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41 Centers for Disease Control and Prevention. (2008). *Guideline for disinfection and sterilization in healthcare facilities, 2008.* Accessed on June 9, 2017 from https://www.cdc.gov/hicpac/pdf/guidelines/Disinfection_Nov_2008.pdf

42 Centers for Disease Control and Prevention. (2002, October 25). Guideline for hand hygiene in health-care settings: Recommendations of The Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force. *MMWR;51*(No.RR-16). Accessed on June 9, 2017 from http://www.cdc.gov/mmwr/PDF/rr/rr5116.pdf

43 Centers for Disease Control and Prevention (2009, July 20). *OPRP – General information on hand hygiene.* Accessed on June 9, 2017 from https://www.cdc.gov/nceh/vsp/cruiselines/hand_hygiene_general.htm.

44 Association for the Advancement of Medical Instrumentation (AAMI). (2009). *ANSI/AAMI ST65:2008/(R)2013. Processing of reusable surgical textiles for use in health care facilities, 2008.* Arlington, VA.

"Infection preventionist"*: term used for the person(s) designated by the facility to be responsible for the infection prevention and control program.* ***NOTE:*** *Designation of a specific individual, detailed training, qualifications, and hourly requirements for an infection preventionist are not required until implementation of Phase 3.*

"Personal protective equipment (PPE)": protective items or garments worn to protect the body or clothing from hazards that can cause injury *and to protect residents from cross-transmission.*

"(Regulated) Medical waste": *liquid or semi-liquid blood or other potentially infectious materials; contaminated items that would release blood or other potentially infectious materials in a liquid or semi-liquid state if compressed; items that are caked with dried blood or other potentially infectious materials and are capable of releasing these materials during handling (e.g., blood-soaked bandages); contaminated sharps.*[45]

NOTE*: Authorities having jurisdiction may have more stringent regulations than OSHA.*

"Standard Precautions": infection prevention practices that apply to all residents, regardless of suspected or confirmed diagnosis or presumed infection status. *Standard precautions is based on the principle that all blood, body fluids, secretions, excretions except sweat, regardless of whether they contain visible blood, non-intact skin, and mucous membranes may contain transmissible infectious agents. Furthermore, equipment or items in the patient environment likely to have been contaminated with infectious body fluids must be handled in a manner to prevent transmission of infectious agents. Standard precautions include but are not limited to hand hygiene; use of gloves, gown, mask, eye protection, or face shield, depending on the anticipated exposure; safe injection practices, and respiratory hygiene/cough etiquette. Also, equipment or items in the patient environment likely to have been contaminated with infectious body fluids must be handled in a manner to prevent transmission of infectious agents (e.g., wear gloves for direct contact, properly clean and disinfect or sterilize reusable equipment before use on another patient).*[40]

"Transmission-based precautions" (a.k.a. "Isolation Precautions"): actions (precautions) implemented, in addition to standard precautions, that are based upon the means of transmission (airborne, contact, and droplet) in order to prevent or control infections. ***NOTE****: Although the regulatory language refers to "isolation," the nomenclature widely accepted and used in this guidance will refer to "transmission-based precautions" instead of "isolation".*

NOTE: *References to non-U. S. Department of Health and Human Services (HHS) sources or sites on the internet are provided as a service and do not constitute or imply endorsement of these organizations or their programs by CMS. CMS is not responsible for the content of pages found at these sites. URL addresses were current as of the date of this publication.*

GUIDANCE §483.80(a),(e),(f)

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45 Occupational Safety and Health Administration. *Title 29 Part 1910.1030. Bloodborne pathogens.* Accessed on June 9, 2017 from http://www.ecfr.gov/cgi-bin/text-idx?SID=4e5245f66094d270bc2bd93105f6a92d&mc=true&node=se29.6.1910_11030&rgn=div8

Effective November 28, 2017

INFECTION PREVENTION AND CONTROL PROGRAM

Healthcare-associated infections (HAIs) can cause significant pain and discomfort for residents in nursing homes and can have significant adverse consequences. The facility must establish and maintain an IPCP designed to provide a safe, sanitary, and comfortable environment and to help prevent the development and transmission of communicable diseases and infections. This program must include, at a minimum, a system for preventing, identifying, reporting, investigating, and controlling infections and communicable diseases for all residents, staff, and visitors. The IPCP must follow national standards and guidelines.

For purposes of this guidance, we would expect facilities to tailor the emphasis of their IPCP for visitors. We expect facilities to work to prevent transmission of infection to the resident from the visitor using reasonable precautions and national standards.[40] For example, passive screening through the use of signs at the entrances to alert visitors with signs and symptoms of communicable diseases not to enter the facility.[40] If a facility has a visitor exception protocol (e.g., end-of-life care), this would need to be determined by the facility. In this case, if a symptomatic visitor/family member must enter the facility, the visitor must still follow the facility's policies for prevention of transmission (e.g., following respiratory hygiene/cough etiquette procedures).

The Infection Prevention and Control Program must include the following parts:

- *A system for preventing, identifying, reporting, investigating, and controlling infections and communicable diseases that:*
  - *Covers all residents, staff, volunteers, visitors, and other individuals providing services under a contractual arrangement;*
  - *Is based on the individual facility assessment;*
  - *Follows accepted national standards;*
- *Written standards, policies and procedures in accordance with §483.80(a)(2);*
- *A system for recording incidents identified under the IPCP and corrective actions taken by the facility; and*
- *An antibiotic stewardship program (ASP) (F881).*

FACILITY ASSESSMENT

Pursuant to §483.70(e) (F838), the facility must conduct and document a facility-wide assessment to determine what resources are necessary to care for its residents competently during both day-to-day operations and emergencies. The facility must review and update that assessment, as necessary, and at least annually. The facility must also review and update this assessment whenever there is, or the facility plans for, any change that would require a substantial modification to any part of this assessment. The facility assessment must address or include a facility-based and community-based risk assessment, utilizing an all-hazards approach. See §483.70(e) (F838) for guidance on the facility assessment. The results of the facility assessment must be used, in part, to establish and update the IPCP, its policies and/or protocols to include a system for preventing, identifying, reporting, investigating, and controlling infections and communicable diseases for residents, staff, and visitors.

NOTE: *A community-based risk assessment should include review for risk of infections (e.g., multidrug-resistant organisms- MDROs) and communicable diseases such as tuberculosis and*

influenza. Appropriate resident tuberculosis screening should be performed based on state requirements.

***NOTE**: While not required for compliance, a sample tool of an infection control risk assessment is available for adaptation.*[46]

INFECTION CONTROL POLICIES AND PROCEDURES

The facility must develop and implement written policies and procedures for the provision of infection prevention and control. The facility administration and medical director should ensure that current standards of practice based on recognized guidelines are incorporated in the resident care policies and procedures. These IPCP policies and procedures must include, at a minimum:

- *As necessary, and at least annually, review and revision of the IPCP based upon the facility assessment (according to 483.70(e)) which includes any facility and community risk;*
- *An ongoing system of surveillance designed to identify possible communicable diseases or infections before they can spread to other persons in the facility;*
- *When and to whom possible incidents of communicable disease or infections should be reported within the facility;*
- *Which communicable diseases are reportable to local/state public health authorities;*
- *How to use standard precautions and how and when to use transmission-based precautions (i.e., contact precautions, droplet precautions, airborne isolation precautions). The areas described below are part of standard and transmission-based precautions*[40] *which are further described under their respective sections. For example:*
    - *Hand hygiene (HH) (e.g., hand washing and/or ABHR): consistent with accepted standards of practice such as the use of ABHR instead of soap and water in all clinical situations except when hands are visibly soiled (e.g., blood, body fluids), or after caring for a resident with known or suspected Clostridium (C.) difficile or norovirus infection during an outbreak, or if infection rates of C. difficile infection (CDI) are high; in these circumstances, soap and water should be used;*[47] ***NOTE:** According to the CDC, strict adherence to glove use is the most effective means of preventing hand contamination with C. difficile spores as spores are not killed by ABHR and may be difficult to remove even with thorough hand washing. For further information on appropriate hand hygiene practices see the following CDC website: http://www.cdc.gov/handhygiene/providers/index.html*
    - *The selection and use of PPE (e.g., indications, donning/doffing procedures) and the clinical conditions for which specific PPE should be used (e.g., CDI, influenza);*
    - *Addressing the provision of facemasks for residents with new respiratory symptoms;*

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46 Association for Professionals in Infection Control and Epidemiology. *IC risk assessment tool form and IC risk assessment analysis.* Accessed on June 9, 2017 from

47 Dubberke, E.R., & Gerding, D.N. (2011). Rationale for hand hygiene recommendations after caring for a patient with *Clostridium difficile* infection. *In A compendium of strategies to prevent healthcare-associated infections in acute care hospitals: A fall 2011 update.* Accessed on June 9, 2017 from https://www.shea-online.org/images/patients/CDI-hand-hygiene-Update.pdf

- *Addressing resident room assignment (e.g. single/private room/cohorted) as appropriate and/or available, based on a case by case analysis of the presence of risk factors for increased likelihood of transmission (e.g., uncontained drainage, stool incontinence);*[40]
- *The process to manage a resident on transmission-based precautions when a single/private room is not available;*
- *Limiting the movement of a resident with a highly infectious disease (e.g., norovirus, CDI) who is on transmission-based precautions with active symptoms (e.g., resident has diarrhea, vomiting, draining wounds, or other uncontained excretions or secretions) while outside of his/her room for medically necessary purposes only;*[40] *and*
- *Respiratory Hygiene/Cough Etiquette*[40]*: Implementing policies and procedures would include providing resources and instructions for performing HH in or near lobby areas or entrances; provide conveniently-located dispensers of ABHR and supplies for hand washing where sinks are available. During times of increased prevalence of respiratory infections in the community, facilities must have facemasks available and should offer facemasks to coughing or sneezing visitors and other symptomatic persons (e.g., family who accompany ill residents upon entry to the facility). Symptomatic (e.g., coughing) visitors should wear a facemask or maintain at least a three foot separation from others in common areas (e.g., admitting office). In addition, the facility should consider posting signs in the facility with instructions to family/visitors with symptoms of respiratory infection to cover their mouth/nose when coughing or sneezing; use and dispose of tissues; perform hand hygiene after contact with respiratory secretions; and to take appropriate precautions if they are having symptoms of respiratory infection or other communicable diseases.*

- *Resident Care Activities:*
  - *The use and care of urinary catheters, which must include a written rationale for the use, consistent with evidence-based guidelines (e.g., acute urinary retention, bladder outlet obstruction, neurogenic bladder or terminally ill for comfort measures) (Refer to §483.25(e)(2)(i)(ii)&(iii) Incontinence, F690, for further information.);*
  - *Wound care, fecal/urinary incontinence care, and skin care. Since the IPCP must be based on the facility assessment, the presence of certain resident conditions would require that the facility have policies and procedures related to other specific services such as mechanical ventilation, infusion therapy, and/or dialysis either onsite or at an offsite dialysis facility;*
  - *Performing fingersticks and point-of-care testing (e.g., assisted blood glucose monitoring) to the extent identified as a resident need based on the facility assessment;*
  - *Preparation, administration, and care for medications administered by injection or peripheral and central venous catheters, if performed by the facility; and*
  - *Use and care of peripheral and central venous catheters, if performed by the facility.*
- *Environmental cleaning/disinfection:*
  - *Routine cleaning and disinfection of high-touch surfaces in common areas, resident rooms, and at the time of discharge; and*

***NOTE**: Privacy curtains in the resident's room should be changed when visibly dirty by laundering or cleaning with an Environmental Protection Agency (EPA)-registered disinfectant per manufacturer's instructions.*

- *Cleaning/disinfection of resident care equipment including equipment shared among residents (e.g., blood pressure cuffs, rehabilitation therapy equipment, blood glucose meters, etc.).*

- *Written occupational health policies that address:*
  - *Reporting of staff illnesses and following work restrictions per nationally recognized standards and guidelines;*[48]
  - *Prohibiting contact with residents or their food when staff have potentially communicable diseases or infected skin lesions;*
  - *Assessing risks for tuberculosis (TB) based on regional/community data and screening staff to the extent permitted under applicable federal guidelines* [49] *and state law;*
  - *Monitoring and evaluating for clusters or outbreaks of illness among staff;*
  - *Implementing an exposure control plan in order to address potential hazards posed by blood and body fluids, from dialysis, glucose monitoring or any other point of care testing; and*
  - *Education and competency assessment: facilities must ensure staff follow the IPCP's standards, policies and procedures. Therefore, staff must be informed and competent. Knowledge and skills pertaining to the IPCP's standards, policies and procedures are needed by all staff in order to follow proper infection control practices (e.g., hand hygiene and appropriate use of personal protective equipment) while other needs are specific to particular roles, responsibilities, and situations (e.g., injection safety and point of care testing). Furthermore, residents and their representatives should receive education on the facility's IPCP as it relates to them (e.g., hand hygiene, cough etiquette) and to the degree possible/consistent with the resident's capacity. For example, residents should be advised of the IPCP's standards, policies and procedures regarding hand hygiene before eating and after using the restroom.*

SURVEILLANCE

The facility must establish a system for surveillance based upon national standards of practice and the facility assessment, including the resident population and the services and care provided. The facility must establish routine, ongoing, and systematic collection, analysis, interpretation, and dissemination of surveillance data to identify infections (i.e., HAI and community-acquired), infection risks, communicable disease outbreaks, and to maintain or improve resident health status. As part of the system of surveillance, identification and

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48 Bolyard, E.A., Tablan, O.C., Williams, W.W., Pearson, M.L., Shapiro, C.N., Deitchman, S.D., & The Healthcare Infection Control Practices Advisory Committee. (1998). Guideline for infection control in health care personnel, 1998. *American Journal of Infection Control 26*, 289-354. Accessed on June 9, 2017 from https://www.cdc.gov/hicpac/pdf/InfectControl98.pdf

49 Jensen, P.A., Lambert, L.A., Iademarco, M.F., & Ridzon, R. (CDC's Division of Tuberculosis Elimination, National Center for HIV, STD, and TB Prevention). (2005, December 30). Guidelines for preventing the transmission of *Mycobacterium tuberculosis* in health-care settings, 2005. *MMWR; 54* (No.RR-17). Accessed on June 9, 2017 from https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5417a1.htm

prevention, the facility should determine how it will track the extent to which staff are following the facility's IPCP policies and procedures, and facilities would want to particularly address any areas that are related to a corrective action.

The facility's surveillance system must include a data collection tool and the use of nationally-recognized surveillance criteria such as but not limited to CDC's National Healthcare Safety Network (NHSN) Long Term Care Criteria to define infections or updated McGeer criteria[50]. Furthermore, the facility must know when and to whom to report communicable diseases, healthcare-associated infections (as appropriate), and potential outbreaks (e.g., list of communicable diseases which are reportable to local/state public health authorities). The facility must document follow-up activity in response to important surveillance findings (e.g., outbreaks).

In addition, the facility must establish and implement a system, including who to notify (e.g. infection preventionist), for early detection and management of a potentially infectious, symptomatic resident at the time of admission. This includes the identification and use of appropriate transmission-based precautions.[40] This is important to incorporate into the resident's baseline care plan that must be developed within 48 hours of admission and include the minimum healthcare information necessary to properly care for a resident, including physician orders (e.g., medication orders). See §483.21, Comprehensive Person-Centered Care Planning for further information.

Furthermore, the facility must have a process for communicating information at the time of transfer (e.g., CDC, state, or other standardized inter-facility infection transfer form) when a resident has an infection or is colonized.[51] When a resident is transferred, the information provided to the receiving provider must include special instructions or precautions for ongoing care and other necessary information including a discharge summary. When a resident is discharged, the discharge summary must include the resident's disease diagnoses and health conditions, course of illness/treatment or therapy, medications, and pertinent lab, radiology, consultation results, and instructions or precautions for ongoing care. See §483.21(c)(2), Discharge Summary (F661) and §483.15(c)(2)(iii), Transfer and Discharge (F622) for further information on these requirements.

Additionally, as part of the overall IPCP for surveillance, the facility shall establish process and outcome surveillance.

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50 Stone, N.D., Ashraf, M.S., Calder, J., Crnich, C. J., Crossley, K., Drinka, P.J., …Bradley, S.F. (2012). Surveillance definitions of infections in long-term care facilities: Revisiting the McGeer criteria. *Infect Control Hosp Epidemiology*. 33(10), 965-977.

51 Siegel, J.D., Rhinehart, E., Jackson, M., and Chiarello, L. (2006). *Management of multidrug-resistant organisms in healthcare settings, 2006.* Accessed on June 9, 2017 from https://www.cdc.gov/hicpac/pdf/mdro/mdroguideline2006.pdf

Process Surveillance

Process surveillance is the review of practices by staff directly related to resident care.[52] *The purpose is to identify whether staff implement and comply with the facility's IPCP policies and procedures. Some areas that facilities may want to consider for process surveillance are the following:*

- *Hand hygiene;*
- *Appropriate use of personal protective equipment (e.g., gowns, gloves, facemask);*
- *Injection safety;*
- *Point-of-care testing (e.g., during assisted blood glucose monitoring);*
- *Implementation of infection control practices for resident care such as but not limited to urinary catheter care, wound care, injection/IV care, fecal/urinary incontinence care, skin care, respiratory care, dialysis care, and other invasive treatments;*
- *Managing a bloodborne pathogen exposure.*

  ***NOTE**: This may not lend itself to monitoring and feedback;*

- *Cleaning and disinfection products and procedures for environmental surfaces and equipment;*
- *Appropriate use of transmission-based precautions; and*
- *Handling, storing, processing, and transporting linens so as to prevent the spread of infection.*

Outcome Surveillance

Another component of a system of identification is outcome surveillance. For example, this addresses the criteria that staff would use to identify and report evidence of a suspected or confirmed HAI or communicable disease. This process consists of collecting/documenting data on individual *resident* cases and *comparing* the collected data to standard written definitions (criteria) of infections.

