CMS Manual System

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Department of Health & Human Services (DHHS)
Centers for Medicare & Medicaid Services (CMS)

Transmittal 229 **Date: April 25, 2025**

SUBJECT: Revisions to State Operations Manual (SOM), Appendix PP

I. SUMMARY OF CHANGES: Updated tags and guidance

NEW/REVISED MATERIAL - EFFECTIVE DATE: **April 25, 2025**
IMPLEMENTATION DATE: April 28, 2025

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	Preamble Note
R	F550/Procedures §483.10(a)-(b)(1)&(2)
R	F560/Definitions/Campus
R	F562/Guidance/NOTE
R	F604/Regulation /§483.10(e)(1)
R	F604/Regulation/§483.12(a)(2)
R	F604/Deficiency Categorization
R	F604/Deficiency Categorization/ Examples of Severity Leve 4 Noncompliance Immediate Jeopardy to Resident Health or Safety include, but are not limited to/ The facility failed to identify bed rails as a physical restraint,
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R	F605/Regulation/§483.12(a)
N	F605/Regulation/§483.45(c)(3)
N	F605/Regulation/§483.45(d)
N	F605/Regulation/§483.45(e)
R	F605/Intent
R	F605/Definitions
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R	F605 Deficiency Categorization

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D	F623/entire tag
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N	F628/Guidance/483.15(c)(4) Time of the Notice
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R	F841/Guidance/ 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.
R	F841/Guidance/ 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.

R	F841/Guidance/ In addition, the medical director responsibilities should include, but are not limited to
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R	F911/Guidance/Reconstruction
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R	F918/Procedures

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

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

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(Rev. 229; Issued: 04-25-25)

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NOTE: In the regulation text that is noted under the following-Tags : F540, F584, F620*, F621, F627, F628*, 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 determin*ation* 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.

F550

(Rev. 229; Issued: 04-25-25; Effective: 04-25-25; Implementation: 04-28-25)

§483.10(a) Resident Rights.

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 assisting the resident in maintaining and enhancing 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 avoiding:

    - Daily use of disposable cutlery and dishware;

    - Bibs or clothing protectors instead of napkins (except by resident choice);

    - Staff standing over residents while assisting them to eat;

    - Staff interacting/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, avoiding the use of labels for residents such as "feeders" or "walkers." Residents should not be excluded 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.

Consider 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. For 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).

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 *located in the Survey Resources zip file located at https://www.cms.gov/medicare/provider-enrollment-and-certification/guidanceforlawsandregulations/nursing-homes*.

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. Walking 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 participating 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, refer 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.

If the survey team identifies potential compliance issues related to social services, refer to §483.40(d), F745, Social Services.

F560

(Rev. 229; Issued: 04-25-25; Effective: 04-25-25; Implementation: 04-28-25)

§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 *location*, 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 transferred or discharged 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.

F562

(Rev. 229; Issued: 04-25-25; Effective: 04-25-25; Implementation: 04-28-25)

§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.

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 *location.*

F604

(Rev. 229; Issued: 04-25-25; Effective: 04-25-25; Implementation: 04-28-25)

§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 . . . 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 . . . 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:

- Prohibits 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
- Limits 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;

- Cannot be removed easily by the resident; and

- Restricts the resident's freedom of movement or normal access to his/her body[i].

"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 bed rail keeps a resident from voluntarily getting out of bed in a safe manner due to his/her physical or cognitive inability to lower the bed rail independently. 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:

- 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 prevents 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 [See §483.12(a)(2)].

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 (see § 483.20 – Resident Assessment), care planning by the interdisciplinary team (see § 483.21-Comprehensive Person-Centered Care Planning), and documentation of the medical symptoms and use of the physical restraint for the least amount of time possible and provide ongoing re-evaluation [see §483.12(a)(2)].

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.

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 asses 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 generally 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 [§§ 483.10(e)(1) and 483.12(a)(2)]. 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. (See §483.25(n) – Bed Rails).

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

- 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(g), 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 Psychosocial Outcome Severity Guide *located in the Survey Resources zip file located at https://www.cms.gov/medicare/provider-enrollment-and-certification/guidanceforlawsandregulations/nursing-homes*).

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 *substantial/maximal* 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.

See CMS Minimum Data Set Resident Assessment Instrument Manual.

F605

(Rev. 229; Issued: 04-25-25; Effective: 04-25-25; Implementation: 04-28-25)

§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 . . . 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 . . . chemical restraints imposed for purposes of discipline or convenience and that are not required to treat the resident's medical symptoms.

. . . .

§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(d) Unnecessary drugs—General. *Each resident's drug regimen must be free from unnecessary drugs. An unnecessary drug is any drug when used—*

(1) In excessive dose (including duplicate drug therapy); or
(2) For excessive duration; or
(3) Without adequate monitoring; or

(4) Without adequate indications for its use; or
(5) In the presence of adverse consequences which indicate the dose should be reduced or discontinued; or
(6) Any combinations of the reasons stated in paragraphs (d)(1) through (5) of this section.

§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
The intent of these requirements is to ensure residents only receive psychotropic medications when other nonpharmacological interventions are clinically contraindicated. Also, residents must only remain on psychotropic medications when a gradual dose reduction and behavioral interventions have been attempted and/or deemed clinically contraindicated. Additionally, medication should only be used to treat resident's medical symptoms and not used for discipline or staff convenience, which would be deemed a chemical restraint.

NOTE:
- ***For concerns related to unnecessary medications, excluding psychotropic medications, surveyors should assess compliance with §483.45(d), F757.***
- ***This guidance uses the terms "medications," and, "drugs," interchangeably.***

- ***For purposes of this guidance, references to "the pharmacist" mean the facility's licensed pharmacist, whether employed directly by the facility or under arrangement.***

The regulations and guidance are not intended to supplant the judgment of a practitioner in consultation with facility staff, the resident, and his/her representatives and in accordance with professional standards of practice. Rather, the regulations and guidance are intended to ensure psychotropic medications are used only when a practitioner determines that 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). However, surveyors must review the resident's medical record for evidence which supports and documents the clinical indication for psychotropic medication use.