***NOTE**: Refer to the CDC/SHEA Position Statement: Surveillance Definitions of Infections in Long-Term Care Facilities: Revisiting the McGeer Criteria*[50] *or NHSN at https://www.cdc.gov/nhsn/ for examples of nationally accepted surveillance definitions.*

The following are some sources of data that can be utilized in outcome surveillance for infections, antibiotic use and susceptibility: Monitoring a resident(s) with fever or *other signs or symptoms suspicious for infection*;

- Laboratory cultures or other diagnostic test results consistent with potential infections to detect clusters, trends, *or susceptibility patterns*;
- Antibiotic orders;
- Medication regimen review reports;
- *Documentation from the clinical record of residents with suspicion of an infection such as physician orders/progress notes; and/or*

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52 Smith, P.W., Bennett, G., Bradley, S., Drinka, P., Lautenbach, E., Marx, J.... Stevenson, K. (2008). SHEA/APIC Guideline: infection prevention and control in the long-term care facility. *Infect Control Hosp Epidemiology*. *29*(9), 785-814.

- *Transfer/discharge summaries for new or readmitted residents for infections.*[52]

SYSTEM OF SURVEILLANCE: DATA ANALYSIS, DOCUMENTATION AND REPORTING

The facility's policies and procedures for a system of surveillance must include data to properly identify communicable diseases or infections before they spread. Therefore, the policies and procedures would include identifying:

- *Data to be collected, including how often and the type of data to be documented, including:*
  - *The infection site (i.e., type of infection), pathogen (if available), signs and symptoms, and resident location, including summary and analysis of the number of residents (and staff, if applicable) who developed infections;*
  - *Observations of staff including the identification of ineffective practices (e.g., not practicing hand hygiene and/or using PPE when indicated as well as practices that do not follow the facility's IPCP policies and procedures), if any; and*
  - *The identification of unusual or unexpected outcomes (e.g. foodborne outbreak), infection trends and patterns.*
- *How the data will be used and shared with appropriate individuals (e.g., staff, medical director, director of nursing, quality assessment and assurance committee- QAA), when applicable, to ensure that staff minimize spread of the infection or disease (e.g., require revision of staff education and competency assessment).*

The facility must identify how reports will be provided to staff and/or prescribing practitioners in order to revise interventions/approaches and/or re-evaluate medical interventions related to the infection rates and outcomes.

RECOGNIZING, CONTAINING AND REPORTING COMMUNICABLE DISEASE OUTBREAKS

The facility must know how to recognize and contain infectious disease outbreaks. An outbreak is the occurrence of more cases than expected in a given area or among a specific group of people over a particular period of time.[53] *If a condition is rare or has serious health implications, an outbreak may involve only one case. While a single case of a rare infectious condition or one that has serious health implications may or may not constitute an outbreak, facilities should not wait for the definition of an outbreak to act. For example, one case of laboratory confirmed influenza in a resident should alert the facility to begin an outbreak investigation.*[54] *If an outbreak is identified, the facility must:*

- *Take the appropriate steps to diagnose and manage cases, implement appropriate precautions, and prevent further transmission of the disease as well as documentation of follow-up activity in response; and*
- *Comply with state and local public health authority requirements for identification, reporting, and containing communicable diseases and outbreaks.*

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53 Centers for Disease Control and Prevention. (2015, January 21). *Epidemiology glossary.* Accessed on June 9, 2017 from http://www.cdc.gov/reproductivehealth/data_stats/glossary.html#O

54 Schweon, S., Burdsall D., Hanchett, M., Hilley, S., Greene, D., Kenneley, I., Marx, J., Rosenbaum, P. (2013). *Infection preventionist's guide to long-term care.* Washington DC: APIC.

NOTE: *Some states have specific regulations regarding responding to and reporting outbreaks that must be included in the IPCP.*

PREVENTION AND CONTROL OF TRANSMISSION OF INFECTION

Infectious organisms (e.g., bacteria, viruses, or parasites) may be transmitted by direct contact (e.g., skin-to-skin) or indirect contact (e.g., inanimate objects). Healthcare *staff* and resident care equipment often move from resident to resident and therefore may serve as a vehicle for transferring infectious organisms.

Direct *Contact* Transmission (Person-to-Person) occurs when microorganisms *such as methicillin-resistant Staphylococcus aureus (MRSA), vancomycin-resistant enterococci (VRE), carbapenem-resistant Enterobacteriaceae (CRE), influenza, or mites from a scabies-infected resident* are transferred from an infected or colonized person to another person. *In nursing homes, resident-to-resident direct contact transmission may occur in common areas of the facility such as the recreation room, rehabilitation area, and/or dining room.*

Indirect *Contact* Transmission: involves the transfer of an infectious agent through a contaminated *inanimate* object *or person.*

The following are examples of opportunities for indirect *contact transmission:*

- Clothing, uniforms, laboratory coats, or isolation gowns used as PPE may become contaminated with potential pathogens after care of a resident colonized or infected with an infectious agent, (e.g., MRSA, VRE, and *C. difficile*); and
- *Contamination of high touch environmental surfaces (e.g., bedside table, bed rails, toilets, sinks, and handrails), contributes to transmission of pathogens including C. difficile and norovirus.*

Certain pathogens may contaminate and survive on equipment and environmental surfaces for long periods of time. Examples include, but are not limited to:

- *C. difficile spores* can live on inanimate surfaces for up to 5 months;[55]
- The hepatitis B virus can last up to a week on inanimate surfaces;[56] and
- The influenza virus can survive on fomites (e.g., any inanimate object or substance capable of carrying infectious organisms and transferring them from one individual to another) for up to 8 hours.[57]

Mechanisms to prevent and control transmission of infectious organisms through direct and indirect contact include standard and transmission-based precautions and are described in their subsequent sections.

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55 Kim, K.H., Fekety, R., Batts, D.H.,Brown, D., Cudmore , M., Silva, J. Jr., & Waters, D. (1981, January 1). Isolation of *Clostridium difficile* from the environment and contacts of residents with antibiotic-associated colitis. *Journal of Infectious Disease. 143*(1), 42-50.

56 Centers for Disease Control and Prevention (CDC). *Hepatitis B FAQs for health professionals.* Accessed on June 9, 2017 from http://www.cdc.gov/hepatitis/HBV/HBVfaq.htm

57 Centers for Disease Control and Prevention (CDC). (2007, February 15). *Preventing seasonal flu.* Accessed on June 9, 2017 from https://www.cdc.gov/flu/protect/vaccine/index.htm

Effective November 28, 2017

STANDARD PRECAUTIONS

Standard precautions represent the infection prevention measures that apply to all resident care, regardless of suspected or confirmed infection status of the resident, in any setting where healthcare is being delivered. These evidence-based practices are designed to protect healthcare staff and residents by preventing the spread of infections among residents and ensuring staff do not carry infectious pathogens on their hands or via equipment during resident care. As mentioned in the definitions section, standard precautions include hand hygiene, use of PPE (e.g., gloves, gowns, facemasks), respiratory hygiene and cough etiquette, safe injection practices, and safe handling of equipment or items that are likely contaminated with infectious body fluids, as well as cleaning and disinfecting or sterilizing of potentially contaminated equipment.[40]

In order to perform hand hygiene appropriately, soap, water, ABHR, and a sink should be readily accessible in appropriate locations including but not limited to resident care areas, and food and medication preparation areas. Staff must perform hand hygiene (even if gloves are used):

- *Before and after contact with the resident;*
- *Before performing an aseptic task;*
- *After contact with blood, body fluids, visibly contaminated surfaces or after contact with objects in the resident's room;*
- *After removing personal protective equipment (e.g., gloves, gown, facemask);*
- *After using the restroom; and*
- *Before meals.*

If residents need assistance with hand hygiene, staff should assist with washing hands after toileting, before meals, and use of ABHR or soap and water at other times when indicated.

The use of PPE during resident care is determined by the nature of staff interaction and the extent of anticipated blood, body fluid, or pathogen exposure to include contamination of environmental surfaces. Furthermore, appropriate use of PPE includes but is not limited to the following:

- *Gloves worn before and removed after contact with blood or body fluid, mucous membranes, or non-intact skin;*
- *Gloves changed and hand hygiene performed before moving from a contaminated-body site to a clean-body site during resident care;*
- *Gown worn for direct resident contact if the resident has uncontained secretions or excretions or with contaminated or potentially contaminated items;*
- *Appropriate mouth, nose, and eye protection (e.g., facemasks, face shield) is worn for procedures that are likely to generate splashes or sprays of blood or body fluids;*
- *PPE appropriately discarded after resident care prior to leaving room followed by hand hygiene; and*
- *Supplies necessary for adherence to proper PPE use (e.g., gloves, gowns, masks) are readily accessible in resident care areas (i.e., nursing units, therapy rooms) although, equipment supply carts should not be brought into the resident's room.*

Effective November 28, 2017

The facility must prevent infections through indirect contact transmission. This requires the decontamination (i.e., cleaning and/or disinfecting an object to render it safe for handling) of resident equipment, medical devices, and the environment. Alternatively, the facility may also consider using single-use disposable devices or designating reusable equipment for only an individual resident. ***NOTE****: Refer to the CDC website for information on environmental cleaning - https://www.cdc.gov/hicpac/pdf/guidelines/eic_in_HCF_03.pdf*

The facility must identify the decontamination method based upon the risk of infection to the resident coming into contact with equipment or medical devices. Equipment or items in the resident environment likely to have been contaminated with infectious fluids or other potentially infectious matter must be handled in a manner so as to prevent transmission of infectious agents, (e.g., wear gloves for handling soiled equipment and properly clean and disinfect or sterilize reusable equipment before use on another resident).[40]

The CDC has adopted the Spaulding classification system that identifies three risk levels associated with medical and surgical instruments: critical, semi-critical, and noncritical.[58] *This includes:*

- Critical items (e.g., needles, intravenous catheters, indwelling urinary catheters) enter sterile tissue or the vascular system. These items or equipment must be sterile when used, based on one of several accepted sterilization procedures. Most of the items in this category should be purchased as sterile or be sterilized;
- *Semi-critical items (e.g., dental, podiatry equipment, electric razors) contact mucous membranes or non-intact skin. Such items require meticulous cleaning followed by high-level disinfection treatment using a Food and Drug Administration (FDA)- approved high-level chemical disinfectant, or they may be sterilized. High-level disinfection is traditionally defined as complete elimination of all microorganisms in or on an instrument, except for small numbers of bacterial spores. Refer to the specific disinfectant label claim to determine effectiveness; and*
- *Non-critical items are those that come in contact with intact skin but not mucous membranes. Noncritical items are divided into noncritical resident care items (e.g., blood pressure cuffs, stethoscopes, wheelchairs, therapy equipment) and noncritical environmental surfaces (e.g., bed rails, bedside tables).* They require low level disinfection by cleaning periodically and after visible soiling, *following manufacturer's instructions* with an EPA-*registered* disinfectant, detergent or germicide that is approved for health care settings. *All applicable label instructions on EPA-registered disinfectant products must be followed (e.g., use-dilution, shelf life, storage, material compatibility, safe use and disposal).*

Single-use disposable equipment is an alternative to sterilizing reusable medical instruments. Single-use devices must be discarded after use and are never used for more than one resident. Nursing homes may purchase reprocessed single-use devices when these devices are reprocessed by an entity or a third party reprocessor that is registered with the FDA. The

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58 Sehulster, L.M., Chinn, R.Y., Arduino, M.J., Carpenter, J., Donlan, R., Ashford, D., … Cleveland, J. (2003, June 6). Guidelines for environmental infection control in health-care facilities. Recommendations from CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC). *MMWR; 52(*No. RR-10). Accessed on June 9, 2017 from https://www.cdc.gov/hicpac/pdf/guidelines/eic_in_HCF_03.pdf

nursing home must have documentation from the third party reprocessor that indicates that it has been cleared by the FDA to reprocess the specific device in question.

NOTE: *Refer to the CDC website for information on disinfection and sterilization – https://www.cdc.gov/infectioncontrol/guidelines/Disinfection/index.html*

TRANSMISSION-BASED PRECAUTIONS

Transmission-based precautions must be used when a resident develops signs and symptoms of a transmissible infection, arrives at a nursing home with symptoms of an infection (pending laboratory confirmation), or has a laboratory confirmed infection and is at risk of transmitting the infection to other residents. For example, a resident with influenza and signs of infection should wear a facemask (e.g., surgical or procedure facemask) when leaving his/her room for medically-necessary care (i.e., droplet precautions for the duration of the illness). The diagnosis of many infections is based on clinical signs and symptoms, but often requires laboratory confirmation. However, since laboratory tests (especially those that depend on culture techniques) may require two or more days to complete, transmission-based precautions may need to be implemented while test results are pending, based on the clinical presentation and the likely category of pathogens.[40, 51]

Facility policies must identify the type (i.e., contact, droplet, airborne) and duration of the transmission-based precautions required, depending upon the infectious agent or organism involved. Furthermore, transmission-based precautions should be the least restrictive possible for the resident based on his/her clinical situation and used for the least amount of time. When used appropriately, transmission-based precautions is not to be considered involuntary seclusion. However, once the resident is no longer a risk for transmitting the infection (e.g., duration of the illness and/or can contain secretions), removing transmission-based precautions is required in order to avoid unnecessary involuntary seclusion. For example, a resident with vancomycin-resistant enterococci (VRE) who is colonized based on a urine culture, but is continent and cognizant, should be instructed regarding or as necessary, assisted with performing hand hygiene before leaving his/her room, but is not placed on transmission-based precautions.

Facility staff should take measures to reduce or minimize any potential psychosocial negative effects of isolation for whom transmission-based precautions are being used. Boredom, anger, withdrawal or depression are just some of the mood changes that could occur. The facility must pro-actively ensure that individualized needs (e.g., activities) are met.

Implementation of Transmission-Based Precautions

When implementing transmission-based precautions, consideration should be given to the following:[40]

- *The identification of resident risk factors that increase the likelihood of transmission, (such as uncontained secretions or excretions, non-compliance, cognition deficits, incontinence, etc.);*
- *The provision of a private room as available/appropriate;*
- *Cohorting residents with the same pathogen*; and
- *Sharing a room with a roommate with limited risk factors (e.g., without indwelling or*

invasive devices, without open wounds, and not immunocompromised) as appropriate.

When a resident is placed on transmission-based precautions, the staff should implement the following:

- *Clearly identify the type of precautions and the appropriate PPE to be used;*
- *Place signage in a conspicuous place outside the resident's room such as the door or on the wall next to the doorway identifying the CDC category of transmission-based precautions (e.g. contact, droplet, or airborne), instructions for use of PPE, and/or instructions to see the nurse before entering. Ensure that signage also complies with residents' rights to confidentiality and privacy;*
- *Make PPE readily available near the entrance to the resident's room;*
- *Don appropriate PPE upon entry into the environment (e.g., room or cubicle) of resident on transmission-based precautions (e.g., contact precautions);* [40]
- *Use disposable or dedicated noncritical resident-care equipment (e.g., blood pressure cuff, bedside commode). If noncritical equipment is shared between residents, it will be cleaned and disinfected following manufacturer's instructions with an EPA-registered disinfectant after use;* [40]
- *Clean and disinfect objects and environmental surfaces that are touched frequently (e.g., bed rails, over-bed table, bedside commode, lavatory surfaces in resident bathrooms) with an EPA-registered disinfectant for healthcare use at least daily and when visibly soiled;* [40] *and*
- *Provide education to residents (to the degree possible/consistent with the resident's capacity) and their representatives or visitors on the use of transmission-based precautions.*

NOTE: *Refer to CDC guidelines for current recommendations on standard and transmission-based precautions. http://www.cdc.gov/hicpac/2007IP/2007isolationPrecautions.html*

Contact Precautions

Contact precautions *are intended* to prevent *transmission of* infections that are spread by *direct (e.g.,* person-to-person*) or indirect* contact *with the resident or environment,* and require the use of appropriate PPE, including a gown and gloves upon entering *(i.e., before making contact with the resident or resident's environment)* the room *or cubicle.* Prior to leaving the resident's room *or cubicle*, the PPE is removed and hand hygiene is performed.

Droplet Precautions

The use of droplet precautions applies when respiratory droplets contain viruses or bacteria particles which may be spread to another susceptible individual. Respiratory viruses can enter the body via the nasal mucosa, conjunctivae and less frequently the mouth.[59] Examples of droplet-borne organisms that may cause infections include, but are not limited to Mycoplasma pneumoniae, influenza, and other respiratory viruses.

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59 Hall, C.B., Douglas, Jr., R.G., Schnabal, K.C., and Geiman, J.M. (1981, September). Infectivity of respiratory syncytial virus by various routes of inoculation. *Infection and Immunity*. *33*(3), 779-783.

Respiratory droplets are generated when an infected person coughs, sneezes, talks, or during procedures such as suctioning, endotracheal intubation, cough induction by chest physiotherapy, and cardiopulmonary resuscitation.[40] The maximum distance for droplet transmission is currently unresolved, but the area of defined risk based on epidemiological findings is approximately 3-10 feet.[40] In contrast to airborne pathogens, droplet-borne pathogens are generally not transmitted through the air over long distances.

Facemasks are to be used upon entry *(i.e., within three feet of a resident)* into a resident's room or cubicle with respiratory droplet precautions.[40] *If substantial spraying of respiratory secretions is anticipated, gloves and gown as well as goggles (or face shield in place of goggles) should be worn.*[40] *The preference for a resident on droplet precautions would be to place the resident in a private room.*[40] *If a private room is not available, the resident could be cohorted with a resident with the same infectious agent, or share a room with a roommate with limited risk factors.*[40] *Spatial separation of at least 3 feet and drawing the curtain between resident beds is especially important for residents in multi-bed rooms with infections transmitted by the droplet route.*[40]

Airborne Precautions

Airborne transmission occurs when pathogens are so small that they can be easily dispersed in the air, and because of this, there is a risk of transmitting the disease through inhalation. These small particles containing infectious agents may be dispersed over long distances by air currents and may be inhaled by individuals who have not had face-to-face contact with (or been in the same room with) the infectious individual. Staff caring for residents on airborne precautions should wear a fit-tested N95 or higher level respirator that is donned prior to room entry.[40]

NOTE: *According to the CDC, preventing the spread of pathogens that are transmitted by the airborne route requires the use of special air handling and ventilation systems such as an airborne infection isolation room (AIIR) to contain and then safely remove the infectious agent.*[40] *Residents with infections requiring an AIIR must be transported to an acute care setting unless the facility can place the resident in a private AIIR room with the door closed.* In cases when AIIR is required, *such as for a resident with TB*, it is important for the facility to have a plan (e.g., public health notification and exposure workup) in place to effectively manage a situation involving a resident with suspected or active TB while awaiting the resident's transfer to an acute care setting.[40]

MEDICAL DEVICE SAFETY

Medical devices may be used for administration of medications, point-of-care testing, or for other medical uses.

Point-of-Care Testing

Point-of-care testing is diagnostic testing that is performed at or near the site of resident care. This may be accomplished through use of portable, handheld instruments such as blood glucose meters or prothrombin time meters. This testing may involve obtaining a blood specimen from the resident using a fingerstick device. The guidance regarding fingerstick devices and blood glucose meters is applicable to other point-of-care devices where a blood specimen is obtained (e.g., prothrombin time meters).

Effective November 28, 2017

Fingerstick Devices

CDC recommends the use of single-use, auto-disabling fingerstick devices in settings where assisted blood glucose monitoring is performed. This practice prevents inadvertent reuse of fingerstick devices for more than one person. Additionally, the use of single-use, auto-disabling fingerstick devices protects healthcare staff from needlestick injuries. If reusable fingerstick devices are used for assisted monitoring of blood glucose, then they ***must never be used for more than one resident****. Although the package instructions for some fingerstick devices may indicate or imply the potential for multiple resident use, CMS guidance, based upon nationally recognized standards of practice from the CDC and FDA, prohibits the use of fingerstick devices for more than one resident.*

NOTE: If fingerstick devices are used on more than one resident, surveyors must cite at this tag and utilize the guidelines in Appendix Q for immediate jeopardy. *Furthermore, the state survey agency (SA) must notify the appropriate state public health authority of the deficient practice.*

NOTE: *For information on fingerstick safety, please refer to:*

- *https://www.cdc.gov/injectionsafety/fingerstick-devicesbgm.html*
- *https://www.cdc.gov/injectionsafety/providers/blood-glucose-monitoring_faqs.html*

Blood Glucose Meters

Blood glucose meters, can become contaminated with blood and, if used for multiple residents, must be cleaned and disinfected after each use according to manufacturer's instructions for multi-patient use. Additionally, staff must ***not*** *carry blood glucose meters in pockets.*
The FDA has released guidance for manufacturers regarding appropriate products and procedures for cleaning and disinfection of blood glucose meters. This guidance can be found at the FDA's website:
http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/ucm227935.htm
An excerpt from this guidance reads:

> *"The disinfection solvent you choose should be effective against HIV, Hepatitis C, and Hepatitis B virus. Outbreak episodes have been largely due to transmission of Hepatitis B and C viruses. However, of the two, Hepatitis B virus is the most difficult to kill. Please note that 70% ethanol solutions are not effective against viral bloodborne pathogens and the use of 10% bleach solutions may lead to physical degradation of your device." A list of Environmental Protection Agency (EPA) registered disinfectants can be found at the following website: https://www.epa.gov/pesticide-registration/selected-epa-registered-disinfectants.*

Furthermore, "healthcare personnel should consult the manufacturers of blood glucose meters in use at their facilities to determine what products, meeting the criteria specified by the FDA, are compatible with their meter prior to using any EPA-registered disinfectant for disinfection

purposes. If manufacturers are unable to provide this information then the meter should not be used for multiple patients."[60]

Blood glucose meters dedicated for single-resident use should be stored in a manner that will protect against inadvertent use of the device for additional residents and also cross-contamination via contact with other meters or equipment.

NOTE: *If the facility failed to clean and disinfect, per device manufacturer's instructions, and blood glucose meters are used for more than one resident, surveyors must cite this tag and utilize the guidelines in Appendix Q as it may constitute immediate jeopardy.*

For more information on point-of-care testing, refer to CDC's website at: https://www.cdc.gov/injectionsafety/blood-glucose-monitoring.html

Safe Medication Administration

All injectable medications must be prepared and administered in accordance with safe injection practices, including but not limited to the following:

- *Injections are prepared using aseptic technique in a clean area, free from potential sources of contamination (e.g., blood, body fluids, contaminated equipment);*
- *Needles and syringes are used for only one resident (this includes manufactured prefilled syringes and cartridge devices such as insulin pens).*

  NOTE: *If it is identified that needles or syringes are used for more than one resident, surveyors must cite noncompliance at this tag and utilize the guidelines in Appendix Q for immediate jeopardy. The SA must notify the appropriate state public health authority of the deficient practice;*

- *Medication containers are entered with a new needle and a new syringe, even when obtaining additional doses for the same resident. If noncompliance is found, further investigation is warranted.*

  NOTE: *If the medication container is used for more than one resident, a new needle and/or syringe was not used with each access, and the container was then used for another resident, surveyors must cite noncompliance at this tag and utilize the guidelines in Appendix Q for immediate jeopardy. The SA must notify the appropriate state public health authority of the deficient practice;*

- *Single dose (single-use) medication vials, ampules, and bags or bottles of intravenous solution are used for only one resident;*
- *Medication administration tubing and connectors are used for only one resident.*

  NOTE: *Surveyors must cite at this tag if noncompliance is identified and utilize the guidelines in Appendix Q for immediate jeopardy. The SA must notify the appropriate state*

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60 Centers for Disease Control and Prevention. (2016). *Frequently asked questions (FAQs) regarding assisted blood glucose monitoring and insulin administration.* Accessed on June 9, 2017 from https://www.cdc.gov/injectionsafety/providers/blood-glucose-monitoring_faqs.html

public health authority of the deficient practice; and

- *Multi-dose vials to be used for more than one resident are kept in a centralized medication area (e.g., medication room or cart) and do not enter the immediate resident treatment area (e.g., resident room). If multi-dose vials enter the immediate resident treatment area, they should be discarded immediately after use.*

  ***NOTE**: For more information on multi-dose vials, please refer to: https://www.cdc.gov/injectionsafety/providers/provider_faqs_multivials.html*

Insulin pens are pen-shaped injector devices that contain a reservoir for insulin or an insulin cartridge. These devices are designed to permit self-injection and are intended for single-person use, using a new needle for each injection. ***Insulin pens are designed to be used multiple times by a single resident only and must never be shared.*** *Facility staff must follow manufacturer's instructions for administration. Regurgitation of blood into the insulin cartridge after injection will create a risk of bloodborne pathogen transmission if the pen is used for more than one resident, even when the needle is changed. The FDA makes the following recommendations to prevent transmission of bloodborne infections in residents who require insulin pens:*

- *Insulin pens containing multiple doses of insulin are meant for single-resident use only, and must never be used for more than one person, even when the needle is changed;*
- *Insulin pens must be clearly labeled with the resident's name and other identifiers to verify that the correct pen is used on the correct resident; and*
- *Facilities should review their policies and procedures and educate their staff regarding safe use of insulin pens.*

***NOTE:** Sharing insulin pens, or similar devices, between residents is similar to reusing needles or syringes for more than one resident. If noncompliance is found, surveyors must cite at this tag and utilize the guidelines in Appendix Q for immediate jeopardy. The SA must notify the appropriate state public health authority of the finding.*

For more information on insulin pens, please refer to: https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHeathcareProfessionals/ucm133352.htm

Accessing Vascular Devices

Vascular access devices, especially central venous catheters (CVC), increase the risk for local and systemic infections as well as additional complications such as septic thrombophlebitis. Intravascular access devices such as implanted ports may be accessed multiple times per day, for hemodynamic measurements or to obtain samples for laboratory analysis, thus increasing the risk of contamination and subsequent clinical infection. Limiting access to CVCs for only the primary purpose may help reduce the risk of infection. The following CDC guidelines are provided as a reference for current standards of practice for the care of CVCs:

- *http://www.cdc.gov/HAI/settings/outpatient/basic-infection-control-prevention-plan-2011/central-venous-catheters.html*
- *http://www.cdc.gov/dialysis/PDFs/collaborative/Hemodialysis-Central-Venous-Catheter-STH-Protocol.pdf*

- *http://www.cdc.gov/dialysis/PDFs/collaborative/Catheter-Exit-Site-Care-Observations.pdf*
- *http://www.cdc.gov/hicpac/pdf/guidelines/bsi-guidelines-2011.pdf*

SYSTEM OF RECORDING IPCP INCIDENTS

A facility must develop and implement a system for recording incidents identified under the facility's IPCP and the corrective actions taken by the facility based on the investigation of the incidents. A facility-identified incident (e.g., HAI) may include the spread of disease due to errors in infection prevention and control. The facility's system should include defining, identifying, analyzing, and reporting incidents related to failures in infection control practices to the director of nursing, medical director, and the QAA committee. These may include but are not limited to the following:

- *Identification of methods by which the facility would obtain information on incidents from residents, family, and direct care/direct access staff;*
- *A description of how the facility addresses and investigates the incident(s);*
- *Measures to be implemented for the prevention of incidents or potential incidents as they relate to infection prevention and control;*
- *Development and implementation of corrective actions;*
- *Monitoring for the effectiveness of its implemented changes; and*
- *Methods for feedback to appropriate individuals involved in the failed practices.*

LINENS

Laundry Services

The facility must develop and follow practices on handling, storing, processing, and transporting laundry. The facility must monitor to ensure that the laundry practices are implemented, any deviations from practices must be identified, and corrective actions are put in place.

Laundry includes resident's personal clothing, linens, (i.e., sheets, blankets, pillows), towels, washcloths, and items from departments such as nursing, dietary, rehabilitative services, beauty shops, and environmental services. Laundry services may be provided onsite or the facility may have a written agreement in place for offsite laundry services. Regardless of the location where the laundry is processed, the facility must ensure that all laundry is handled, stored, processed and transported in a safe and sanitary method.

Handling Laundry

The facility staff should handle all used laundry as potentially contaminated and use standard precautions (i.e., gloves). Alternatively, if not all used linens are handled as potentially contaminated, staff would provide separation with special identification of bags and containers for contaminated linens with labels, color coding, or other alternative means of separation of the laundry for appropriate handling and processing. The facility should use the following practices:

- *Contaminated laundry is bagged or contained at the point of collection (i.e., location where it was used);* [58]
- *Leak-resistant containers or bags are used for linens or textiles contaminated with blood or body substances;*[58]
- *Sorting and rinsing of contaminated laundry at the point of use, hallways, or other open resident care spaces is prohibited; and* [58]

- *Staff should handle soiled textiles/linens with minimum agitation to avoid the contamination of air, surfaces, and persons.* [58]

Transport of Laundry

The facility practices must include how staff will handle and transport the laundry with appropriate measures to prevent cross-contamination. This includes but is not limited to the following:

- *Contaminated linen and laundry bags are not held close to the body or squeezed when transporting;*[45]
- *No special precautions (i.e., double bagging) or categorizing for linen originating in transmission-based precaution rooms is necessary;*[58]
- *Double bagging of linen is only recommended if the outside of the bag is visibly contaminated or is observed to be wet through to the outside of the bag;*[45]
- *Contaminated linen carts must be cleaned and disinfected whenever visibly soiled and according to a schedule developed by the facility;*[41]
- *Separate carts must be used for transporting clean and contaminated linen. If this is not possible, the contaminated linen cart should be thoroughly cleaned and disinfected per facility protocol before being used to move clean linens; and* [58]
- *Clean linens must be transported by methods that ensure cleanliness and protect from dust and soil during intra or inter-facility loading, transport, and unloading.* [58]

Linen Storage

Facility practices must address linen storage, and should include but are not limited to:

- *Covers are not needed on contaminated textile hampers in resident care areas (unless state licensing rules require them); and* [58]
- *Clean linen must always be kept separate from contaminated linen. The use of separate rooms, closets, or other designated spaces with a closing door provides the most secure methods for reducing the risk of accidental contamination.*[61]

Processing Laundry Including the Use of Laundry Equipment and Detergents in the Facility

The facility must have a process to clean laundry. Detergent and water physically remove many microorganisms from the linen through dilution during the wash cycle. Advances in laundry equipment technology allow modern-day detergents to be much more effective in removing soil and reducing the presence of microbes than those used in the past when much of the research on laundry processing was first conducted. *Washing/drying processes includes the use of manufacturer's instructions for use (IFU) for laundry additives and equipment maintenance. The facility staff must prevent contamination of laundry in processing areas. The facility has laundry practices that includes but are not limited to the following:*

- *Availability and use of hand hygiene products, as well as appropriate PPE (i.e., gloves and gowns) while sorting and handling contaminated linens;* [58]
- *The receiving area for contaminated textiles is clearly separated from clean laundry areas. Workflow should prevent cross-contamination;* [58]

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61 Healthcare Laundry Accreditation Council. (2015). *Checklist: Accreditation standards 2016 edition.* Accessed on June 9, 2017 from http://media.wix.com/ugd/076879_24e999ab2b484cac8c3c30ee9af77cc0.pdf

- *If using fans in laundry processing areas, prevent cross-contamination of clean linens from air blowing from soiled processing areas (i.e., the ventilation should not flow from soiled processing areas to clean laundry areas);* [58]
- Laundry equipment (e.g., washing machines, dryers) is used and maintained according to the manufacturer's IFU to prevent microbial contamination of the system; [58]
- Damp laundry is not left in machines overnight; [58]
- *Laundry detergents, rinse aids or other additives are used according to the manufacturer's IFU's;* [58]

  NOTE: *Facilities should communicate information regarding allergies that may impact how an individual resident's laundry is processed.*

- Ozone cleaning systems are acceptable for processing laundry;
- If laundry chutes are used, they are designed and maintained so as to minimize dispersion of aerosols from contaminated laundry (e.g., no loose items in the chute and bags are closed before tossing into the chute); [58] and
- *The facility should be using the fabric manufacturer's recommended laundry cycles, water temperatures and chemical detergent products:*
  - Recommendations for laundry processed in hot water temperatures is 160ºF (71ºC) for 25 minutes;[58] and
  - For laundry that is not hot water compatible, low temperature washing at 71 to 77 ºF (22-25 ºC) plus a 125-part-per-million (ppm) chlorine bleach rinse has been found to be effective and comparable to high temperature wash cycles.[58]

  NOTE*: The facility is not required to monitor water temperatures during laundry processing cycles, unless specified by state rules.* A chlorine bleach rinse is not required for all laundry items processed in low temperature washing environments due to the availability of modern laundry detergents that are able to produce hygienically clean laundry without the presence of chlorine bleach. *The facility should refer to the manufacturer's recommendations for the use of the detergent and items being laundered.*

Offsite Professional Laundry Services

If linen is sent off-site to a professional laundry, the facility has practices that address how the service will be provided, including how linen is processed and handled to prevent contamination from dust and dirt during loading and transport. The facility should assure that this laundry service meets healthcare industry laundry standards.

Mattresses and Pillows

Standard *permeable* mattresses and pillows can become contaminated with body substances during resident care if the integrity of the covers of these items is compromised. A mattress cover is generally a fitted, protective material, the purpose of which is to prevent the mattress from becoming contaminated with body fluids and substances. A linen sheet placed on the mattress is not considered a mattress cover. Patches for tears and holes in mattress covers do not provide an impermeable surface over the mattress. ***NOTE****: Bed and bath linens must be maintained in good condition (Refer to §483.10(i) Safe environment, F584, for further information).*

The facility must have practices that address the methods for cleaning and disinfecting items that are to be used for another resident after an individual resident's use such as but not limited to the following:[58]

- Mattress covers with tears or holes are replaced;
- Moisture resistant mattress covers are cleaned and disinfected between use for different residents with an EPA-approved germicidal detergent to help prevent the spread of infections;
- Fabric mattress covers are laundered between use for different residents;
- Pillow covers and washable pillows are laundered in a hot water laundry cycle between use for different residents or when they become contaminated with body substances; and
- Mattresses are discarded if bodily fluids have penetrated into the mattress fabric.

ANNUAL REVIEW OF IPCP

The facility's IPCP and its standards, policies and procedures must be reviewed at least annually to ensure effectiveness and that they are in accordance with current standards of practice for preventing and controlling infections; the IPCP must be updated as necessary. In addition, the facility population and characteristics may change over time, and the facility assessment may identify components of the IPCP that must be changed accordingly.

INVESTIGATIVE SUMMARY

Surveyors would use the Infection Control Facility Task to determine compliance with the infection control part of the survey. One surveyor should coordinate the review of the facility's overall infection prevention and control program ***(****IPCP), however, each member of the survey team should assess for compliance throughout the entire survey when observing his/her assigned areas and tasks. The IPCP must be facility-wide and include all departments and contracted services. The surveyor should corroborate any concerns observed through interviews and record and/or document review.*

Observations

Specific observations for the provision of infection prevention and control practices such as following standard precautions (e.g., hand hygiene and the appropriate use of PPE) should be made by all team members throughout the survey. Observe care of a resident on transmission-based precautions, if any, to determine if implemented appropriately based on precaution type (i.e., contact, droplet, airborne). If concerns are identified, expand the sample to include more residents with transmission-based precautions.

Observe laundry services throughout the survey (e.g., resident and laundry rooms) to determine whether staff handle, store, and transport linens appropriately.

Interviews

Surveyors should interview appropriate facility staff regarding the IPCP. In addition, any potential concerns should be followed up with interviews and record reviews as needed.