DEFINITIONS

"Adequate Indications for use" *refers to the identified, documented clinical rationale for administering a medication that is based upon an assessment of the resident's condition and therapeutic goals, and after any other treatments have been deemed clinically contraindicated. For psychotropic medications, without documentation in the record explaining that the practitioner has determined that other treatments have been deemed clinically contraindicated, the indication for use is* ***inadequate.*** *Also, adequate indication for use means that the medication administered 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.*

"Adverse consequence" *refers to unwanted, unintended, 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) refers to 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" *refers to 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" *refers to individualized, nonpharmacological 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.*

*"**Chemical restraint**" refers to any drug used for discipline or that makes it more convenient (i.e., less effort) for staff to care for a resident, and not required to treat medical symptoms. This includes instances when a psychotropic medication may be approved to treat certain symptoms, however, nonpharmacological interventions should be used or attempted, unless clinically contraindicated, because they are less dangerous to a resident's health and safety. In these instances, a medication would be deemed not required to treat a resident's symptoms, because a safer alternative should be used. For example, if a nonpharmacological intervention should be used or attempted and is not clinically contraindicated, but a medication is administered and has the effect consistent with the definition of convenience (defined below), the medication would be classified as a chemical restraint.*

"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.*

"Extrapyramidal symptoms (EPS)" *refers to 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)" *refers to 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.*

*"**Medical symptom**" refers to an indication or characteristic of a medical, physical, or psychological condition.*

***"Neuroleptic Malignant Syndrome (NMS)"** refers to 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" or "psychotropic medication"** 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"** refers to 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

Chemical Restraints and Unnecessary Psychotropic Drugs

*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. Psychotropic medications have the potential to create symptoms consistent with sedation, creating convenience for staff (as explained below), which would be considered a chemical restraint. In order to keep residents free from chemical restraints used for discipline or convenience and that are not required to treat the resident's medical symptoms, the facility must prevent the unnecessary use of psychotropic medications. Therefore, noncompliance with the requirements to keep residents free from chemical restraints and prevent the unnecessary use of psychotropic medications are both cited at this F-tag. Furthermore, if a surveyor identifies that a medication has caused symptoms consistent with prolonged sedation that is not addressed (e.g., excessive sleeping, drowsiness, withdrawal, decreased participation in activities), noncompliance is cited, at a minimum of **severity level 3 (harm)**.*

Applicability of the Definition of Psychotropic Medications

In accordance with §483.45(d)(4) and §483.45(e)(1), residents are not given any medications

which are not adequately clinically indicated and necessary to treat a specific condition. The medical record must include documentation of the adequate clinical indication and necessity for prescribed psychotropic medication. (§483.45(e)(1)). The definition of "psychotropic medication" at 483.45(c)(3) is any medication that may affect brain activities associated with mental processes and behavior. Associated risks (e.g., nausea, insomnia, itching) exist regardless of the indication for their use, therefore the psychotropic medication requirements in §483.45(e) apply to the four categories of drugs (anti-psychotic, anti-depressant, anti-anxiety and hypnotic) listed in §483.45(c)(3) ***without exception.*** *Other medications not classified in these four categories can also affect brain activity and should not be used as a substitution for another psychotropic medication listed in §483.45(c)(3), unless prescribed with a documented clinical indication consistent with accepted clinical standards of practice and in accordance with §483.45(d)(4). Categories of medications which affect brain activity include antihistamines, anti-cholinergic medications and central nervous system agents used to treat conditions such as seizures, mood disorders, pseudobulbar affect, and muscle spasms or stiffness. The requirements pertaining to psychotropic medications apply to these types of medications when their documented use appears to be a substitution for another psychotropic medication rather than for the original or approved indication. For example, if a resident is prescribed valproic acid (an anti-convulsant medication) and the medical record shows no history of seizures or migraine headaches, but there is documentation that the medication is being used to treat a mental health disorder, then the use of valproic acid in this example is considered a psychotropic medication and subject to the requirements under §483.45(e).*

Chemical Restraints: Convenience and Discipline

In accordance with §483.10(e)(1) and §483.12(a)(2), residents have 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. 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 being administered to treat a medical symptom, the medication is acting as a chemical restraint. These effects could indicate an intentional action to discipline or make care more convenient for staff. or the facility did not intend to sedate or subdue a resident, but an unnecessary medication is being administered that has that effect.

Convenience *refers to the unnecessary administration of a medication that causes (intentionally or unintentionally) a change in a resident's behavior (e.g., sedation) such that the resident is subdued and/or requires less effort from staff. Therefore, if a medication causes symptoms consistent with sedation (e.g., excessive sleeping, drowsiness, withdrawal, decreased activity), it may take less effort to meet a resident's behavioral needs, which meets the definition of convenience.*

Discipline *refers to any action, such as the administration of a medication, taken by facility staff for the purpose of punishing or penalizing residents.*
For example:

- *A resident has been wandering into other resident's rooms and staff administer a medication to restrict the resident to their room.*

- *Staff become upset with a resident who resists receiving a bath and pinches staff. The staff did not assess the resident's needs or implement non-pharmacological interventions to address their resistance to bathing. Instead, staff administer medication to subdue the resident prior to providing the next bath.*

A medication used for staff convenience or to discipline and is not required to treat medical symptoms, may cause:

- *Sedation, such as sleeping during hours that he/she would not ordinarily sleep;*
- *Withdrawal from activities and socializing;*
- *Loss of autonomy and dignity;*
- *Confusion, cognitive decline, and depression;*
- *Weight loss, decline in skin integrity, or continence level; and/or*
- *Decline in physical functioning including an increased dependence in activities of daily living.*

These effects may result in convenience for the staff, as the resident may require staff to exert less effort than previously. Even if a medication was initially administered for a medical symptom, the continued administration of a medication in the absence of such symptom, that sedates a resident or otherwise makes it easier to care for them, would be deemed a chemical restraint.

Comprehensive Assessment and Behavioral (Nonpharmacological) Interventions

The indications for initiating, maintaining, or discontinuing medication(s), as well as the use of non-pharmacological approaches, in accordance with §483.45(e)(2), are determined by evaluating the resident's physical, behavioral, mental, and psychosocial signs and symptoms in order to identify and rule out any underlying medical conditions, including the assessment of relative benefits and risks, and the preferences and goals for treatment. The use of non-pharmacological approaches must be attempted, unless clinically contraindicated, to minimize the need for psychotropic medications, use the lowest possible dose, or discontinue the medications. The resident's medical record should include documentation of this evaluation and the rationale for chosen treatment options.

Additionally, the facility should ensure that the resident's behaviors (expressions or indications of distress), which may have prompted the initiation or change in a psychotropic medication, are not:

- *Upsetting to the resident or a safety concern to the resident or others;*
- *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;*
- *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; and*
- *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.*

Circumstances that warrant evaluation of a resident's underlying medical condition and medication(s) include:

- *Admission or re-admission: Some residents may be admitted to the facility on psychotropic medications that were started in the hospital or the community without a clear documented indication (i.e., history of schizophrenia without documentation to support the diagnosis per the DSM-5-TR) for why the medication was begun or should be continued.The prescribing practitioner and the IDT should subsequently determine if continuing the medication is justified by conducting a comprehensive medical and psychiatric evaluation;*
- *A new or worsening change in condition/status;*
- *An irregularity identified in the pharmacist's medication regimen review. See F756 for guidance related to the medication regimen review; and*
- *New medication order as an emergency measure – When a resident is experiencing an acute medical problem or psychiatric emergency and the acute phase has stabilized, the staff and prescriber should consider whether medications are still relevant.*

Additional information as well as examples of non-pharmacological interventions may be found in other guidance for regulations at (F741) §483.40, Behavioral Health Services and (F679) §483.24, Quality of Life (Activities).

Determining the Necessity to use Psychotropic Medications

*§483.45(e)(1) prohibits the use of psychotropic drugs unless the medication is **necessary** to treat a specific condition as diagnosed and documented in the clinical record. Also, §483.10(e)(1) and §483.12(a)(2) prohibit the use of medications that are not required to treat the resident's medical symptoms. These prohibitions include instances when a medication may be approved to treat certain symptoms or conditions, however alternative interventions should be used or attempted first, unless clinically contraindicated, because they are less dangerous to a resident's health and safety.*

Proper psychotropic 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 psychotropic 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 have serious side effects, such as sedation, depression, confusion, immobility, falls, and hip fractures, which can be especially dangerous for elderly residents with dementia, in addition to an increased risk of death. The American Geriatrics Society 2023 updated AGS Beers Criteria® for Potentially Inappropriate Medication Use in Older Adults provides information on safely prescribing medications for older adults, https://agsjournals.onlinelibrary.wiley.com/doi/full/10.1111/jgs.18372.

Diagnoses alone do not necessarily warrant the use of a psychotropic medication. Psychotropic 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 medical symptoms which are presenting a danger or significant distress; and/or*
- *GDR was attempted, but clinical symptoms returned.*

Therefore, if a resident is receiving a psychotropic medication, regardless of whether the medication is approved for the resident's condition, there must be documentation that the facility has attempted behavioral (nonpharmacological) interventions, and that these interventions have been deemed clinically contraindicated. If a facility has documentation that other interventions were attempted and were not successful at treating the resident's condition, this would serve as evidence that the medication was necessary to treat the resident (notwithstanding other requirements). Documentation from a physician could also describe that alternative treatments are clinically contraindicated, including the rationale for how this conclusion was reached. However, without evidence that non-pharmacological interventions had been ruled out to treat the resident, the psychotropic medication would be deemed ***not necessary*** *to treat the resident, and noncompliance would be cited.*

If the record shows evidence of prescribing multiple psychotropic medications or switching from one type of psychotropic medication, specifically an antipsychotic medication, to another category of psychotropic medication, the medical record should show a rationale for the change in medication regimen.

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. Psychotropic medications should be the last resort for treatment.

Concerns related to inappropriate prescribing of psychotropic medications should be investigated through record review and interviews with the practitioner(s), facility medical director, consultant pharmacist, other appropriate nursing home staff and the resident. If the facility is unable to provide documentation which supports the prescribing of the antipsychotic medication(s) in question, which may include but is not limited to evaluation of the resident's physical, behavioral, mental, psychosocial status, and comorbid conditions, indications of distress, changes in functional status, resident complaints, behaviors, symptoms, and state PASARR evaluation, then non-compliance exists.

CMS is aware of situations where residents are given a diagnois of schizophrenia without sufficient supporting documentation that meets the criteria in the current version of the DSM for diagnosing schizophrenia. If the non-compliance causes actual harm or the likelihood of serious harm to one or more residents or the surveyor identifies a pattern (e.g., three or more) by the same practitioner prescribing antipsychotic medication for any new diagnosis (such as schizophrenia) with lack of supporting documentation, the survey team should discuss their findings with their state survey agency for consideration to refer the individual to the State Medical Board or Board of Nursing.

When concerns related to inappropriate prescribing of psychotropic medications are identified, surveyors should also review:

- *F658: to determine if the documentation supports a diagnosis in accordance with standards of practice.*
- *F641: to determine if the facility completed an assessment which accurately reflects the resident's status.*
- *F644: to determine if the facility made a referral to the state designated authority when a newly evident or possible serious mental disorder was identified (PASARR).*
- *F841: to evaluate the medical director's oversight of medical care.*

Mental Disorders should be diagnosed , using evidence-based criteria and professional standards, such as the current version of the Diagnostic and Statistical Manual of Mental Disorders (DSM), and documented in the resident's medical record.

Resident's Right to be Informed

In accordance with the requirements at §483.10(c), residents have the right to be informed of and participate in their treatment. Prior to initiating or increasing a psychotropic medication, the resident, family, and/or resident representative must be informed of the benefits, risks, and alternatives for the medication, including any black box warnings for antipsychotic medications, in advance of such initiation or increase. The resident has the right to accept or decline the initiation or increase of a psychotropic medication. To demonstrate compliance, the resident's medical record must include documentation that the resident or resident representative was informed in advance of the risks and benefits of the proposed care, the treatment alternatives or other options and was able to choose the option he or she preferred. A written consent form may serve as evidence of a resident's consent to psychotropic medication, but other types of documentation are also acceptable. If a psychotropic medication has been initiated or increased, and there is not documentation demonstrating compliance with the resident's right to be informed and participate in their treatment, noncompliance with §483.10(c) exists and F552 must be cited.

Dose and Duration

The dose and duration of medications, in accordance with §483.45(d)(1) and (d)(2), are 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 Interdisciplinary Team (IDT) about the resident, including the resident's preferences and goals, the type of medication(s), and therapeutic goals being considered or used.