KEY ELEMENTS OF NONCOMPLIANCE

To cite deficient practice at F880, the surveyor's investigation will generally show that the facility failed to do ***any one*** *or more of the following:*

- *Establish and maintain an IPCP designed to provide a safe, sanitary, and comfortable environment and to help prevent development and transmission of disease and infection;*
- *The IPCP must be reviewed at least annually and updated as necessary;*
- *Implement a system for preventing, identifying, reporting, investigating, and controlling infections and communicable diseases for all residents, staff, volunteers, visitors, and other individuals providing services under a contractual arrangement, based on the facility assessment (see §483.70(e)) and follows accepted national standards*;
- *Develop and implement written IPCP standards, policies, and procedures that are current and based on national standards. These must include:*
  - *When and to whom possible incidents of communicable diseases should be reported;*
  - *Developing and implementing a system of surveillance to identify infections or communicable diseases;*
  - *How to use standard precautions (to include appropriate hand hygiene) and how and when to use transmission-based precautions (i.e., "isolation precautions"); and/or*
  - *Prohibiting staff with a communicable disease or infected skin lesions from direct contact with residents or their food, if direct contact will transmit disease.*
- *Assure that staff handle, store, process and transport laundry to prevent the spread of infection; and/or*
- *Maintain a system for recording identified incidents, and taking appropriate corrective actions.*

DEFICIENCY CATEGORIZATION

Examples of Severity Level 4 Non-Compliance: Immediate Jeopardy to Resident Health or Safety include but are not limited to:

- The facility failed to follow standard precautions during the performance of routine testing of blood glucose. The facility reused fingerstick devices for more than one resident. This practice of reusing fingerstick devices for more than one resident created an immediate jeopardy to resident health by potentially exposing residents who required blood glucose testing to the spread of bloodborne infections in the facility.
- The facility failed to investigate, document surveillance of, and implement preventative measures to address an outbreak of gastrointestinal illness among residents in one unit of the facility. As a result, several residents in an adjoining unit became seriously ill with diarrheal illnesses resulting in dehydration.
- *Facility staff failed to handle soiled linens using safe and sanitary techniques. A resident was observed to have an acute onset of vomiting and diarrhea resulting in soiled clothing and linens. The nursing staff removed the soiled/contaminated clothing and linens, rinsed them out in the bathroom sink, and placed the wet/soiled linen onto the floor. The bathroom was shared with a roommate who utilized the sink for oral hygiene purposes and stored his/her toothbrush and glass on the sink. The roommate, subsequently developed vomiting and diarrhea, with the development of severe dehydration, resulting in hospitalization.*

An Example of Severity Level 3 Non-Compliance: Actual Harm that is not Immediate Jeopardy includes but is not limited to:

- *The facility failed to identify and prevent the spread of infestation when a case of scabies (i.e., a highly contagious skin condition caused by the itch mite Sarcoptes scabiei) was*

not diagnosed or adequately treated, and the resident was not placed on transmission-based precautions. Resident A was admitted with an undiagnosed, reddened, itchy pin-point rash which spread, became infected, and disrupted the resident's sleep. A month later, multiple residents developed a red, pin-point rash with severe itching, which was not present prior to resident A being admitted. The facility failed to identify through assessment and therefore, implement control measures to prevent the transmission of scabies among multiple residents in the facility, causing the residents physical harm. In addition to the physical harm, the residents experienced psychosocial harm due to anxiety and loss of sleep from severe itching and lack of timely diagnosis.

- *The facility failed to ensure that linens were handled and processed in a manner to prevent the spread of pediculosis (i.e., head lice) after a resident (resident A) in a semi private room was diagnosed with pediculosis. Staff were aware of the presence of pediculosis, but did not handle the resident's linens or clothing appropriately, removing bed linens and placing them on the roommate's chairs and other furnishings. The resident's roommate (resident B) became infested with pediculosis. The resident's roommate was non-verbal and unable to express that he had intense itching and began to scratch himself.*

An Example of Severity Level 2 Non-Compliance: No Actual Harm with Potential for more than Minimal Harm that is not Immediate Jeopardy includes but is not limited to:

- *The facility failed to ensure that its staff demonstrates proper use of gloves with hand hygiene between residents to prevent the spread of infections. The nurse administered medications to a resident via a gastric tube and while wearing the same gloves proceeded to administer oral medications to another resident. The nurse did not remove the used gloves nor perform hand hygiene between the two residents.*
- *The facility failed to implement appropriate measures for the transport of contaminated linens. As a result, the potential exists for transmission of organisms from contaminated uniforms to residents during the delivery of care. A nursing assistant was observed removing bed linens contaminated with urine and fecal material without the use of gloves, and carrying the contaminated linens against his/her uniform down the hall to the laundry bin. The nursing assistant proceeded to assist the resident's roommate with transferring to his/her chair, and his/her uniform made contact with the resident's skin and clothing.*
- *The facility failed to ensure that a staff member implemented appropriate processes related to handling and storing wound care supplies. As a result, the potential existed for transmission of organisms between residents who received dressing changes. A staff member who was providing wound care, was observed to place dressing supplies on one resident's bedding and after completing the dressing change, placed the supplies, which are used for other residents, in the unit's dressing cart.*

An Example of Severity Level 1 Non-Compliance: No actual harm with potential for minimal harm includes but is not limited to:

- *The facility failed to ensure that the IPCP program was reviewed annually. The survey was conducted and it was determined that the facility last reviewed the IPCP at 14 months instead of annually (i.e., 12 months). There were no infection control findings outside of annual review and documentation.*

Effective November 28, 2017

POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION

For staff competency concerns, refer to the following F tags:

- *F725 or 726, §483.35(a),(c) for Nursing Services;*
- *F741, §483.40 for any Behavioral Health staff caring for residents with dementia or a history of trauma and/or post-traumatic stress disorder;*
- *F801, §483.60(a) for Food and Nutrition staff; and*
- *F839, §483.70(f), Administration for any other staff not referenced above.*

If the surveyor has concerns about 1) the overuse of transmission-based ("isolation") precautions, 2) the inappropriate transferring of rooms unnecessarily; or 3) the inappropriate use of PPE such as gloves when used unnecessarily, where residents indicate they are "untouchable," dirty or unclean, review under §483.10(a)(1), F550, Resident Rights (Dignity) or §483.24, F675, Quality of Life.

For concerns related to possible involuntary seclusion, refer to §483.12 (a)(1), F603.

Data from injectable, scheduled drug tracking should be regularly reviewed and discrepancies or unusual access patterns are investigated including whether residents should be screened for exposure to bloodborne pathogens (refer to 483.45, F755, Pharmacy Services for further information on reconciliation concerns).

For concerns related to the QAA committee's responsibility to identify or correct quality deficiencies, which may include systemic infection control concerns, refer to 483.75(g)(2)(ii), F867, QAA Activities.

For concerns related to the medical director's role in responsibility for care, refer to §483.70(h), F841, Medical Director.

F881

§483.*80(a) Infection prevention and control program.*

The facility must establish an infection prevention and control program (IPCP) that must include, at a minimum, the following elements:

§483.*80(a)(3) An antibiotic stewardship program that includes antibiotic use protocols and a system to monitor antibiotic use.*

INTENT

The intent of this regulation is to ensure that the facility:

- *Develops and implements protocols to optimize the treatment of infections by ensuring that residents who require an antibiotic, are prescribed the appropriate antibiotic;*
- *Reduces the risk of adverse events, including the development of antibiotic-resistant organisms, from unnecessary or inappropriate antibiotic use; and*
- *Develops, promotes, and implements a facility-wide system to monitor the use of antibiotics.*

Effective November 28, 2017

DEFINITIONS

"Antibiotic": *a medication used to treat bacterial infections. They are not effective for infections caused by viruses (e.g., influenza or most cases of bronchitis).*

"Antibiotic Stewardship": *refers to a set of commitments and actions designed to optimize the treatment of infections while reducing the adverse events associated with antibiotic use.*[62] *This can be accomplished through improving antibiotic prescribing, administration, and management practices thus reducing inappropriate use to ensure that residents receive the right antibiotic for the right indication, dose, and duration.*[63]

"Clostridium difficile infection (C. difficile or CDI)": *an infection from a bacterium that causes colitis, an inflammation of the colon, causing diarrhea.*

"Colonization": *the presence of microorganisms on or within body sites without detectable host immune response, cellular damage, or clinical expression.*

"Methicillin-resistant Staphylococcus aureus (MRSA)" *(a.k.a. Oxacillin-resistant Staphylococcus aureus)****:*** *Staphylococcus aureus bacteria that are resistant to treatment with one of the semi-synthetic penicillins (e.g., Oxacillin/Nafcillin/Methicillin).*

"Multidrug-Resistant Organisms (MDROs)*": microorganisms, predominantly bacteria, that are resistant to one or more classes of antimicrobial agents.*[51] *Although the names of certain MDROs describe resistance to only one agent, these pathogens are frequently resistant to most available antimicrobial agents and include multidrug-resistant gram negative bacteria (GNB), Carbapenem-resistant Enterobacteriaceae (CRE), and extended spectrum beta-lactamase-producing Enterobacteriaceae (ESBLs).*

"Vancomycin resistant enterococcus (VRE)": *species of enterococcus which have developed resistance to the antibiotic, vancomycin.*

GUIDANCE

Antibiotic Stewardship

As part of their IPCP programs, facilities must develop an antibiotic stewardship program that promotes the appropriate use of antibiotics and includes a system of monitoring to improve resident outcomes and reduce antibiotic resistance. [64, 65, 66] *This means that the antibiotic is*

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62 Centers for Disease Control and Prevention. (2014). *Core elements of hospital antibiotic stewardship programs.* Accessed on June 9, 2017 from https://www.cdc.gov/getsmart/healthcare/implementation/core-elements.html

63 Centers for Disease Control and Prevention. (2015). *The core elements of antibiotic stewardship for nursing homes.* Accessed on June 9, 2017 from https://www.cdc.gov/longtermcare/prevention/antibiotic-stewardship.html

64 Centers for Disease Control and Prevention. (2013). *Antibiotic resistance threats in the United States, 2013.* Accessed on June 9, 2017 from http://www.cdc.gov/drugresistance/threat-report-2013/pdf/ar-threats-2013-508.pdf

65 Spellberg, B., Bartlett, J.G., & Gilbert, D. N. (January 24, 2013). The future of antibiotics and resistance. *The New England Journal of Medicine, 368*, 299-302.

66 The White House. (2014). *National Strategy for Combating Antibiotic Resistant Bacteria.* Accessed on June 9, 2017 from https://obamawhitehouse.archives.gov/sites/default/files/docs/carb_national_strategy.pdf

prescribed for the correct indication, dose, and duration to appropriately treat the resident while also attempting to reduce the development of antibiotic-resistant organisms.

Nursing home residents are at risk for adverse outcomes associated with the inappropriate use of antibiotics that may include but are not limited to the following:

- *Increased adverse drug events and drug interactions (e.g., allergic rash, anaphylaxis or death);*
- *Serious diarrheal infections from C. difficile;*
- *Disruption of normal flora (e.g., this can result in overgrowth of Candida such as oral thrush); and/or*
- *Colonization and/or infection with antibiotic-resistant organisms such as MRSA, VRE, and multidrug-resistant GNB.*

NOTE: *The Centers for Disease Control and Prevention (CDC) has identified core actions to prevent antibiotic resistance within the control of the nursing home. For more information, refer to CDC NH Core Elements at:*
http://www.cdc.gov/longtermcare/pdfs/core-elements-antibiotic-stewardship-appendix-a.pdf

NOTE: *For examples of antibiotic use protocols, policies and practices developed by the Agency for Healthcare Research and Quality, see: http://www.ahrq.gov/nhguide/index.html*

NOTE: *References to non-U. S. Department of Health and Human Services (HHS) sources or sites on the internet are provided as a service and do not constitute or imply endorsement of these organizations or their programs by CMS. CMS is not responsible for the content of pages found at these sites. URL addresses were current as of the date of this publication.*

Antibiotic Stewardship Program

As summarized by the CDC [63], the core elements for antibiotic stewardship in nursing homes include:

- *Facility leadership commitment to safe and appropriate antibiotic use;*
- *Appropriate facility staff accountable for promoting and overseeing antibiotic stewardship;*
- *Accessing pharmacists and others with experience or training in antibiotic stewardship;*
- *Implement policy(ies) or practice to improve antibiotic use;*
- *Track measures of antibiotic use in the facility (i.e., one process and one outcome measure);*
- *Regular reporting on antibiotic use and resistance to relevant staff such as prescribing clinicians and nursing staff; and*
- *Educate staff and residents about antibiotic stewardship.*

The facility must develop an antibiotic stewardship program which includes the development of protocols and a system to monitor antibiotic use. This development should include leadership support and accountability via the participation of the medical director, consulting pharmacist, nursing and administrative leadership, and individual with designated responsibility for the infection control program if different.[63]

Effective November 28, 2017

The antibiotic stewardship program protocols shall describe how the program will be implemented and antibiotic use will be monitored, consequently protocols must:

- *Be incorporated in the overall infection prevention and control program;*
- *Be reviewed on an annual basis and as needed;*
- *Contain a system of reports related to monitoring antibiotic usage and resistance data. Examples may include the following:*
  - *Summarizing antibiotic use from pharmacy data, such as the rate of new starts, types of antibiotics prescribed, or days of antibiotic treatment per 1,000 resident days;*[63]
  - *Summarizing antibiotic resistance (e.g., antibiogram) based on laboratory data from, for example, the last 18 months; and/or* [63]
  - *Tracking measures of outcome surveillance related to antibiotic use (e.g., C. difficile, MRSA, and/or CRE).* [63]
- *Incorporate monitoring of antibiotic use, including the frequency of monitoring/review. Monitor/review when the resident is new to the facility; when a prior resident returns or is transferred from a hospital or other facility* [63]*; during each monthly medication regimen review when the resident has been prescribed or is taking an antibiotic, or any antibiotic regimen review as requested by the QAA committee. In addition, establish the frequency and mode or mechanism of feedback (e.g., verbal, written note in record) to prescribing practitioners regarding antibiotic resistance data, their antibiotic use and their compliance with facility antibiotic use protocols.* [63] *Feedback on prescribing practices and compliance with facility antibiotic use protocols may include information from medical record reviews for new antibiotic starts to determine whether the resident had signs or symptoms of an infection; laboratory tests ordered and the results; prescription documentation including the indication for use (i.e., whether or not an infection or communicable disease has been documented), dosage and duration; and clinical justification for the use of an antibiotic beyond the initial duration ordered such as a review of laboratory reports/cultures in order to determine if the antibiotic remains indicated or if adjustments to therapy should be made (e.g., more narrow spectrum antibiotic);*
- *Assess residents for any infection using standardized tools and criteria* [63] *(e.g., SBAR tool for urinary tract infection (UTI) assessment* [67]*, Loeb minimum criteria for initiation of antibiotics* [68]*); and*
- *Include the mode (e.g., verbal, written, online) and frequency (as determined by the facility) of education for prescribing practicitioners and nursing staff on antibiotic use (stewardship) and the facility's antibiotic use protocols.* ***NOTE:*** *Prescribing practitioners can include attending physicians and non-physician practitioners (NPP) (i.e., nurse practitioners, clinical nurse specialists, and physician assistants).*

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67 Agency for Healthcare Research and Quality. (2016). *Toolkit 3. Minimum criteria for common infections.* Accessed on June 9, 2017 from http://www.ahrq.gov/nhguide/toolkits/determine-whether-to-treat/toolkit3-minimum-criteria.html

68 Loeb, M., Brazil, K., Lohfeld, L., McGeer, A., Simor, A., Stevenson, K., Zoutman, D…..Walter, S.D. (2005). Effect of a multifaceted intervention on number of antimicrobial prescriptions for suspected urinary tract infections in residents of nursing homes: Cluster randomised controlled trial. *BMJ*, 331, 669. Accessed on June 9, 2017, from http://www.bmj.com/content/bmj/early/2004/12/31/bmj.38602.586343.55.full.pdf

Effective November 28, 2017

The Antibiotic Stewardship Program in Relation to Pharmacy Services
The assessment, monitoring, and communication of antibiotic use shall occur by a licensed pharmacist in accordance with §483.45(c), F756, Drug Regimen Review. A pharmacist must perform a medication regimen review (MRR) at least monthly, including review of the medical record and identify any irregularities, including unnecessary drugs.

INVESTIGATIVE SUMMARY
Surveyors should use the Infection Control Facility Task to assess for compliance with the antibiotic stewardship program during the standard survey.

Antibiotic Stewardship Review
Determine whether the facility's antibiotic stewardship program includes antibiotic use protocol(s) addressing antibiotic prescribing practices (i.e., documentation of the indication, dose, and duration of the antibiotic; review of laboratory reports to determine if the antibiotic is indicated or needs to be adjusted; an infection assessment tool or management algorithm is used when prescribing) and a system to monitor antibiotic use (i.e., antibiotic use reports, antibiotic resistance reports).

Specific Concerns That May Warrant Further Investigation
If concerns have been identified, it may be necessary to conduct record reviews of one (or more) residents receiving antibiotics to identify whether the documented indication for the use of the antibiotic, dosage, and duration is appropriate. It may also be necessary to interview the appropriate person, (e.g., director of nursing, medical director, consulting pharmacist, administrator, or infection preventionist) to verify how antibiotic use is monitored in the facility. Furthermore, review records including evidence of actions taken by the QAA committee related to antibiotic use and stewardship.

KEY ELEMENTS OF NONCOMPLIANCE
To cite deficient practice at F881, the surveyor's investigation will generally show that the facility failed to do any one or more of the following:

- *Develop and implement antibiotic use protocols to address the treatment of infections by ensuring that residents who require antibiotics are prescribed the appropriate antibiotics;*
- *Develop and implement antibiotic use protocols that address unnecessary or inappropriate antibiotic use thereby reducing the risk of adverse events, including the development of antibiotic-resistant organisms; and/or*
- *Develop, promote and implement a facility-wide system to monitor the use of antibiotics.*

DEFICIENCY CATEGORIZATION
An Example of Severity Level 4 Non-Compliance: Immediate Jeopardy to Resident Health or Safety includes but is not limited to:

- *The facility failed to develop and implement an antibiotic use protocol which included reporting results of laboratory data to the ordering practitioner. Medical record review indicated the prescribing practitioner had ordered a culture and sensitivity for a resident and prescribed an antibiotic for treatment of pneumonia prior to receipt of the results of the lab test. The facility received the results of the lab test which indicated that the*

bacteria was resistant to the antibiotic prescribed, however, they did not provide this information to the practitioner. As a result, the antibiotic was not adjusted accordingly and the resident was hospitalized for complications related to the pneumonia.