***Dose** refers to 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.*

***Polypharmacy** refers to the use of five or more medications for an individual which can increase the risk of adverse outcomes such as falls, frailty, disability, and mortality in older adults. Polypharmacy also increases the possibility of prescribing cascades when additional drugs are prescribed to treat the adverse effects of one of the current medications.*

Duplicate therapy *refers to two or more medications of the same pharmacological class/category without a clear distinction of when one medication should be administered over another. 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 medication containing the same ingredient, use of more than one drugs within the same class, or medications from different therapeutic categories with similar effects or properties.*

The risk for polypharmacy and duplicate therapy 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 each medication and the approach to monitor the benefits and any adverse consequences.

Excessive dose *refers to 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.*

NOTE: *If the resident's condition has not responded to treatment or has declined despite treatment, it is important to re-evaluate both the medication and the dose. The clinical rationale for continued use of a medication(s) should be documented in the medical record. Examples of inappropriate duration may include:*

- *The initiation of a psychotropic medication was indicated but was not used for the lowest dose and least amount of time.*
- *A medication was initiated because of a time-limited condition (for example, delirium, pain, infection, nausea and vomiting, cold and cough symptoms, or itching). However, there was no documentation showing that the original condition had been monitored or evaluated. The medication continued to be administered while the original condition may have resolved, leading to excessive duration.*
- *A medication was administered beyond the stop date established by the prescriber, without evidence of clinical indication for continued use of the medication.*

Gradual Dose Reduction

In accordance with §483.45(e)(2), residents who use psychotropic drugs receive gradual dose reductions (GDRs), unless clinically contraindicated, in an effort to discontinue these drugs. For any resident who is receiving a psychotropic medication, the facility must show evidence that a GDR has been attempted unless clinically contraindicated. If there is no evidence of a GDR and there is no description of the clinical contraindications, then noncompliance exists.

The purpose of the required GDR or tapering of medication is to find an optimal dose or to determine whether continued use of the medication is benefiting the resident or could have dangerous side effects. 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.

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. Dose reductions should occur in modest increments over adequate periods of time to minimize withdrawal symptoms and to monitor symptom recurrence. Compliance with the requirement to perform a GDR may be met if, for example, within the first year in which a resident is admitted on a psychotropic medication or after the prescribing practitioner has initiated a psychotropic medication, a facility attempts a GDR in two separate quarters (with at least one month between the attempts), unless clinically contraindicated. Additional information related to gradual dose reduction may be found The American Psychiatric Association Practice Guidelines on the use of Antipsychotics to Treat Agitation or Psychosis in Patients with Dementia, 2016, https://psychiatryonline.org/doi/full/10.1176/appi.books.9780890426807.ap02 and at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3119470/, Discontinuing Medications: A Novel Approach for Revising the Prescribing Stage of the Medication-Use Process (2008).

Some medications (e.g., antidepressants, sedative/hypnotics, opioids) require more gradual tapering to minimize or prevent withdrawal symptoms or other adverse consequences. Additionally, some residents with specific, enduring, progressive, or terminal conditions such as chronic depression, Parkinson's disease psychosis, or recurrent seizures may need specific types of psychotropic medications or other medications which affect brain activity indefinitely.

For any individual who is receiving a psychotropic medication, a GDR may be considered clinically contraindicated for reasons that include, but that are not limited to, the following:

- *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, exacerbate an underlying medical or psychiatric disorder or increased distressed behavior.*

GDR Documentation

- *Medical record documentation should reflect the date of the GDR attempt, the outcome of the dose reduction attempt, and the plan regarding future GDR attempts.*
- *Physician documentation should contain the rationale for why GDR attempts are clinically contraindicated for the resident.*

For residents currently receiving antipsychotic medications:

Surveyors may use the MDS assessment to guide their review and determine what portion of the medical record is needed to review documentation of a GDR attempt or a clinical contraindication rationale.

Review the most recent Resident Assessment Instrument or MDS Section N, item N0450 for a date that a GDR was attempted or a date that the physician determined that a GDR was contraindicated. Review the portion of the medical record that corresponds with the MDS dates to ensure the GDR was attempted or that a clinical contraindication rationale was provided.

If there is no documented date for a GDR or a clinical contraindication on the most recent MDS assessment, review the medical record to determine if a GDR may have been attempted or a clinical contraindication rationale provided since the last MDS assessment and the time of the survey. If there is no evidence of a GDR and there is no description of the clinical contraindications, then noncompliance exists.

Additionally, surveyors should investigate compliance with F641 if there are discrepancies in GDR documentation between the medical record and the MDS assessment(s).

Monitoring and Adverse Consequences

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, in accordance with §483.45(d)(3) and (d)(5), as well as documenting medication management steps. Monitoring and accurate documentation of the resident's response to any treatment (such as, lab results, vital signs, progress notes, behavior flow sheets, medication administration records and the consultant pharmacist's drug regimen review) is essential to evaluate the ongoing effectiveness, benefits as well as risks of non-pharmacological approaches and psychotropic medications.

NOTE: *The facility's pharmacist is a valuable source of information about medications. The pharmacist and attending physician must adhere to the requirements for reporting and responding to identified irregularities (See F756 Drug Regimen Review).*

When there are multiple prescribers, 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 be clinically indicated, and documented in the resident's medical record. If it is determined through monitoring that changes in the resident's treatment plan need to be made, surveyors must review the medical record to determine whether the prescribing practitioner provided a rationale. Without a rationale, the use of the medication(s) may be unnecessary and therefore, noncompliant.

The surveyor must review documentation to confirm that residents are being adequately monitored and re-evaluated for adverse consequences and the need for tapering. Adverse consequences related to medications are common enough to warrant serious attention and close monitoring, and can range from minimal harm to functional decline, hospitalization, permanent injury, and death.

Specifically, antipsychotic medications have serious side effects and can be especially dangerous for elderly residents, as described in the article Antipsychotic Medications,

https://www.ncbi.nlm.nih.gov/books/NBK519503/. 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.

One of the existing mechanisms to warn prescribers about risks associated with medications is the Food and Drug Administration (FDA) requirement that manufacturers include 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: https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program or search for "FDA Safety Alerts for Human Medical Products." Manufacturers are required to place statements about serious problems or contraindications in a prominently displayed box ("black box") in the medication labelling. The boxed warning is reserved for prescription drugs that pose a significant risk of serious or life-threatening adverse effects, based on medical studies. 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 in determining whether a facility has systems and processes in place to minimize risk factors and mitigate harm to residents. This tool and other resources are available on the CMS Adverse Events in Nursing Homes website, https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/QAPI/Adverse-Events-NHs. Additionally, as part of a facility's QAPI program, a facility may track its use of certain classes of medications, such as antipsychotics, through reports from the long-term care pharmacist which could identify trends and reduce adverse events.

PRN Medication Use

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. For acute or emergency situations where the symptoms have stabilized, the staff and prescriber should consider whether medications are still relevant. The attending physician or prescribing practitioner must document the diagnosed specific condition and indication for the PRN medication in the medical record. (§483.45(e)(3-5).

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 medications, excluding antipsychotics	14 days	Order may be extended beyond 14 days if the attending physician or prescribing	Attending physician or prescribing practitioner should document the rationale for the extended time

Type of PRN order	Time Limitation	Exception	Required Actions
		practitioner believes it is appropriate to extend the order.	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 believes it is appropriate 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 because 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.

INVESTIGATIVE PROCEDURES

Use the Unnecessary Medications, Chemical Restraints/Psychotropic Medications, and Medication Regimen Review Critical Element (CE) Pathway along with the interpretive guidance when investigating concerns and determining if the facility meets the requirements.

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
• 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
	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
	• Monitoring for and reporting of:
	  ○ Response to medications and progress toward therapeutic goals and resident's goals
	  ○ Emergence of medication-related adverse consequences
	• Adverse consequences, if present and potentially medication-related, note if there was:
	  ○ Recognition, evaluation, reporting, and management by the IDT
	  ○ Physician action regarding potential medication-related adverse consequences
	• The resident's goals and preferences for medications and treatments

SYMPTOMS, SIGNS, AND CONDITIONS THAT MAY BE ASSOCIATED WITH MEDICATIONS	REVIEW FOR HOW THE IDT MANAGED MEDICATIONS FOR THE RESIDENT
• 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.	

Interview the resident, his or her family, and representative(s) and the IDT, as needed to gather information about use of medications and any possible side effects in the facility. Evaluate if the resident may have experienced psychosocial harm related to side effects of medications. Did side effects such as sedation, lethargy, agitation, mental status changes, or behavior changes:

- *affect a resident's abilities to perform activities of daily living or to interact with others,*
- *cause the resident to withdraw or decline from usual social patterns,*
- *show the resident has decreased engagement in activities,*
- *cause diminished ability to think or concentrate.*

For a resident who is unable to communicate psychosocial outcomes related to medication side effects, the surveyor should consider how a reasonable person in the resident's condition would experience the changes caused by medication side effects as explained in the Psychosocial Outcome Severity Guide, on the CMS Nursing Homes Survey Resources website. 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.

POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION

- *F552, Right to be Informed/Make Treatment Decisions*
- *F553, Right to Participate Planning Care*
- *F580, Notification of Changes*
- *F656, Develop/Implement Comprehensive Care Plan*
- *F679, Activities*
- *F725 and F726, Sufficient and Competent Staff*
- *F710, Physician Supervision*
- *F740, Behavioral Health Services*
- *F742, Treatment/Svc for Mental/Psychosocial Concerns*
- *F756, Drug Regimen Review*
- *F841, Medical Director*

DEFICIENCY CATEGORIZATION

See also the Psychosocial Outcome Severity Guide on the CMS Nursing Homes Survey Resources website for additional information on evaluating the severity of psychosocial outcomes.

Examples of Level 4, immediate jeopardy to resident health and safety include, but are not limited to:

- *The resident was admitted to the facility and was independent in mobility and ambulation and did not require assistance to eat. The resident experienced episodes of wandering into other residents' rooms and became argumentative when redirected. Staff reported difficulty monitoring the resident while taking care of other residents and requested a psychotropic medication from the physician to reduce the resident's wandering behavior. During the survey, the resident was observed sleeping, was difficult to arouse, and required assistance with many activities of daily living, including eating. Medical records showed no attempts with non-pharmacological interventions and no other underlying medical reason for the resident's decline and sedation.*
- *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 their room, sleeping in a recliner or in bed. The antipsychotic medication was continued without an adequate clinical rationale and evidence of non-pharmacological approaches documented in the medical record, resulting in serious psychosocial harm.*
- *After initiating use of a psychotropic medication, a GDR was not attempted and there was no documented rationale of the clinical contraindication. Further, there was no evidence of monitoring for drug interactions or adverse events. This indicates a likelihood of serious harm due to continued use of the psychotropic medication along with other failures to protect the resident's health.*
- *A PRN antipsychotic medication initiated more than 14 days ago, originally prescribed for acute delirium, continued to be administered daily without re-evaluation, and with no evidence of monitoring for adverse consequences. The failures to monitor for adverse consequences and re-evaluate the appropriateness of giving the medication created a likelihood for serious harm from adverse consequences and a significant decline in functioning.*

Examples of Level 3, actual harm that are not immediate jeopardy include, but are not limited to:

- *Failure to evaluate and monitor the resident and discontinue a psychotropic medication originally prescribed to treat a resident's delirium. Delirium symptoms subsided but the resident remained drowsy from continued administration of the medication. While the resident remains independent with ADLs, the resident has missed some group activities due to the drowsiness.*
- *A resident has an order for a PRN psychotropic medication that the resident can take for anxiety. However, staff regularly administer the PRN psychotropic medication to the resident with no documented indication but during an interview, staff explained the medication helps the resident sleep, so they've been giving it nightly even though the resident did not request it. Since*

receiving the medication, the resident has been sleeping through breakfast and has experienced significant weight loss.

Examples of Level 2, no actual harm with potential for more than minimal harm that is not immediate jeopardy, include but are not limited to:

- *A resident has been receiving a psychotropic medication for several months to treat symptoms documented in the medical record. The resident is being monitored for side effects from the medication and the target symptoms have decreased. However, there is no evidence of a GDR attempt or documentation of a clinical contraindication for not attempting a GDR.*

- *A resident was prescribed a PRN psychotropic medication for episodes of anxiety which can have a sedating effect. The resident is no longer experiencing anxiety and has not requested the medication for over a week. Although the medication has not been administered recently, the PRN order has been in place for more than 14 days and there is no documented rationale for extending the order for the medication.*

Severity Level 1:

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).
- 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. *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.*

F620

(Rev. 229; Issued: 04-25-25; Effective: 04-25-25; Implementation: 04-28-25)

§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 *location,* 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 provisions at §483.15(a)(2)(i) and (ii) prohibit both direct and indirect requests 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. 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. *If an individual does not actually have legal access to the resident's funds, the facility may not request or require the individual to pay the facility.* 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.