An Example of Severity Level 3 Non-Compliance: Actual Harm that is not Immediate Jeopardy includes but is not limited to:

- *The facility did not develop a protocol for antibiotic use, and did not develop or implement a system to monitor antibiotic use. Based on record review, two residents were currently being treated with antibiotics without an appropriate indication for use. The two residents had indwelling urinary catheters and were asymptomatic for UTIs. There was no established criteria for use in the facility for when to treat a catheter-associated urinary tract infection. As a result of the antibiotic therapy, the two residents developed numerous watery, foul-smelling stools, elevated temperature, nausea, and decreased appetite. The medical record revealed that stool cultures identified positive bacteria for antibiotic-related colitis (C. difficile). The two residents were treated for antibiotic-related colitis, but did not require hospitalization and fully recovered.*

An Example of Severity Level 2 Non-Compliance: No Actual Harm with Potential for more than Minimal Harm that is not Immediate Jeopardy includes but is not limited to:

- *The facility failed to implement its protocol for antibiotic use and failed to monitor actual antibiotic use. Record review indicated that the facility developed a protocol which indicated "residents with MDROs are not to be treated with antibiotics for colonization". However, record review revealed one resident colonized with an MDRO receiving an antibiotic to eliminate colonization. As a result, the potential exists for residents to develop antibiotic resistance.*

An Example of Severity Level 1 Non-Compliance: No Actual Harm with Potential for Minimal Harm includes but is not limited to:

- *The facility failed to implement their protocol to monitor the rate of new starts of antibiotics monthly. On review, the monitoring was not completed for 6 weeks. There were no findings of increased MDROs or CDI in the facility.*

POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION

Additionally, refer to §483.45(c), F756, for concerns related to the failure of the pharmacist to review and report any unnecessary antibiotic irregularity and §483.45(d), F757, for concerns related to unnecessary antibiotic use.

Refer to 483.10(c)(1), 483.10(c)(4) - (6):– the right to be fully informed in advance about care and treatment (F552) for concerns about education of residents and their representatives.

F882

§483.80(b) Infection preventionist

[§483.80(b) and all subparts will be implemented beginning November 28, 2019 (Phase 3)]

The facility must designate one or more individual(s) as the infection preventionist(s) (IP)(s) who are responsible for the facility's IPCP. The IP must:

Effective November 28, 2017

§483.80(b)(1) Have primary professional training in nursing, medical technology, microbiology, epidemiology, or other related field;

§483.80(b)(2) Be qualified by education, training, experience or certification;

§483.80(b)(3) Work at least part-time at the facility; and

§483.80(b)(4) Have completed specialized training in infection prevention and control.

§483.80 (c) IP participation on quality assessment and assurance committee.
The individual designated as the IP, or at least one of the individuals if there is more than one IP, must be a member of the facility's quality assessment and assurance committee and report to the committee on the IPCP on a regular basis.

F883
§483.80(d) **Influenza and pneumococcal immunizations**
§483.80(d)**(1) Influenza. The facility must develop policies and procedures to ensure that-**

- **(i) Before offering the influenza immunization, each resident or the resident's representative receives education regarding the benefits and potential side effects of the immunization;**
- **(ii) Each resident is offered an influenza immunization October 1 through March 31 annually, unless the immunization is medically contraindicated or the resident has already been immunized during this time period;**
- **(iii) The resident or the resident's representative has the opportunity to refuse immunization; and**
- **(iv)The resident's medical record includes documentation that indicates, at a minimum, the following:**
  - **(A) That the resident or resident's representative was provided education regarding the benefits and potential side effects of influenza immunization; and**
  - **(B) That the resident either received the influenza immunization or did not receive the influenza immunization due to medical contraindications or refusal.**

§483.*80(d)*(2) Pneumococcal disease. The facility must develop policies and procedures *to* ensure that-

- **(i) Before offering the pneumococcal immunization, each resident or the resident's representative receives education regarding the benefits and potential side effects of the immunization;**
- **(ii) Each resident is offered a pneumococcal immunization, unless the immunization is medically contraindicated or the resident has already been immunized;**
- **(iii) The resident or the resident's representative has the opportunity to refuse immunization; and**
- **(iv)The resident's medical record includes documentation that indicates, at a minimum, the following:**
  - **(A) That the resident or resident's representative was provided education regarding the benefits and potential side effects of pneumococcal immunization; and**

(B) That the resident either received the pneumococcal immunization or did not receive the pneumococcal immunization due to medical contraindication or refusal.

INTENT

The intent of this regulation is to:

- Minimize the risk of residents acquiring, transmitting, or experiencing complications from influenza and pneumococcal disease by *ensuring* that each resident:
  - Is informed about the benefits and risks of immunizations; and
  - Has the opportunity to receive the influenza and pneumococcal vaccine*(s)*, unless medically contraindicated, refused or was already immunized.
- *Ensure* documentation in the resident's medical record of the information/education provided regarding the benefits and risks of immunization and the administration or the refusal of or medical contraindications to the vaccine(s).

DEFINITIONS

"The Advisory Committee on Immunization Practices (ACIP)"*: a group of medical and public health experts that develops recommendations on how to use vaccines to control diseases in the United States. ACIP's recommendations stand as public health advice that will lead to a reduction in the incidence of vaccine preventable diseases and an increase in the safe use of vaccines and related biological products.* See *http://www.cdc.gov/vaccines/acip/index.html for further information.*

"Medical contraindication": a condition or risk that precludes the administration of a treatment or intervention because of the substantial probability that harm to the individual may occur.

"Precaution": a condition in a potential recipient that might increase the risk for a serious adverse reaction or that might compromise the vaccine's induction of immunity. For example, as a result of the resident's condition, complications could result, or a person might experience a more severe reaction to the vaccine than would have otherwise been expected. However, the risk for this happening is less than expected with medical contraindications.

GUIDANCE

Overview

Receipt of vaccinations is essential to the health and well-being of long-term care residents. Establishing an immunization program *against influenza and pneumococcal* disease facilitates achievement of this objective. *Influenza* outbreaks place both the residents and staff at risk of infection. Pneumococcal pneumonia, a type of bacterial pneumonia, is a common cause of hospitalization and death in older people. People 65 years or older are two to three times more likely than the younger population to get pneumococcal infections.

An effective immunization program involves collaborating with the medical director to develop resident care policies for immunization(s) that reflect current standards of practice and that include:

- Physician approved policies for orders of influenza and pneumococcal vaccines (administration must be based on an assessment of each resident for possible medical contraindications – see *483.30(b)(3), F711, for* physician orders for vaccinations);
- *Review of the resident's* record of vaccination and immunization status, including assessment for potential medical contraindications;
- How pertinent information *and education* will be provided to residents *or their representatives*. The facility may wish to use educational resources such as those provided by the U. S. Centers for Disease Control *and Prevention* (CDC)[69]; and
- The vaccination schedule including mechanisms for recording and monitoring for administration of both influenza and pneumococcal *vaccines in accordance with national recommendations.*[70]

NOTE: *Review facility policies regarding the provision of vaccines in order to determine if the policies reflect current standards of practice. Refer to §483.21(b)(3)(i)- the services provided or arranged by the facility must meet professional standards of quality (F658). Also, refer to F880 for concerns with infection prevention and control.*

Provision of Immunizations

In order for a resident to exercise his or her right to make informed choices, it is important for the facility to provide the resident *or resident representative* with education regarding the benefits and potential side effects of immunizations. Facilities are required to document the provision of this education and the administration, refusal of the immunization or the medical contraindication of the immunization. There may be clinical indications or other reasons that a resident may not have received immunizations. The resident's record should show vaccination administration unless it contains documentation as to why the vaccine was not administered, including but not limited to the following:

- A decision may have been made to delay vaccination for a resident because a precaution is present. According to the CDC, "*in general*, vaccinations should be deferred when a precaution is present. However, a vaccination might be indicated in the presence of a precaution because the benefit of protection from the vaccine outweighs the risk for an adverse reaction…The presence of a moderate or severe acute illness with or without a fever is a precaution to administration of all vaccines".[70] *The benefits and risks of receiving the vaccine should be discussed with the resident or resident representative if a resident has a precaution to a vaccine. The vaccine can be administered if the benefit of the vaccine outweighs the risk, the resident or resident representative provides consent, and the resident's physician approves (refer to §483.30 Physician Services for further information on physician supervision);*
- A resident may be in the end stages of a terminal illness and receiving care that is limited to comfort or palliative measures only *and although eligible, the resident or representative has refused the vaccination(s);*

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69 Centers for Disease Control and Prevention. *Vaccine information statements.* Accessed on June 9, 2017 from https://www.cdc.gov/vaccines/hcp/vis/index.html

70 Centers for Disease Control and Prevention. (2011). General recommendations on immunization: Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR;60*(RR02), **1-60.** Accessed on June 9, 2017 from https://www.cdc.gov/mmwr/preview/mmwrhtml/rr6002a1.htm

- A resident may have a medical contraindication *to receiving an* influenza *or pneumococcal* vaccine *such as severe allergic reaction to a vaccine component or following prior dose of vaccine;*
- The resident *or representative* refused the vaccine; or
- The resident has already been immunized.

***NOTE**: For information related to current vaccine recommendations including scheduling and contraindications, refer to http://www.cdc.gov/vaccines/acip/index.html or https://www.cdc.gov/vaccines/pubs/pinkbook/chapters.html.*

***NOTE**: A nursing home may encounter residents who do not have adequate documentation of vaccinations. With the **exception** of influenza vaccine and pneumococcal polysaccharide vaccine (PPSV), providers should only accept written, dated records as evidence of vaccination. Self-reported doses of influenza vaccine and PPSV are acceptable. A resident representative can report on behalf of the resident if he/she is unable to self-report and the representative has knowledge of the resident's medical care. State laws may have more stringent requirements related to documentation.*

Influenza Immunization

The influenza vaccine is given seasonally. The CDC indicates that administering the vaccine ***when it becomes available each season**, rather than date specific, (i.e., "October 1")* is most effective. *Facilities should administer the influenza vaccine when it becomes available to the facility.* Residents admitted late in the influenza season *(typically* February or March) should be offered the influenza vaccine as late season outbreaks do occur. If a resident was admitted outside the influenza season, the facility is not expected to offer the influenza vaccine to the resident, *but it may, at its discretion*.

***NOTE:** Flu seasons are unpredictable in a number of ways. They can vary in different parts of the country and from season to season. While flu spreads every year, the timing, severity, and length of the season varies from one year to another.*

If there is a national shortage of influenza vaccine or other issue with availability leading to an inability to implement the influenza vaccine program, ask the facility to demonstrate that:

- *The vaccine has been ordered and the facility received a confirmation of the order indicating that the vaccine has been shipped or that the product is not available but will be shipped when the supply is available;*
- *Plans are developed on how and when the vaccines are to be administered;*
- *Residents have been screened to determine how many and which residents are eligible and wish to receive the vaccine; and*
- *Education regarding immunizations has been implemented.*

Pneumococcal Immunizations

The regulation requires that each resident is offered pneumococcal immunization, unless the immunization is medically contraindicated or the resident has already been immunized. There should be documentation in the medical record if there is reason to believe that pneumococcal vaccine*(s)* was given previously, but the date cannot be verified, and this had an impact upon the

decision regarding administration of the vaccine*(s)*. *Facilities must follow the CDC and ACIP recommendations for vaccines.*

***NOTE**: As of the date of publication of this guidance, ACIP recommends that "both 23-valent pneumococcal polysaccharide vaccine (PPSV23) and 13-valent pneumococcal conjugate vaccine (PCV13) vaccines should be administered routinely in series to all adults aged ⩾65 years."[71] ACIP explained that PPSV23 is effective in preventing invasive pneumococcal disease (IPD) but the effectiveness of PPSV23 in preventing non-bacteremic pneumococcal pneumonia has been inconsistent. ACIP expects administration of both PCV13 and PPSV23 will provide optimal protection against pneumococcal infections. The recommendations for adults aged <65 years are different than for adults aged ⩾65 years so they should be vaccinated based on the ACIP recommendations for their age group. For more up-to-date information on timing and intervals between vaccines, please refer to ACIP vaccine recommendations located at http://www.cdc.gov/vaccines/hcp/acip-recs/index.html and https://www.cdc.gov/vaccines/schedules/hcp/index.html.*

INVESTIGATIVE SUMMARY

Surveyors must use the Infection Control Facility Task for investigating compliance with this tag. A summary of this facility task is provided below.

Sampling Procedure

Select five residents in the sample to review for the provision of influenza and pneumococcal immunizations. Give precedence in selection to those residents whom the survey team has selected as sampled residents.

Record Review

Review sampled residents' records for education on and provision, refusal, or documentation of medical contraindications for influenza and pneumococcal immunizations. As necessary, determine if the facility developed influenza and pneumococcal vaccine policies and procedures.

KEY ELEMENTS OF NONCOMPLIANCE

To cite deficient practice at F883, the surveyor's investigation will generally show that the facility failed to do any one or more of the following:

- *Develop, maintain, or follow policies and procedures for immunization of residents against influenza and pneumococcal disease in accordance with national standards of practice;*
- *Vaccinate an eligible resident with the influenza and/or the pneumococcal vaccine(s), unless the resident had previously received the vaccine, refused, or had a medical contraindication present;*
- *Allow a resident or a resident's representative to refuse either the influenza and/or the pneumococcal vaccine(s);*

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71 Centers for Disease Control and Prevention. (2014). Use of 13-valent pneumococcal conjugate vaccine and 23-valent pneumococcal polysaccharide vaccine among adults aged ≥65 years: Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR: 63*(37); 822-825. Accessed on June 9, 2017 from https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6337a4.htm

- *Provide and/or document the provision of pertinent information regarding the immunizations to the resident or the resident's representative such as the benefits and potential side effects of the influenza and, as applicable, the pneumococcal immunization(s); and/or*
- Document that the resident either received the *pneumococcal and influenza vaccine(s)* or did not receive the vaccine(s) due to medical contraindications, *previous vaccination,* or refusal.

DEFICIENCY CATEGORIZATION

Examples of Severity Level 4 Non-Compliance: Immediate Jeopardy to Resident Health or Safety include but are not limited to:

- *The facility failed to ensure that medical contraindications were identified for the influenza or pneumococcal vaccine, and administered the vaccine to a resident with identified allergies/contraindications. As a result, the resident experienced a life-threatening reaction of anaphylactic shock requiring immediate treatment and admission to the hospital.*
- *The facility failed to ensure that eligible residents received the influenza vaccines because it did not have a program for vaccinating residents. As a result, several unvaccinated residents in one unit developed influenza, with elevated temperatures, coughing, labored breathing, and required hospitalization for respiratory compromise and dehydration.*

Examples of Severity Level 3 Non-Compliance: Actual Harm that is not Immediate Jeopardy include but is not limited to:

- *A resident who was not eligible to receive the influenza vaccine due to medical contraindications received the vaccine and experienced a reaction that was not serious or life-threatening (i.e., hives and dizziness). The reaction resulted in fear and anxiety that was not to the level of panic and immobilization, but required treatment.*
- *The facility failed to administer the influenza vaccine for several weeks, despite its availability. The facility failed to offer influenza immunizations to three residents who were eligible to receive the vaccine. Record review and staff interview revealed that the three residents had been admitted in the past two months, but their names were not included in the facility's monitoring log for residents who had not received the vaccine and when they had last received one. During interviews, two of the three residents stated that they had not taken "a flu shot in over a year", and one stated that he had never taken a flu shot, but all three stated they would have taken one if offered. Based on record review, two of the three residents were diagnosed with influenza with symptoms of a fever, chills, body aches, and had received treatment with an antiviral in the facility. The two residents were unable to participate in activities or leave their rooms due to the acute illness. Record review corroborated the interview information and when interviewed, staff stated they had overlooked the three residents.*

Examples of Severity Level 2 Non-Compliance: No Actual Harm with Potential for more than Minimal Harm that is not Immediate Jeopardy include but is not limited to:

- An eligible resident did not receive the vaccine, but did not develop symptoms of influenza.

- An eligible resident received two doses of the *same* pneumococcal vaccine. *The facility could have determined the resident already received the vaccine had it documented in the medical record when it was previously given by the facility. The resident did not experience any untoward reactions from the second immunization.*
- The staff did not assess *a resident* for medical contraindications prior to providing the vaccines, but there were no reactions to the vaccine.

An Example of Severity Level 1 Non-Compliance: No Actual Harm with Potential for Minimal Harm includes but is not limited to:

- *The facility failed to document that the resident was provided education on the influenza vaccine prior to administration. When interviewed, the resident stated he had received a copy of the information on influenza risks and benefits and provided the copy to the surveyor. However, the medical record did not reflect receipt of the information.*

F895

§483.85 Compliance and ethics program.
[§483.85 and all subparts will be implemented beginning November 28, 2019 (Phase 3)]

§483.85(a) Definitions.
For purposes of this section, the following definitions apply:
Compliance and ethics program means, with respect to a facility, a program of the operating organization that—

§483.85(1) Has been reasonably designed, implemented, and enforced so that it is likely to be effective in preventing and detecting criminal, civil, and administrative violations under the Act and in promoting quality of care; and

§483.85(2) Includes, at a minimum, the required components specified in paragraph (c) of this section.

High-level personnel means individual(s) who have substantial control over the operating organization or who have a substantial role in the making of policy within the operating organization.
Operating organization means the individual(s) or entity that operates a facility.

§483.85(b) General rule.
Beginning on November 28, 2019, the operating organization for each facility must have in operation a compliance and ethics program (as defined in paragraph (a) of this section) that meets the requirements of this section.

§483.85(c) Required components for all facilities.
The operating organization for each facility must develop, implement, and maintain an effective compliance and ethics program that contains, at a minimum, the following components:

Effective November 28, 2017

§483.85(c)(1) Established written compliance and ethics standards, policies, and procedures to follow that are reasonably capable of reducing the prospect of criminal, civil, and administrative violations under the Act and promote quality of care, which include, but are not limited to, the designation of an appropriate compliance and ethics program contact to which individuals may report suspected violations, as well as an alternate method of reporting suspected violations anonymously without fear of retribution; and disciplinary standards that set out the consequences for committing violations for the operating organization's entire staff; individuals providing services under a contractual arrangement; and volunteers, consistent with the volunteers' expected roles.