Thus, language that specifically requests a third party to personally guarantee payment to a facility is noncompliant. Also, language can be noncompliant even if it does not specifically reference a "guarantee" by a third party. Any language contained in an agreement that seeks to hold a third party personally responsible for paying the facility would violate this requirement. Examples of noncompliant language include, but are not limited to:

- *Language that holds both (1) the resident and (2) the representative or other individual jointly responsible for any sums due to the facility (however, language that holds the resident solely responsible without joining the representative is allowable).*

- *Language that holds the representative or other third-party individual personally liable for breach of an obligation in the agreement, such as (1) failing to apply for Medicaid in a timely and complete manner or (2) allowing someone other than a signatory to the agreement to spend the resident's resources that would be used to pay the nursing home.*

- *Language that does not specifically mention a third-party guarantee but that implies the resident could be discharged if the representative does not voluntarily agree to personally pay to prevent the discharge.*

- *Language that holds the representative or other individual personally liable for any amounts not paid to the facility in a timely manner because the representative or other individual did not provide accurate financial information or notify the facility of changes in the resident's financial information.*

Admission agreements containing language like the examples above, or which contain other language which confers personal liability upon a third party, represent noncompliance with this provision. Such language is noncompliant if it appears in the main document that a facility uses as its admission agreement or in other documents that are signed at admission. In addition, after a resident is admitted, the facility cannot use such language in agreements regarding a resident's continued stay in the facility.

§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 <u>not</u> 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 F627, *Inappropriate* Transfer and Discharge).

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 *location* 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

(Rev. 229; Issued: 04-25-25; Effective: 04-25-25; Implementation: 04-28-25)

§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 *location,* 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 pharmacy 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 *location* 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?

F627

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§483.15(c) Transfer and discharge-

§483.15(c)(1) Facility requirements-

§483.15(c)(1)(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.

§483.15(c)(1)(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.

§483.15(c)(7) Orientation for transfer or discharge.

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.

§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.

§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.

§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:

(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

- *These regulations and guidance address inappropriate discharges and:*
    - Specify the limited conditions under which a skilled nursing facility or nursing facility may transfer or discharge a resident, the documentation that must be included in the medical record, and who is responsible for making the documentation.

- *Ensure policies are developed and implemented which allow residents to return to the facility following hospitalization or therapeutic leave.*

- *Ensure a facility does not transfer or discharge a resident in an unsafe manner, such as a location that does not meet the resident's needs, does not provide needed support and resources, or does not meet the resident's preferences and, therefore, should not have occurred.*

- *Ensure the discharge planning process* 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

"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). The definition and 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.

"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.

"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 paragraph (2) of this definition at §483.5, 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 §483.5 described above. Requirements specific to distinct part SNFs or NFs are found at §483.5.

"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).

"Therapeutic Leave": Resident absences for purposes other than required hospitalization.

"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. (See §483.5). Specifically, transfer refers to the movement of a resident from a bed in one facility to a bed in another 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 facility or other location in the community, when return to the original facility is not expected.

GUIDANCE

Investigating noncompliance with the transfer and discharge requirements begins when conducting offsite preparation. The team coordinator (TC) should contact the local ombudsman and inquire if there are specific residents from whom the ombudsman has received complaints related to inappropriate discharges for review (see Investigative Procedure section below). The TC should also be sure to review complaints and survey history of the facility for indications of noncompliance with the requirements for transfer and/or discharge.

§483.15(c)(1)(i)-(ii) Transfer and Discharge Requirements

Use guidance at this Ftag to determine if noncompliance exists when evidence suggests a facility should not have transferred or discharged a resident at the time of discharge, or at all. These circumstances may include, but are not limited to, the following:

- *When evidence in the medical record does not support the basis for discharge, such as:*
    - *Discharge based on an inability to meet the resident's needs, but there is no evidence of facility attempts to meet the resident's needs, or no*
    - *evidence of an assessment at the time of discharge indicating what needs cannot be met;*
    - *Discharge based on improvement of resident's health such that the services provided by the facility are no longer needed, but documentation shows the resident's health did not improve or actually declined;*
    - *Discharge based on the endangerment of the safety or health of individuals in the facility, but there is no documentation in the resident's medical record that supports this discharge;*
    - *Discharge based on failure to pay, however there is no evidence that the facility offered the resident to pay privately or apply for Medical Assistance or that the resident refused to pay or have paid under Medicare or Medicaid;*
    - *Discharge occurs even though the resident appealed the discharge, the appeal is pending, and there is no documentation to support the failure to discharge would endanger the health and safety of individuals in the facility.*
- *When evidence in the medical record shows a resident was not permitted to return following hospitalization or therapeutic leave, and there is no valid basis for discharge.*
- *There is no evidence that the facility considered the care giver's availability, capacity, and/or capability to perform needed care to the resident following discharge.*
- *The post-discharge plan of care did not address resident limitations in ability to care for themself.*

These regulations *describe the requirements that must be met in order for* a facility *to* transfer or discharge *a resident*, thus protecting nursing home residents from transfers and discharges which *should not have occurred, and thus* violate federal regulations.

§483.15(c)(1)(i)(A), (C) or (D) - Discharge when Needs Cannot be Met, or when Safety or Health of Individuals is Endangered

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 requirements at §483.71 (see also F838, Facility Assessment). For residents the facility has admitted, §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, residents have a right to remain in the facility unless the discharge or transfer meets one of the specified exceptions in §§483.15(c)(1)(i)(A)-(F). Discharging a resident is a violation of this right unless the facility can demonstrate that one of the limited circumstances listed in the regulation is met.

Surveyors must ensure that for discharges related to circumstances *at §483.15(c)(1)(i)(A), (C), or (D)* 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 an acute care facility. *Without an assessment of the resident's status and needs at the time of proposed return to the facility, there can be no determination of (A), the resident's needs cannot be met, or (C) and (D), that the safety or health of individuals would be endangered.*

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.) The facility must be able to demonstrate that the resident or, if applicable, resident representative, received information regarding the risks of refusal of treatment, (§483.10(c)(5) and (6), F552 and F578) 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, and see also §§483.20 Resident Assessment and 483.35 Nursing Services).