§483.85(c)(2) Assignment of specific individuals within the high-level personnel of the operating organization with the overall responsibility to oversee compliance with the operating organization's compliance and ethics program's standards, policies, and procedures, such as, but not limited to, the chief executive officer (CEO), members of the board of directors, or directors of major divisions in the operating organization.

§483.85(c)(3) Sufficient resources and authority to the specific individuals designated in paragraph (c)(2) of this section to reasonably assure compliance with such standards, policies, and procedures.

§483.85(c)(4) Due care not to delegate substantial discretionary authority to individuals who the operating organization knew, or should have known through the exercise of due diligence, had a propensity to engage in criminal, civil, and administrative violations under the Social Security Act.

§483.85(c)(5) The facility takes steps to effectively communicate the standards, policies, and procedures in the operating organization's compliance and ethics program to the operating organization's entire staff; individuals providing services under a contractual arrangement; and volunteers, consistent with the volunteers' expected roles. Requirements include, but are not limited to, mandatory participation in training as set forth at §483.95(f) or orientation programs, or disseminating information that explains in a practical manner what is required under the program.

§483.85(c)(6) The facility takes reasonable steps to achieve compliance with the program's standards, policies, and procedures. Such steps include, but are not limited to, utilizing monitoring and auditing systems reasonably designed to detect criminal, civil, and administrative violations under the Act by any of the operating organization's staff, individuals providing services under a contractual arrangement, or volunteers, having in place and publicizing a reporting system whereby any of these individuals could report violations by others anonymously within the operating organization without fear of retribution, and having a process for ensuring the integrity of any reported data.

§483.85(c)(7) Consistent enforcement of the operating organization's standards, policies, and procedures through appropriate disciplinary mechanisms, including, as appropriate, discipline of individuals responsible for the failure to detect and report a violation to the compliance and

ethics program contact identified in the operating organization's compliance and ethics program.

§483.85(c)(8) After a violation is detected, the operating organization must ensure that all reasonable steps §483.85(identified in its program are taken to respond appropriately to the violation and to prevent further similar violations, including any necessary modification to the operating organization's program to prevent and detect criminal, civil, and administrative violations under the Act.

§483.85(d) Additional required components for operating organizations with five or more facilities.
In addition to all of the other requirements in paragraphs (a), (b), (c), and (e) of this section, operating organizations that operate five or more facilities must also include, at a minimum, the following components in their compliance and ethics program:

§483.85(d)(1) A mandatory annual training program on the operating organization's compliance and ethics program that meets the requirements set forth in §483.95(f).

§483.85(d)(2) A designated compliance officer for whom the operating organization's compliance and ethics program is a major responsibility. This individual must report directly to the operating organization's governing body and not be subordinate to the general counsel, chief financial officer or chief operating officer.

§483.85(d)(3) Designated compliance liaisons located at each of the operating organization's facilities.

§483.85 (e) Annual review.
The operating organization for each facility must review its compliance and ethics program annually and revise its program as needed to reflect changes in all applicable laws or regulations and within the operating organization and its facilities to improve its performance in deterring, reducing, and detecting violations under the Act and in promoting quality of care.
[§483.85 and all subparts will be implemented beginning November 28, 2019 (Phase 3)]

§483.90 Physical Environment.
The facility must be designed, constructed, equipped, and maintained to protect the health and safety of residents, personnel and the public.

§483.90(a) Life safety from fire.

§483.90(a)(1) Except as otherwise provided in this section –

§483.90(a)(1)(i) The LTC facility must meet the applicable provisions and must proceed in accordance with the Life Safety Code (NFPA 101 and Tentative Interim Amendments TIA 12-1, TIA 12-2, TIA 12-3, and TIA 12-4.)

Effective November 28, 2017

§483.90(a)(1)(ii) Notwithstanding paragraph (a)(1)(i) of this section, corridor doors and doors to rooms containing flammable or combustible materials must be provided with positive latching hardware. Roller latches are prohibited on such doors.

§483.90(a)(2) In consideration of a recommendation by the State survey agency or Accrediting Organization or at the discretion of the Secretary, may waive, for periods deemed appropriate, specific provisions of the Life Safety Code, which would result in unreasonable hardship upon a long-term care facility, but only if the waiver will not adversely affect the health and safety of the patients.

§483.90(a)(3) The provisions of the Life safety Code do not apply in a State where CMS finds, in accordance with applicable provisions of sections 1819(d)(2)(B)(ii) and 1919(d)(2)(B)(ii) of the Act, that a fire and safety code imposed by State law adequately protects patients, residents and personnel in long term care facilities.

§483.90(a)(4) A long-term care facility may install alcohol-based hand rub dispensers in its facility if the dispensers are installed in a manner that adequately protects against inappropriate access.

§483.90(a)(5) A long term care facility must:

§483.90(a)(5)(i) Install, at least, battery-operated single station smoke alarms in accordance with the manufacturer's recommendations in resident sleeping rooms and common areas.

§483.90(a)(5)(ii) Have a program for inspection, testing, maintenance, and battery replacement that conforms to the manufacturer's recommendations and that verifies correct operation of the smoke alarms.

§483.90(a)(5)(iii) Exception:

§483.90(a)(5)(iii)(A) The facility has system-based smoke detectors in patient rooms and common areas that are installed, tested, and maintained in accordance with NFPA 72, National Fire Alarm Code, for system-based smoke detectors; or

§483.90(a)(5)(iii)(B) The facility is fully sprinklered in accordance with NFPA 13, Standard for the Installation of Sprinkler Systems.

§483.90(a)(6) A long term care facility must:

§483.90(a)(6)(i) Install an approved, supervised automatic sprinkler system in accordance with the 1999 edition of NFPA 13, Standard for the Installation of Sprinkler Systems, as incorporated by reference, throughout the building by August 13, 2013. The Director of the Office of the Federal Register has approved the NFPA 13 1999 edition of the Standard for the Installation of Sprinkler Systems, issued July 22, 1999 for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the Code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore,

MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269.

§483.90(a)(6)(ii) Test, inspect, and maintain an approved, supervised automatic sprinkler system in accordance with the 1998 edition of NFPA 25, Standard for the Inspection, Testing, and Maintenance of Water-Based Fire Protection Systems, as incorporated by reference. The Director of the Office of the Federal Register has approved the NFPA 25, Standard for the Inspection, Testing, and Maintenance of Water-Based Fire Protection Systems, 1998 edition, issued January 16, 1998 for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the Code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269.

§483.90(a)(6)(iii) Subject to approval by CMS, a long term care facility may be granted an extension of the sprinkler installation deadline for a time period not to exceed 2 years from August 13, 2013, if the facility meets all of the following conditions:

§483.90(a)(6)(iii)(A) It is in the process of replacing its current building, or undergoing major modifications to improve the living conditions for residents in all unsprinklered living areas that requires the movement of corridor, room, partition, or structural walls or supports, in addition to the installation of a sprinkler system; or, has had its planned sprinkler installation so impaired by a disaster or emergency, as indicated by a declaration under section 319 of the Public Health Service Act, that CMS finds it would be impractical to meet the sprinkler installation due date.

§483.90(a)(6)(iii)(B) It demonstrates that it has made the necessary financial commitments to complete the building replacement or modification; or pursuant to a declared disaster or emergency, CMS finds it impractical to make reasonable and necessary financial commitments.

§483.90(a)(6)(iii)(C) Before applying for the deadline extension, it has submitted plans to State and local authorities that are necessary for approval of the replacement building or major modification that includes the required sprinkler installation, and has received approval of the plans from State and local authorities.

§483.90(a)(6)(iii)(D) It agrees to complete interim steps to improve fire safety, as determined by CMS.

§483.90(a)(6)(iv) An extension granted under paragraph (a)(8)(iii) of this section may be renewed once, for an additional period not to exceed 1 year, if the following conditions are met:

§483.90(a)(6)(iv)(A) CMS finds that extenuating circumstances beyond the control of the facility will prevent full compliance with the provisions in paragraph (a)(8)(i) of this section by the end of the first waiver period.

§483.90(a)(6)(iv)(B) All other conditions of paragraph (a)(8)(iii) of this section are met.

§483.90(a)(8) When a sprinkler system is shut down for more than 10 hours, the LTC facility must:

§483.90(a)(8)(i) Evacuate the building or portion of the building affected by the system outage until the system is back in service, or

§483.90(a)(8)(ii) Establish a fire watch until the system is back in service.

GUIDANCE: §483.90(a)
For additional guidance on life safety from fire and the survey procedures for these regulatory requirements, reference Appendix I in the SOM. Concerns regarding the above regulatory provisions would be addressed through the Life Safety Code survey (K-Tags).

§483.90(b) Standard: Building safety.

Except as otherwise provided in this section, the LTC facility must meet the applicable provisions and must proceed in accordance with the Health Care Facilities Code (NFPA 99 and Tentative Interim Amendments TIA 12-2, TIA 12-3, TIA 12-4, TIA 12-5 and TIA 12-6).

§483.90(b)(1) Chapters 7, 8, 12, and 13 of the adopted Health Care Facilities Code do not apply to a LTC facility.

§483.90(b)(2) If application of the Health Care Facilities Code required under paragraph (b) of this section would result in unreasonable hardship for the LTC facility, CMS may waive specific provisions of the Health Care Facilities Code, but only if the waiver does not adversely affect the health and safety of residents.

GUIDANCE: §483.90(b)
For additional guidance and procedures on building safety reference Appendix I in the SOM.

F906
Reserved

F907
§483.*90*(d) Space and Equipment

Effective November 28, 2017

The facility must--

§483.*90*(d)(1) Provide sufficient space and equipment in dining, health services, recreation, and program areas to enable staff to provide residents with needed services as required by these standards and as identified in each resident's *assessment and* plan of care; and

INTENT: §483.*90*(d)(1)
The intent of this regulation is to ensure that dining, health services, recreation, activities and programs areas are large enough to comfortably accommodate the needs of the residents who usually occupy this space.

Dining, health services, recreation, and program areas should be large enough to comfortably accommodate the persons who usually occupy that space, including the wheelchairs, walkers, and other ambulating aids used by the many residents who require more than standard movement spaces. "**Sufficient space**" means the resident can access the area, it is not functionally off-limits, and the resident's functioning is not restricted once access to the space is gained.

Program areas where resident groups engage in activities focused on manipulative skills and hand-eye coordination should have sufficient space for storage of their supplies and "works in progress."

Program areas where residents receive physical therapy should have sufficient space and equipment to meet the needs of the resident's therapy requirement.

"**Recreation/activities area**" means any area where residents can participate in those activities identified in their plan of care.

PROCEDURES: §483.*90*(d)(1)
In the use of space, consider if available space *and equipment is sufficient in dining, health services, recreation, and program areas to* allow residents to pursue activities and receive health services and programs as identified in their assessment and care plan.

Is there sufficient space for storing and utilizing mobility devices, assistive technology, physical therapy or adaptive equipment as identified in the resident assessment or plan of care?

F908
§483.*90*(d)(2) Maintain all mechanical, electrical, and patient care equipment in safe operating condition.

PROCEDURES/PROBES: §483.*90*(d)(2)
How does the facility assure all mechanical, electrical and patient care equipment is maintained in safe operating condition?

Is essential equipment (e.g., boiler room equipment, nursing unit/medication room refrigerators, kitchen refrigerator/freezer and laundry equipment) in safe operating condition?

Effective November 28, 2017

Inspect the bed control panel covering for signs of damage where liquids could leak in.

Inspect the bed's power cord, cord plug and wall plug in for damage if electrically powered bed.

Is equipment maintained according to manufacturer's recommendations?

F909
§483.*90*(d)(3) ***Conduct Regular inspection of all bed frames, mattresses, and bed rails, if any, as part of a regular maintenance program to identify areas of possible entrapment. When bed rails and mattresses are used and purchased separately from the bed frame, the facility must ensure that the bed rails, mattress, and bed frame are compatible.***

GUIDANCE: §483.90(d)(3)
For concerns related to the inspection or compatibility of bed frames, mattresses and bed rails, cite those here. For additional guidance on the assessment of individual's needs, including the potential risks and benefits of the use of bed rails, refer to F700 Bed Rails located in Quality of Care at §483.25(n).

PROCEDURES: §483.90(d)(3)
When investigating F909, surveyors may reference Food and Drug Administration (FDA) documents entitled "Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment" dated March 10. 2006, "Practice Hospital Bed Safety" dated February 2013, and "Guide to Bed Safety Rails in Hospitals, Nursing Homes and Home Health Care: The Facts" as to the proper dimensions and distances apart of various parts of the bed such as distance between bed frames and mattresses, bed rails and mattress etc. to prevent entrapment by users of the bed.

PROBES: §483.90(d)(3)
How does the facility assure the inspection of all bed frames, mattresses and bed rails, if any, as part of their regular maintenance program?

Is equipment inspected and maintained according to manufacturer's recommendations and requirements and timeframes?

Does the mattress fit the bed frame properly limiting entrapment zones?

Is the bed rail securely and properly installed according to manufacturer's requirements to limit entrapment zones?

F910
§483.*90*(e) Resident Rooms
Resident rooms must be designed and equipped for adequate nursing care, comfort, and privacy of residents.

F911
§483.*90* (e)(1) Bedrooms must

Effective November 28, 2017

§483.*90*(e)(1)(i) Accommodate no more than four residents. ***For facilities that receive approval of construction or reconstruction plans by State and local authorities or are newly certified after November 28, 2016, bedrooms must accommodate no more than two residents.***

GUIDANCE: §483.*90*(e)(1)(i)
As residents are transferred or discharged from rooms with more than four residents, beds should be removed from the variance until the number of residents occupying the room does not exceed four.

See §483.*90*(e)(3) regarding variances.

*"**Reconstruction**" means the facility undergoes reconfiguration of the space such that the space is not permitted to be occupied, or the entire building or an entire occupancy within the building, such as a wing of the building, is modified. The requirement applies to the reconstructed area, so that where reconstruction involves a limited area within a building, we would not expect the entire building to upgrade to the new requirements of no more than two residents per room.*

When a facility undergoes a change of ownership under §489.18 and the new owner does not accept assignment of the existing provider agreement and requires a "new initial certification" for a new provider agreement that would be effective after November 28, 2016, the facility would be expected to be upgraded to meet these new requirements of each bedroom accommodating not more than two residents. This would also apply when the provider agreement was terminated by CMS and another provider is working to reopen the facility.

In the case of a natural disaster where the Secretary has declared a public health emergency, a waiver of certain requirements under section 1135 of the Act may be available under certain conditions. The waiving of specific requirements under section 1135 for affected facilities would depend on the many factors, including the extent of damage to the facility. New construction or Reconstruction of facilities affected by a declared disaster should be discussed with the appropriate CMS Regional Office.

For facilities that receive approval of construction or reconstruction plans from State and local authorities or are newly certified after November 28, 2016 each resident room must meet the new requirements of no more than two residents per room.

PROBES: §483.*90*(e)(1)(i)
Unless a variance has been applied for and approved under §483.*90*(e)(3), do the residents' bedrooms accommodate no more than four residents?

For resident bedrooms constructed in a certified facility or in a facility certified after November 28, 2016, are there a maximum of two beds per bedroom?

F912
§483.*90*(e)(1)(ii) Measure at least 80 square feet per resident in multiple resident bedrooms, and at least 100 square feet in single resident rooms;

Effective November 28, 2017

GUIDANCE: §483.*90*(e)(1)(ii)
See §483.*90*(e)(3) regarding variations.

The measurement of the square footage should be based upon the useable living space of the room. Therefore, the minimum square footage in resident rooms should be measured based upon the floor's measurements exclusive of toilets and bath areas, closets, lockers, wardrobes, alcoves, or vestibules. However, if the height of the alcoves or vestibules reasonably provides useful living area, then the corresponding floor area may be included in the calculation.

The space occupied by movable wardrobes should be excluded from the useable square footage in a room unless it is an item of the resident's own choice and it is in addition to the individual closet space in the resident's room. Non-permanent items of the resident's own choice should have no effect in the calculation of useable living space.

Protrusions such as columns, radiators, ventilation systems for heating and/or cooling should be ignored in computing the useable square footage of the room if the area involved is minimal (e.g., a baseboard heating or air conditioning system or ductwork that does not protrude more than 6 to 8 inches from the wall, or a column that is not more than 6 to 8 inches on each side) and does not have an adverse effect on the resident's health and safety or does not impede the ability of any resident in that room to attain his or her highest practicable well-being. If these protrusions are not minimal they would be deducted from useable square footage computed in determining compliance with this requirement.

The swing or arc of any door which opens directly into the resident's room should not be excluded from the calculations of useable square footage in a room.

PROCEDURES: §483.*90*(e)(1)(ii)
The facility layout may give square footage measurements. Carry a tape measure and take measurements if the room appears small.

PROBES: §483.*90*(e)(1)(ii)
Unless a variation has been applied for and approved under §483.*90*(e)(3), are there at least 80 square feet per resident in multiple resident rooms and at least 100 square feet for single resident rooms?

F913
§483.*90*(e)(1)(iii) Have direct access to an exit corridor;

GUIDANCE: §483.*90*(e)(1)(iii)
Each resident bedroom shall be individually accessible from the corridor without passing through another room.

There is no authority under current regulations to approve a variance to this requirement.

Effective November 28, 2017

Additional guidance is available in the National Fire Protection Association's Life Safety Code 101 (NFPA 101, *2012 ed.)*, 18/19.2.5.1, which is Tag *K254* of the Life Safety Code Survey

F914
§483.*90*(e)(1)(iv) Be designed or equipped to assure full visual privacy for each resident;

§483.*90*(e)(1)(v) In facilities initially certified after March 31, 1992, except in private rooms, each bed must have ceiling suspended curtains, which extend around the bed to provide total visual privacy in combination with adjacent walls and curtains.

GUIDANCE: §483.*90*(e)(1)(iv) and (e)(1)(v)
"**Full visual privacy**" means that residents have a means of completely withdrawing from public view, without staff assistance, while occupying their bed (e.g., curtain, moveable screens, private room).

The guidelines do not intend to limit the provisions of privacy to solely one or more curtains, movable screens or a private room. Facility operators are free to use other means to provide full visual privacy, with those means varying according to the needs and requests of residents. However, the requirement explicitly states that bedrooms must "be designed or equipped to assure full visual privacy for each resident." For example, a resident with a bed by the window cannot be required to remain out of his or her room while his/her roommate is having a dressing change. Room design or equipment must provide privacy.

The term "**initially certified**" is defined as all newly certified nursing facilities (NFs) or SNFs as well as NFs and SNFs which re-enter the Medicare or Medicaid programs, whether they voluntarily or involuntarily left the program after March 31, 1992.

It is not necessary for the bed to be accessible from both sides when the privacy curtain in pulled.

Additional guidance is available in the National Fire Protection Association's Life Safety Code 101 (NFPA 101, *2012 ed.*), 18/19.7.5.1, 18/19.3.5.11, which is Tag *K751* of the Life Safety Code Survey.

PROCEDURES: §483.*90*(e)(1)(iv) and (e)(1)(v)
There are no provisions for physician statements to be used as a basis for *variance* of the requirements for full visual privacy.

PROBES: §483.*90*(e)(1)(iv) and (e)(1)(v)
Observe whether each resident selected for a comprehensive or focused review has a means to achieve full visual privacy.

F915
§483.*90(a)(7) Buildings must have an outside window or outside door in every sleeping room, and for any building constructed after July 5, 2016 the sill height must not exceed 36 inches above the floor. Windows in atrium walls are considered outside windows for the purposes of this requirement.*

Effective November 28, 2017

§483.*90*(e)(1)(vi) - Resident Rooms
Bedrooms must --

§483.*90*(e)(1)(vi) - Have at least one window to the outside; and

GUIDANCE: §483.*90*(a)(7) and §483.*90*(e)(1)(vi)
Every resident/patient sleeping room shall have an outside window. A facility with resident room windows, as defined by K381, or that open to an outside atrium such as a courtyard in accordance with Life Safety Code, can meet this requirement for a window to the outside. Windows facing an interior atrium, skylights, etc., do not meet this requirement.

In addition to conforming to the Life Safety Code, this requirement was included to assist the resident's orientation to day and night, weather, and general awareness of space outside the facility. The facility is required to provide for a "safe, clean, comfortable and homelike environment" by deemphasizing the institutional character of the setting, to the extent possible. Windows are an important aspect in assuring the homelike environment of a facility.

In buildings constructed after July 5, 2016 or for facilities certified after July 5, 2016, the maximum allowable sill height is 36 inches above the floor. The window may be operable.

PROBES: §483.*90*(a)(7) and §483.*90*(e)(1)(vi)
Is there at least one window to the outside?

If the building was constructed or certified as a provider after July 5, 2016, confirm the outside window sill is 36 inches or less above the floor.

F916
§483.*90*(e)(1)(vii) Have a floor at or above grade level.

GUIDANCE: §483.*90*(e)(1)(vii)
"**At or above grade level**" means a room in which the room floor is at or above the surrounding exterior ground level. *No resident rooms in basements or below ground level are allowed.*

PROBES: §483.*90*(e)(1)(vii)
Are the bedrooms at or above ground level?

F917
§483.*10(i)(4)* Private closet space in each resident room, as specified in §483.*90* (e)(2)(iv)

§483.*90*(e)(2) -The facility must provide each resident with--
- **(i) A separate bed of proper size and height for the *safety and* convenience of the resident;**
- **(ii) A clean, comfortable mattress;**
- **(iii) Bedding, appropriate to the weather and climate; and**

(iv) Functional furniture appropriate to the resident's needs, and individual closet space in the resident's bedroom with clothes racks and shelves accessible to the resident.

§483.*90*(e)(3) CMS, or in the case of a nursing facility the survey agency, may permit variations in requirements specified in paragraphs (e)(1) (i) and (ii) of this section relating to rooms in individual cases when the facility demonstrates in writing that the variations

(i) Are in accordance with the special needs of the residents; and

(ii) Will not adversely affect residents' health and safety.

GUIDANCE: §483.*90*(e)(2)(i), (e)(2)(ii), (e)(2)(iii), (e)(2)(iv), §483.*10(i)(4)*, §483.*90*(e)(3), (e)(3)(i), and (e)(3)(ii)

"Functional furniture appropriate to the resident's needs" means that the furniture in each resident's room contributes to the resident attaining or maintaining his or her highest practicable level of independence and well-being. In general, furnishings include a place to put clothing away in an organized manner that will let it remain clean, free of wrinkles, and accessible to the resident while protecting it from casual access by others; a place to put personal effects such as pictures and a bedside clock, and furniture suitable for the comfort of the resident and visitors (e.g., a chair).

For issues with arrangement of room furniture according to resident needs and preferences, see *§483.10(e),* Accommodation of Needs, Tag *F558*.

"Clothes racks and shelves accessible to the resident" means that residents can get to and reach their hanging clothing whenever they choose.

"Private closet space" means that each resident's clothing is kept separate from clothing of roommate(s).

The term "closet space" is not necessarily limited to a space installed into the wall. For some facilities without such installed closets, compliance may be attained through the use of storage furniture such as wardrobes. Out-of-season items may be stored in alternate locations outside the resident's room.

A variation must be in accordance with the special needs of the residents and must not adversely affect the health or safety of residents. Facility hardship is not part of the basis for granting a variation. Since the special needs of residents may change periodically, or different residents may be transferred into a room that has been granted a variation, variations must be reviewed and considered for renewal whenever the facility is certified. If the needs of the residents within the room have not changed since the last annual inspection, the variance should continue if the facility so desires.

PROBES: §483.*90*(e)(2)(i), (e)(2)(ii), (e)(2)(iii), (e)(2)(iv), §483.*10(i)(4)*, §483.*90*(e)(3), (e)(3)(i), and (e)(3)(ii)

Are mattresses clean and comfortable?

Is bedding appropriate to weather and climate?

If a resident uses a wheelchair, is the bed positioned at a height that allows the resident to safely transfer to the bed if he or she is able?

See requirements at §483.90(d)(3) concerning the regular inspection of all bed frames, mattresses, and bed rails to identify areas of possible entrapment.

Functional furniture:
Is there functional furniture, appropriate to resident's needs?

Closet space:
Is there individual closet space with accessible clothes racks and shelves?

If the resident is able to use a closet, can the resident get to and reach her/his hanging clothing as well as items from shelves in the closet?

If a resident is unable to use a closet, does the facility provide the resident with adequate assistance for accessing their clothing, or alternative storage space that the resident is able to access?

If a resident uses a wheelchair, are dressers or shelves available at a height that the resident can access them and reach them.

F918
§483.*90*(f) *Bathroom* Facilities
Each resident room must be equipped with or located near toilet and bathing facilities. ***For facilities that receive approval of construction or reconstruction plans from State and local authorities or are newly certified after November 28, 2016, each residential room must have its own bathroom equipped with at least a commode and sink.***

GUIDANCE: §483.*90*(f)
"**Bathing Facilities**" is defined as a space that contains either a shower(s) or a tub(s) for resident use. See definition of "toilet facilities" for definition of "located near."

"**Reconstruction**" means that the facility undergoes reconfiguration of the space such that the space is not permitted to be occupied, or the entire building or and an entire occupancy with the building, such as a wing of the building is modified. The requirement applies to the reconstructed area, so that where reconstruction involves a limited area within a building, we would not expect the entire building to upgrade to the new requirements *of each resident room being equipped or located near toilet and bathing facilities.*

"**Toilet facilities**" is defined as a space that contains a lavatory and a toilet*/commode. CMS is also using the term "commode" to mean the same as a "toilet" when referring to a plumbing fixture.* If the resident's room is not equipped with an adjoining toilet facility, then "located

near" means residents who are independent in the use of a toilet*/commode*, including chair bound residents, can routinely use a toilet/commode in the unit *that they can access quickly.*

When a facility undergoes a change of ownership under §489.18 and the new owner does not accept assignment of the existing provider agreement and requires a "new initial certification" for a new provider agreement that would be effective after November 28, 2016, the facility would be expected to be upgraded to meet these new requirements of each resident bedroom to have its own bathroom consisting of at least a sink and commode/toilet. This would also apply when the provider agreement was terminated by CMS and another provider is working to reopen the facility.

In the case of a natural disaster where the Secretary has declared a public health emergency, a waiver of certain requirements under section 1135 of the Act may be available under certain conditions. The waiving of specific requirements under section 1135 for affected facilities would depend on the many factors, including the extent of damage to the facility. New construction or Reconstruction of facilities affected by a declared disaster should be discussed with the appropriate CMS Regional Office.

Each resident room must be equipped with or located near toilet/commode and bathing facilities. For facilities that receive approval of construction or reconstruction plans from State and local authorities or are newly certified after November 28, 2016, each resident room must have its own bathroom equipped with at least a commode, and sink.

PROCEDURES: §483.*90*(f)
Are resident rooms equipped with or located near toilet and bathing facilities?

Does each resident room have its own bathroom equipped with at least a commode and sink for facilities that receive approval of construction from State and local authorities or are newly certified after November 28, 2016?

F919
§483.*90*(g) Resident Call System
The facility must be adequately equipped to allow residents to call for staff assistance* through a communication system *which relays the call directly to a staff member or to a centralized staff work area –

§483.90*(g)(1) *Each resident's bedside; and
[483.90(g)(1) will be implemented beginning November 28, 2019 (Phase 3)]

§483.*90*(g)(2) Toilet and bathing facilities.

INTENT: §483.*90*(g)(1) and (g)(2)
The intent of this requirement is that residents, when in their rooms and toilet and bathing areas, have a means of directly contacting caregivers. In the case of an existing centralized nursing station, this communication may be through audible or visual signals and may include "wireless systems." In those cases in which a facility has moved to decentralized nurse/care team work

areas, the intent may be met through other electronic systems that provide direct communication from the resident to the caregivers.

GUIDANCE: §483.*90*(g)(1) and (g)(2)
This requirement is met only if all portions of the system are functioning (e.g., system is not turned off at the nurses' station, the volume too low to be heard, the light above a room or rooms is not working, *no staff at nurses' station*), and calls are being answered. For wireless systems, compliance is met only if staff who answer resident calls, have functioning devices in their possession, and are answering resident calls.

POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION
Issues related to the timeliness of calls being answered should be referred to and examined for sufficient staffing under §483.35 Nursing Services.

PROBES: §483.*90*(g)(1) and (g)(2)
Is there a functioning communication system from rooms, toilets, and bathing facilities in which resident calls are received and answered by staff?

If a resident has disabilities that make use of the facility's communication system inaccessible, are alternatives, auxiliary aids, or services available to meet this requirement and to meet the resident's needs as identified in the resident's assessment or plan of care?

Residents and their representatives should be interviewed about whether calls are being answered.

F920
§483.*90*(h) Dining and Resident Activities
The facility must provide one or more rooms designated for resident dining and activities.

These rooms must--
§483.*90*(h)(1) Be well lighted;

§483.*90*(h)(2) Be well ventilated;

§483.*90*(h)(3) Be adequately furnished; and

§483.*90*(h)(4) Have sufficient space to accommodate all activities.

GUIDANCE: §483.*90*(h)(1), (h)(2), (h)(3) and (h)(4)
"**Well lighted**" is defined as levels of illumination that are suitable to tasks performed by a resident.

"**Well ventilated**" is defined as good air circulation, avoidance of drafts at floor level, and adequate smoke and odor exhaust removal.

Effective November 28, 2017

Reference ASHRAE Standard 179 for ventilation requirements in nursing homes activity and dining areas.

An "**adequately furnished**" dining area accommodates different residents' physical and social needs. An adequately furnished organized activities area accommodates the needs, interests and preferences of its residents.

"**Sufficient space to accommodate all activities**" means that there is enough space available and it is adaptable to a variety of uses and residents' needs.

PROBES: §483.*90*(h)(1), (h)(2), (h)(3) and (h)(4)
Are there adequate and comfortable lighting levels?

Are illumination levels appropriate to tasks with little glare?

Does lighting support maintenance of independent functioning and task performance?

Is the space well ventilated, providing for good air circulation and adequate smoke exhaust removal?

Ask residents if furnishings are adequate for their needs?

Are furnishings structurally sound and functional (e.g., chairs of varying sizes to meet varying needs of residents, wheelchairs can fit under the dining room table)?

Is space sufficient for all resident activities?

Are spaces adaptable for all intended uses?

Is resident access to space limited?

Do residents and staff have maximum flexibility in arranging furniture to accommodate residents who use walkers, wheelchairs, and other mobility aids, *including space for empty wheelchairs if a resident prefers to sit in a regular chair?*

Is there resident crowding?

F921
§483.*90*(i) Other Environmental Conditions
The facility must provide a safe, functional, sanitary, and comfortable environment for residents, staff and the public.

F922
The facility must--
§483.*90*(i)(1) Establish procedures to ensure that water is available to essential areas when there is a loss of normal water supply;

Effective November 28, 2017

GUIDANCE: **§483.*90*(i)(1)**
The facility should have a written procedure which defines the source of water when there is a loss of normal water supply, including provisions for storing the water, both potable and nonpotable, a method for distributing the water and a method for estimating the volume of water required.

PROCEDURES: §483.*90*(i)(1)
During the entrance conference, ask the administrator the facility's procedure to ensure water availability.

F923
§483.*90*(i)(2) Have adequate outside ventilation by means of windows, or mechanical ventilation, or a combination of the two.

PROBES: §483.*90*(i)(2)
Is the space ventilated by means of windows, or mechanical ventilation, or a combination of the two?

Is there good air circulation?

F924
§483.*90*(i)(3) Equip corridors with firmly secured handrails on each side.

GUIDANCE §483.*90*(i)(3)
"**Secured handrails**" means handrails that are firmly affixed to the wall.

PROBES: §483.*90*(i)(3)
Do all corridors have handrails and are the handrails firmly secured and affixed to the corridor walls?

F925
§483.*90*(i)(4) Maintain an effective pest control program so that the facility is free of pests and rodents.

GUIDANCE: §483.*90*(i)(4)
An "**effective pest control progra**m" is defined as measures to eradicate and contain common household pests (e.g., bed bugs, lice, roaches, ants, mosquitoes, flies, mice, and rats).

PROCEDURES: §483.*90*(i)(4)
As part of the overall review of the facility, look for signs of vermin. Evidence of pest infestation in a particular space is an indicator of noncompliance.

PROBES: §483.*90*(i)(4)
Ask staff, residents and their representatives if they have observed any pests/vermin?

Effective November 28, 2017

F926
§483.*90(i)(5) Establish policies, in accordance with applicable Federal, State, and local laws and regulations, regarding smoking, including tobacco cessation, smoking areas and safety, including but limited to non-smoking residents.*

GUIDANCE: 483.90(i)(5)
The use of oxygen in smoking areas and while smoking is forbidden.

PROCEDURES: §483.90(i)(5)
Review F689 guidance concerning smoking in the facility.

As part of the overall review of the facility, look for signs of smoking by residents, staff, visitors, guests, and non-staff.

Look for smoking areas both inside and outside of the facility.

Review policies to determine if they have been developed and are being implemented in accordance with Federal, State and local laws and regulations in regards to smoking, smoking areas and smoking safety for both smoking and non-smoking residents.

PROBES: §483.90(i)(5)
Ask residents who smoke how the facility permits them to smoke.

Does the facility allow smoking and how is it managed?

§483.90(j) The standards incorporated by reference in this section are approved for incorporation by reference by the Director of the Office of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may inspect a copy at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html. If any changes in this edition of the Code are incorporated by reference, CMS will publish a document in the Federal Register to announce the changes.

§483.90(j)(1) National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02169, www.nfpa.org, 1.617.770.3000.

- ***(i) NFPA 99, Standards for Health Care Facilities Code of the National Fire Protection Association 99, 2012 edition, issued August 11, 2011.***
- ***(ii) TIA 12-2 to NFPA 99, issued August 11, 2011.***
- ***(iii) TIA 12-3 to NFPA 99, issued August 9, 2012.***
- ***(iv) TIA 12-4 to NFPA 99, issued March 7, 2013.***
- ***(v) TIA 12-5 to NFPA 99, issued August 1, 2013.***
- ***(vi) TIA 12-6 to NFPA 99, issued March 3, 2014.***
- ***(vii) NFPA 101, Life Safety Code, 2012 edition, issued August 11, 2011;***
- ***(viii) TIA 12-1 to NFPA 101, issued August 11, 2011.***

Effective November 28, 2017

(ix) TIA 12-2 to NFPA 101, issued October 30, 2012.
(x) TIA 12-3 to NFPA 101, issued October 22, 2013.
(xi) TIA 12-4 to NFPA 101, issued October 22, 2013.

§483.95 Training Requirements
NOTE: As published in the Federal Register (Vol. 81, No. 192, 68688, 68698, October 4, 2016), this entire section (§483.95) will be implemented in Phase 3 with the following exceptions, which will be implemented in Phase 1:
(c) Abuse, neglect, and exploitation training;
(g)(1) Regarding in-service training, (g)(2) dementia management & abuse prevention training, (g)(4) care of the cognitively impaired; and
(h) Training of feeding assistants.

F940
§483.95 Training Requirements
A facility must develop, implement, and maintain an effective training program for all new and existing staff; individuals providing services under a contractual arrangement; and volunteers, consistent with their expected roles. A facility must determine the amount and types of training necessary based on a facility assessment as specified at § 483.70(e). Training topics must include but are not limited to—
[§483.95 will be implemented beginning November 28, 2019 (Phase 3)]

F941
§483.95(a) Communication.
A facility must include effective communications as mandatory training for direct care staff.
[§483.95(a) will be implemented beginning November 28, 2019 (Phase 3)]

F942
§483.95(b) Resident's rights and facility responsibilities.
A facility must ensure that staff members are educated on the rights of the resident and the responsibilities of a facility to properly care for its residents as set forth at §483.10, respectively.
[§483.95(b) will be implemented beginning November 28, 2019 (Phase 3)]

F943
§483.95(c) Abuse, neglect, and exploitation.
In addition to the freedom from abuse, neglect, and exploitation requirements in § 483.12, facilities must also provide training to their staff that at a minimum educates staff on—

§483.95(c)(1) Activities that constitute abuse, neglect, exploitation, and misappropriation of resident property as set forth at § 483.12.