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.

§483.15(c)(1)(i)(E) **Nonpayment as Basis for Discharge**
Non-payment for a stay in the facility occurs when the resident has failed, after reasonable and appropriate notice, to pay for a stay at the facility and also may apply:

- When the resident has not submitted the necessary paperwork for third party (including Medicare/Medicaid) payment; or

- After the third party payor (including Medicare or Medicaid) denied the claim and the resident refused to pay for his/her stay.

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.

In situations where a resident's Medicare coverage may be ending, the facility must comply with the requirements at §483.10(g)(17) and (18), F582. If the resident continues to need long-term care services, the facility, under the requirements above, should offer the resident the ability to remain, which may include:

- Offering the resident the option to remain in the facility by paying privately for a bed;

- Providing the Medicaid-eligible resident with necessary assistance to apply for Medicaid coverage in accordance with §483.10(g)(13), F579, with an explanation that:

    - if denied Medicaid coverage, the resident would be responsible for payment for all days after Medicare payment ended; and

    - if found eligible, and no Medicaid bed became available in the facility or the facility participated only in Medicare (SNF only), the resident would be discharged to another facility with available Medicaid beds if the resident wants to have the stay paid by Medicaid.

The resident cannot be discharged for nonpayment while a determination on the resident's Medicaid eligibility is pending.

NOTE: Surveyors should be aware of a facility's Medicare and Medicaid certification status and/or the presence of a distinct part as this can affect whether a resident's discharge for non-payment is justified and is a relevant part of the investigation.

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.

In certain cases, residents are admitted for short-term, skilled rehabilitation under Medicare, but, following completion of the rehabilitation program, they communicate that they are not ready to leave the facility. In these situations, if the facility proceeds with discharge, *the survey team should investigate to determine if* the discharge *violates these requirements,* is *inappropriate and should not have occurred. Additionally, t*hese situations may require further investigation to ensure that discrimination based on payment source has not occurred in accordance with §483.10(a)(2) (F550).

NOTE: Situations in which residents sign out of the facility, or leave Against Medical Advice (AMA) should be thoroughly investigated to determine if the resident or resident representative was forced, pressured, or intimidated into leaving AMA. *Additionally,* the discharge would *require* further investigation to determine compliance with the requirements at 483.15(c), including the requirement to provide a notice at F62*8*. See additional guidance *at* Abuse, Neglect and Exploitation at F600.

NOTE: Residents who are sent to the acute care setting for routine treatment/planned procedures must also be allowed to return to the facility (See F626, Permitting Residents to Return to Facility).

§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.

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.

Successful Appeals on Discharges

For residents who have appealed their discharge and obtained a favorable ruling from the hearing, the resident or their representative may choose to report the discharge as a complaint to the State Survey Agency based on the favorable appeal ruling. However, the State Survey Agency cannot take a survey action, such as citing noncompliance exclusively based on the ruling of the hearing. Rather, the State Survey Agency must triage the complaint and conduct a survey in accordance with the timelines specified in Section 5079.9 of Chapter 5 of the State Operations Manual. During the survey, surveyors must investigate compliance with the applicable regulations, such as the discharge requirements in this F-tag. Surveyors should also consider compliance with §483.70(b), Compliance with Federal, State, and local laws and professional standards at F836. If noncompliance is found, cite the appropriate tag and level of scope and severity. Also, if the resident's discharge location is to a setting that does not meet their health or safety needs, the facility's plan of correction should state that the facility will either, 1) Re-admit the resident until a safe and compliant discharge can be done, or 2) Coordinate a transfer of the resident to another setting where they will be safe. See the Deficiency Categorization section towards the end of this guidance for more information.

§483.15(c)(2) Required Documentation *in the Resident's Medical Record*
To demonstrate that any of the circumstances permissible for a facility to transfer or discharge as specified in *the regulations* have occurred, the medical record must show documentation of the basis for transfer or discharge.

For circumstances *where the discharge or transfer is necessary for the resident's welfare and the facility cannot meet the resident's needs or the resident's health has improved sufficiently so that the resident no longer needs the care of the facility,* the **resident's physician** must document information about the basis for the transfer or discharge. Additionally, *if the facility determines it cannot* 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 *situations where the facility determines a resident's clinical or behavioral status endangers the safety or health of individuals in the facility,* 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.

§483.15(d)(1) – (e)(1)-(2) Bed Hold and Permitting Residents to Return

Facilities must develop and implement policies for bed-hold and permitting residents to return following hospitalization or therapeutic leave. **These policies apply to all residents, regardless of their payment source.** The facility policies must provide that residents who seek to return to the facility within the bed-hold period defined in the State plan are allowed to return to their previous room, if available. Additionally, residents who seek to return to the facility after the expiration of the bed-hold period or when state law does not provide for bed-holds are allowed to return to their previous room if available or immediately to the first available bed in a semi-private room provided that the resident:

- Still requires the services provided by the facility; and
- Is eligible for Medicare skilled nursing facility or Medicaid nursing facility services.

The policies must also provide that if the facility determines that a resident cannot return, the facility must comply with the requirements at 42 CFR 483.15(c).

Medicaid-eligible residents must be permitted to return to the first available bed even if the residents have outstanding Medicaid balances.

Emergency Transfers to Acute Care

When residents are sent emergently to an acute care setting, these scenarios are considered transfers, NOT discharges, because the resident's return is generally expected.

Residents who are sent emergently to an acute care setting, such as a hospital, **must** be permitted to return to the facility. In a situation where the facility discharges *the resident* while *he or she* is in the hospital following emergency transfer, the facility must have evidence that the resident's status at the time the resident seeks to return to the facility (not at the time the resident was transferred for acute care) meets one of the criteria at §483.15(c)(1)(i)(A) through (D). Additionally, the resident has the right to return to the facility pending an appeal of *the* discharge unless the return would endanger the health or safety of the resident or other individuals in the facility. The facility must document the danger that the failure to transfer or discharge would pose. (§483.15(c)(1)(ii)).

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 *her* 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 from the hospital the treatments, medications, and services the facility would need to provide to meet the resident's needs upon returning to the facility. If the facility is unable to provide the treatments, medications, and services needed, the facility may not be able to meet the resident's needs. For example, a resident now requires ventilator care or dialysis, 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.