§483.95(c)(2) Procedures for reporting incidents of abuse, neglect, exploitation, or the misappropriation of resident property

§483.95(c)(3) Dementia management and resident abuse prevention.

Effective November 28, 2017

DEFINITION §483.95(c)
Staff includes for the purposes of the training guidance, all facility staff, (direct and indirect care and auxiliary functions) contractors, and volunteers.

GUIDANCE §483.95(c)
All facilities must develop, implement and permanently maintain an effective training program for all staff, which includes, at a minimum, training on abuse, neglect, exploitation, misappropriation of resident property, and dementia management, that is appropriate and effective, as determined by staff need and the facility assessment (as specified at §483.70(e)).

Changes to the facility's resident population, staff turnover, the facility's physical environment, and modifications to the facility assessment may necessitate ongoing revisions to the facility's training program.

There are a variety of methods that could be used to provide training. For example, staff training may be facilitated through any combination of in-person instruction, webinars and/or supervised practical training hours.

Supervised practical training means training in a setting in which instruction and oversight are provided by a person who has relevant education and/or experience specific to the subject of the training being provided.

All training should support current scope and standards of practice through curricula which detail learning objectives, performance standards and evaluation criteria, and addresses potential risks to residents, staff and volunteers if procedures are not followed. There should be a process in place to track staff participation in the required trainings.

The facility must provide staff orientation and training on the prohibition of all forms of abuse, neglect, and exploitation prohibition. The training must address forms of abuse, neglect, misappropriation of resident property, exploitation and dementia management. Such training would include, but is not limited to:

- *Identifying how person-centered thinking, planning, and practice skills contribute to a facility culture of prevention and identification of abuse, neglect, and exploitation*
- *Identifying and preventing behavior constituting abuse (including injuries from an unknown source), neglect, exploitation, and misappropriation of resident property;*
- *Identifying physical or psychosocial indicators of abuse (including injuries from an unknown source), neglect, exploitation, and misappropriation of resident property from situations which include, but are not limited to:*
  - *Verbal, mental, sexual or physical abuse;*
  - *Taking or using photographs or recordings of residents in a demeaning or humiliating manner and sharing them in any manner, including through the use of technology or social media;*
  - *Theft of a resident's personal belongings;*
  - *Involuntary seclusion of a resident;*
  - *Exploitation of a resident; and*

  - *Neglect of a resident as demonstrated by a pattern of willfully failing to provide care to a resident(s).*
- *Facility procedures and Federal and State requirements for reporting abuse, neglect, exploitation, and misappropriation of resident property, including injuries of unknown sources, timeframes for reporting, and to whom staff and others must report their knowledge related to any alleged violation without fear of retaliation;*
- *Reporting reasonable suspicion of a crime against a resident;*
- *Educating staff on factors related to dementia care and abuse prevention, such as understanding that expressions or indications of distress of residents with dementia are often attempts to communicate an unmet need, discomfort or thoughts that they can no longer articulate with words. However, they may be perceived as challenging behaviors to staff and could increase the risk of resident abuse and neglect. Expressions or indications of distress can include, but are not limited to:*
  - *Aggressiveness;*
  - *Wandering or elopement;*
  - *Agitation;*
  - *Yelling out; or*
  - *Delusions.*
- *Conflict resolution and anger management skills, including resolving conflicts between staff and residents, visitor and resident, and resident-to-resident conflicts; and*
- *Identifying and addressing factors that may precipitate abuse/neglect/exploitation, including, but not limited to:*
  - *Signs of staff burnout, frustration, and stress;*
  - *Staff prejudices to age, culture, race, religion, and sexual orientation;*
  - *Gender differences; and*
  - *Negative attitudes toward working with individuals with disabilities.*

While not required, sources of training materials that facilities may want to consider include:

- *National Center on Elder Abuse. [On-Line]. Available: https://ncea.acl.gov*
- *University of Southern California. Training Resources on Elder Abuse. Available: http://trea.usc.edu/*

References to non-CMS, non-governmental sources do not constitute or imply endorsement of these organizations or their programs by CMS or the U.S. Department of Health and Human Services and were current as of the date of this publication.

PROBES §483.95(c)

If there is a concern that a resident was abused, neglected, or exploited, interview staff and review training records to determine the following:

- *Was staff observed working with residents in a manner that indicates a training need?*
- *Did interviews with residents and/or resident representatives indicate any areas where training was needed?*
- *What type of training do the staff report receiving about the concern identified by the surveyor?*

Effective November 28, 2017

- *What process does the facility have to encourage staff to express concerns and request training in challenging situations? How does the facility respond to staff's concerns and requests?*
- *Review the training coursework to determine if the content meets professional standards/guidelines and covers relevant facility policy and procedures.*
- *How does the facility's abuse, neglect, and exploitation training program ensure staff are instructed to meet the requirements of §483.12(b) Develop/Implement Abuse/Neglect, etc. Policies, tag F607?*
- *How does the facility's policies reflect staff training is in compliance with §483.12 and §483.12(a)(1) Freedom from abuse, neglect, and exploitation, tag F600?*
- *Verify that the facility has a mandatory requirement that all facility staff participate in an abuse, neglect, and exploitation prevention and dementia management training program, with a process in place to track attendance.*
- *How does the facility determine when training content requires updating to be consistent with current professional standards and Federal and State regulations?*
- *How does the facility assess staff to determine if the training has been effective?*

POTENTIAL ADDITIONAL TAGS FOR INVESTIGATION
For concerns related to the development and implementation of written policies and procedures, that includes training related to abuse, neglect, exploitation, and misappropriation of resident property, see 42 CFR §483.12(b)(3) Develop/Implement Abuse/Neglect, etc. Policies, tag F607.

For concerns related to the reporting of a crime, see 42 CFR §483.12(b)(5), Reporting of Reasonable Suspicion of a Crime, tag F608.

F944
§483.95(d) Quality assurance and performance improvement.
A facility must include as part of its QAPI program mandatory training that outlines and informs staff of the elements and goals of the facility's QAPI program as set forth at § 483.75.
[§483.95(d) will be implemented beginning November 28, 2019 (Phase 3)]

F945
§483.95(e) Infection control.
A facility must include as part of its infection prevention and control program mandatory training that includes the written standards, policies, and procedures for the program as described at §483.80(a)(2).
[§483.95(e) will be implemented beginning November 28, 2019 (Phase 3)]

F946
§483.95(f) Compliance and ethics.
The operating organization for each facility must include as part of its compliance and ethics program, as set forth at §483.85—

§483.95(f)(1) An effective way to communicate the program's standards, policies, and procedures through a training program or in another practical manner which explains the requirements under the program.

Effective November 28, 2017

§483.95(f)(2) Annual training if the operating organization operates five or more facilities. [§483.95(f), (f)(1) and (f)(2) will be implemented beginning November 28, 2019 (Phase 3)]

F947
§483.95(g) Required in-service training for nurse aides.
***I*n-service training must—**

§483.95(g)(1) **Be sufficient to ensure the continuing competence of nurse aides, but must be no less than 12 hours per year.**

§483.95(g)(2) **Include dementia management training and resident abuse prevention training.**

§483.95(g)(3) **Address areas of weakness as determined in nurse aides' performance reviews *and facility assessment at § 483.70(e*) and may address the special needs of residents as determined by the facility staff.**

[§483.95(g)(3) was implemented on November 28, 2016 (Phase 1) with the exception of facility assessment which was implemented on November 28, 2017 (Phase 2).]

§483.95(g)(4) **For nurse aides providing services to individuals with cognitive impairments, also address the care of the cognitively impaired.**

DEFINITION §483.95(g)
A nurse aide is any individual providing nursing or nursing-related services to residents in a facility. This term may also include an individual who provides these services through an agency or under a contract with the facility, but is not a licensed health professional, a registered dietitian, or someone who volunteers to provide such services without pay. Nurse aides do not include those individuals who furnish services to residents only as paid feeding assistants as defined in §488.301 of this chapter.

Private duty nurse aides who are not employed or utilized by the facility on a contract, per diem, leased, or other basis, do not come under the nurse aide training provision.

GUIDANCE *§483.95(g)*
All facilities must develop, implement and permanently maintain an in-service training program for nurse aides that is appropriate and effective, as determined by nurse aide evaluation or the facility assessment as specified at §483.70(e). Changes to the facility's resident population, the facility's physical environment, staff turnover, and modifications to the facility assessment may necessitate ongoing revisions to the facility's training program.

There are a variety of methods that could be used to provide training. For example, nurse aide training may be facilitated through any combination of in-person instruction, webinars and/or supervised practical training hours.

Effective November 28, 2017

Supervised practical training means training in a setting in which instruction and oversight are provided by a person who has relevant education and/or experience specific to the subject of the training being provided.

All training should support current scope and standards of practice through curricula which detail learning objectives, performance standards and evaluation criteria, and addresses potential risks to residents, staff and volunteers if procedures are not followed. There should be a process in place to track nurse aide participation in the required trainings.

The adequacy of the in-service education program may be measured not only by documentation of hours of completed in-service education, but also by demonstrated competencies of nurse aide staff through written exam and/or in consistently applying the interventions necessary to meet residents' needs as identified in the facility assessment. Observations of nurse aides that indicate deficiencies in their nurse aide skills may be the result of an inadequate training program and/or inadequate performance review.

A minimum of 12 hours of nurse aide training per year is required under §483.95(g)(1). The training must be sufficient to ensure the continuing competence of the nurse aides, which may require more than 12 hours of training per year to meet identified staff or resident needs.

The survey team does not need to find a negative outcome to cite a deficiency at F947.

PROCEDURES AND PROBES §483.95(g)

If there have been deficient care practices identified during the survey, review as appropriate training received by nurse aides in that corresponding subject area. For example, if a deficiency is being cited related to infection control, review the infection control portion of the facility's in-service nurse aide training program.

- *Were nurse aides observed working with residents in a manner that indicates a training need?*
- *Did interviews with residents and/or resident representatives indicate any areas where training was needed?*
- *What type of training do the nurse aides report receiving about the concern identified by the surveyor?*
- *Verify the mandatory nurse aide in-service program* is no less than 12 hours per year. Calculate the date by which a nurse aide must receive annual in-service education by the employment date rather than the calendar year.
- *Review facility training records which supports mandatory nurse aide attendance.*
- How has in-service education addressed any areas of weakness identified in performance reviews, and any special resident needs, or needs of residents with cognitive impairments?
- *How does the facility evaluate nurse aide performance to determine what topics must be included in in-service training to address areas of weakness?*
- *How does the facility determine when training content must be updated (e.g., in order to remain consistent with current professional standards and guidelines)?*

- *What process does the facility have to encourage nurse aides to express concerns and request training in challenging situations? How does the facility respond to nurse aide's concerns and requests?*
- *Does the facility's training address nurse aide training needs to ensure residents attain or maintain the highest practicable physical, mental, and psychosocial well-being as determined by resident assessments and individual plans of care?*
- *How does the facility assess nurse aides to determine if the training has been effective?*

POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION
For concerns related to nurse aides not demonstrating competent care of a resident that is independent of or related to the training program, see 42 CFR §483.35(c) Proficiency of Nurse Aides tag F726 for guidance.

F948
§483.95(h) **Required training of feeding assistants.**
A facility must not use any individual working in the facility as a paid feeding assistant unless that individual has successfully completed a State-approved training program for feeding assistants, as specified in §483.160.

DEFINITION §483.95(h)
Paid feeding assistant is defined in the regulation at 42 CFR 488.301 as "an individual who meets the requirements specified in §483.60(h)(1) of this chapter and who is paid to feed residents by a facility, or who is used under an arrangement with another agency or organization."

GUIDANCE §483.95(h)
A State-approved training course for paid feeding assistants must include, at a minimum, 8 hours of training in the following:

- Feeding techniques.
- Assistance with feeding and hydration.
- Communication and interpersonal skills.
- Appropriate responses to resident behavior.
- Safety and emergency procedures, including the Heimlich maneuver.
- Infection control.
- Resident rights.
- Recognizing changes in residents that are inconsistent with their normal behavior and the importance of reporting those changes to the supervisory nurse.

A facility must maintain a record of all individuals, used by the facility as feeding assistants, who have successfully completed the training course for paid feeding assistants.

PROBES §483.95(h)

- *Were paid feeding assistants observed working with residents in a manner that indicates a training need?*
- *Did interviews with residents and/or resident representatives indicate any areas where training was needed?*

Effective November 28, 2017

- *What type of training do the paid feeding assistants report receiving about the concern or deficient practice identified by the surveyor?*
- *If the facility is using paid feeding assistants and the residents requiring assistance with eating are determined to have avoidable negative nutritional outcomes, request proof that the paid feeding assistants successfully completed a State-approved training program.*

Tag 948 is only to be cited if it is determined the paid feeding assistant(s) has not completed a State-approved training program as specified in §483.160. It is not required to have an outcome deficiency cited for this tag to be cited related to staff training.

POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION
If concerns related to the performance of the paid feeding assistant are identified, see 42 CFR §483.60(h) Paid Feeding Assistants, tag F811, for guidance.

F949
§483.95(i) Behavioral health.
A facility must provide behavioral health training consistent with the requirements at §483.40 and as determined by the facility assessment at §483.70(e).
[§483.95(i) will be implemented beginning November 28, 2019 (Phase 3)]

Effective November 28, 2017

Transmittals Issued for this Appendix

Effective November 28, 2017

Rev #	Issue Date	Subject	Impl Date	CR#
R168SOM	03/08/2017	Revision to State Operations Manual (SOM) Appendix PP - Incorporate revised Requirements of Participation for Medicare and Medicaid certified nursing facilities	03/08/2017	N/A
R167SOM	02/10/2017	Revision to State Operations Manual (SOM) Appendix PP - Incorporate revised Requirements of Participation for Medicare and Medicaid certified nursing facilities – Rescinded and replaced by Transmittal 168	02/10/2017	N/A
R157SOM	06/10/2016	Revisions to the State Operations Manual (SOM) - Appendix PP – Guidance to Surveyors for Long Term Care Facilities	06/10/2016	N/A
R149SOM	10/09/2015	State Operations Manual (SOM) for All Types of Providers and Suppliers Subject to Certification	10/09/2015	N/A
R133SOM	02/06/2015	Revisions to State Operations Manual (SOM), Appendix PP – "Guidance to Surveyors for Long Term Care Facilities"	02/06/2015	N/A
R130SOM	12/12/2014	Revisions to State Operations Manual (SOM), Appendix PP – "Guidance to Surveyors for Long Term Care Facilities"	12/12/2014	N/A
R127SOM	11/26/2014	Revisions to State Operations Manual (SOM), Appendix PP – "Guidance to Surveyors for Long Term Care Facilities"	11/26/2014	N/A
R107SOM	04/04/2014	State Operations Manual (SOM) Appendix PP LTCF revisions for Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/IID)	04/04/2014	N/A
R70SOM	01/07/2011	Revisions to Appendix PP, State Operations Manual (SOM):Guidance to Surveyors for Long-Term Care Facilities (LTC) for Minimum Data Set (MDS) Implementation October 1, 2010 – Rescinded and replaced by Transmittal 70	10/01/2010	N/A
R66SOM	10/01/2010	Revisions to Appendix PP, State Operations Manual (SOM):Guidance to Surveyors for Long-Term Care Facilities (LTC) for Minimum Data Set (MDS) Implementation October 1, 2010 – Rescinded and replaced by Transmittal 70	10/01/2010	N/A

Effective November 28, 2017

R55SOM	12/02/2009	Revisions to Appendix PP, - “Guidelines for Long-Term Care Facilities”, Tag F441	09/30/2009	N/A
R54SOM	11/30/2009	Revisions to Appendix PP, - “Guidelines for Long-Term Care Facilities”, Tag F441 – Rescinded and replaced by Transmittal 55	09/30/2009	N/A
R52SOM	09/25/2009	Revisions to Appendix PP, - “Guidelines for Long-Term Care Facilities”, Tag F441 – Rescinded and replaced by Transmittal 54	09/30/2009	N/A
R51SOM	07/20/2009	Revisions to Appendix PP, - “Guidelines for Long-Term Care Facilities”, Tag F441 – Rescinded and replaced by Transmittal 52	09/30/2009	N/A
R48SOM	06/12/2009	Revisions to Appendix PP, - “Guidelines for Long-Term Care Facilities”	06/12/2009	N/A
R41SOM	04/10/2009	Revisions to Appendices P and PP	04/10/2009	N/A
R36SOM	08/01/2008	Revisions to Appendix PP - Interpretive Guidelines for Long-Term Care Facilities, Tags F325 and F371	09/01/2008	N/A
R26SOM	08/17/2007	Revised Appendix P and Appendix PP-New Tag F373	08/17/2007	N/A
R22SOM	12/15/2006	Revisions to Appendix P and PP	12/18/2006	N/A
R21SOM	10/20/2006	Revised Appendix P &Appendix PP-New Tag F334	10/15/2006	N/A
R19SOM	06/01/2006	Revisions to Appendix PP	06/01/2006	N/A
R15SOM	11/28/2005	Medical Director Guidance	11/25/2005	N/A
R14SOM	11/25/2005	Medical Director Guidance – Replaced by Transmittal 15	11/25/2005	N/A
R12SOM	10/14/2005	Appendix PP Technical Corrections	10/14/2005	N/A
R08SOM	06/28/2008	Revision of Appendix PP-Section 483.25(d)-Urinary Incontinence, Tags F315 and F316	06/27/2005	N/A
R07SOM	06/27/2005	Revision of Appendix PP-Section 483.25(d)-Urinary Incontinence, Tags F315 and F316 – Replaced by Transmittal 8	06/28/2005	N/A
R05SOM	11/19/2004	Revisions to Appendix P and Appendix PP	11/19/2004	N/A
R04SOM	11/12/2004	Guidance to Surveyors for Long Term Care Facilities	11/12/2004	N/A
R01SOM	05/21/2004	Initial Release of Pub 100-07	N/A	N/A