§483.15(e)(1)(ii) **Not Permitting Residents to Return**

Not permitting a resident to return following hospitalization or therapeutic leave constitutes a discharge and requires a facility to meet the requirements as outlined in §483.15(c)(1)(ii).

Because the facility was able to care for the resident prior to *the hospitalization or* therapeutic leave, documentation related to the basis for discharge must clearly

show why the facility can no longer care for the resident.

If the facility does not permit a resident's return to the facility (i.e., discharges *the resident*) based on inability to meet the resident's needs, documentation must be in accordance with requirements at §483.15(c)(2)(i)(B). The facility must notify the resident, his or her representative, and the LTC ombudsman in writing of the discharge, including notification of appeal rights. (§483.15(c)(3) and (5)(iv)) 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 documented evidence that the resident's return would endanger the health or safety of the resident or other individuals in the facility.

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 whether the facility held the resident's bed in accordance with its bed-hold policies, or, if the resident's stay outside of the facility exceeded the bed-hold period, whether there was an available bed at the time the resident sought return to the facility. If there was not an available bed at the time the resident sought return to the facility, the surveyor should determine whether or not the resident was allowed to return to the first available bed in a semi-private room.

When a facility alleges they cannot meet the resident's needs and does not allow a resident to return, the surveyor should 1) investigate why the resident's needs cannot be met; and 2) review facility admissions to determine if residents with similar care needs have been admitted or permitted to remain, which could indicate the facility has the capability to meet the needs of the resident who is not being allowed to return and demonstrates noncompliance with this requirement**.**

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 discharge *the resident* unless it has

ascertained from the resident or resident representative that the *he or she* does not wish to return.

NOTE: In reviewing complaints for 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.

Composite Distinct Part

If a facility does not have a composite distinct part, §483.15(e)(2) does not apply. 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.
NOTE: 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 Location for clarification.

§483.15(c)(7) Preparation for Transfer or Discharge

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.

§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; *and*
- 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/nursing-home-improvement/resident-assessment-instrument-manual.*

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).
Note: These situations only apply when a resident expresses their wishes to be discharged earlier than outlined in the care plan. These situations do not apply if a facility offers to discharge a resident to a location which does not meet their health and/or safety needs, and the resident agrees (this would constitute noncompliance).

§483.21(c)(1)(viii) **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.

To ensure 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).

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.

INVESTIGATIVE PROTOCOL

Use the Critical Element (CE) Pathways for 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 *on when a facility can transfer or discharge a resident and ensuring the transfer or discharge meets the resident's health and/or safety needs.*

Summary of Investigative Procedure

*Use Offsite Preparation information from the Ombudsman to identify residents or resident representatives (for residents already discharged) who may have concerns with inappropriate discharges. For any residents with concerns, b*riefly review the most recent comprehensive assessment, comprehensive care plan (specifically the discharge care plan), progress notes, and orders to*:*

- *I*dentify the basis for the transfer or discharge,
- *Determine* whether the facility has identified and addressed the resident's goals and discharge needs*;*
- *Determine if the resident was appropriately oriented, prepared, and understood the information provided to him or her.*

*D*uring this review, 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. This information will guide observations and interviews to be made in order to corroborate concerns identified.

DEFICIENCY CATEGORIZATION

In addition to actual or potential physical harm, always consider whether psychosocial harm has occurred when determining severity level (See Psychosocial Outcome Severity Guide, *https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Nursing-Homes.html,* select the Survey Resources download and select the Psychosocial Outcome Severity Guide from the list of resources.

Violations of the requirements at F627, Inappropriate Discharges, would generally be cited at the severity level of Harm (Level 3) or Immediate Jeopardy (Level 4) when using the reasonable person approach in considering psychosocial outcomes as well as the likelihood for serious

physical harm resulting from an unsafe discharge. See State Operations Manual Appendix Q and the Psychosocial Outcome Severity Guide located in the Survey Resources zip file located at https://www.cms.gov/medicare/provider-enrollment-and-certification/guidanceforlawsandregulations/nursing-homes) for additional information about psychosocial/mental harm and using the reasonable person concept.

***NOTE:** For citations at **any** level of scope and severity, if the discharged resident's health and/or safety is threatened in the setting they are currently located, the facility's plan of correction should state that the facility will either, 1) Re-admit the resident until a safe and compliant discharge can be done, or 2) Coordinate a transfer of the resident to another setting where they will be safe. The facility should not be determined in substantial compliance until one of these two items is complete (and all other noncompliance has been corrected). If the resident's needs are being met in their current location, the plan of correction should include specifics on how the facility will prevent inappropriate noncompliant discharges in the future.*

Additionally, for situations in which residents' discharge locations did not meet their health and/or safety needs,, enforcement should be implemented immediately. For example, a discretionary denial of payment for new admissions should be imposed to go into effect within 2 or 15 days (as appropriate) and remain in effect until a return to substantial compliance as evidenced by either, 1) the resident is readmitted and not discharged unless a safe and compliant discharge is done, or 2) the facility coordinates a discharge to another setting where their needs will be met.

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

- *A facility discharged a resident* on the basis that the resident's health had improved *so that the resident no longer needed the services provided by the facility*, however, the resident and her family disagreed and filed an appeal. The facility did not allow the resident to remain in the facility while the appeal was pending and dropped her off at her daughter's home. The resident's daughter previously stated she could not care for her mother at her home where needed medical equipment and wound care was not available*, thus creating an inappropriate discharge for this resident, which did not meet her health needs.*

- A facility discharge*d a resident* based on the facility's inability to meet *the* resident's needs. However, upon complaint investigation, it was determined by interview and record review that, while the resident was depressed and had challenging behavior*s* requiring staff attention, he did not have needs which could not be met in that facility, and there was evidence that the facility was caring for other residents with similar behaviors. The resident was discharged to *an unsafe setting, or in a manner, that placed the resident at risk for serious harm (e.g., the resident still has medical needs, but they cannot be supported in the setting they were*

discharged to).

- *A f*acility failed to allow a resident *requiring the facility's services* to return following therapeutic leave to a family member's home. *Additionally, when the facility refused to allow him to return, they took no steps to comply with the discharge requirements for notice and appeal rights. This resulted* in *an inappropriate discharge.* The resident *was* found living on the street, without *the needed care and* adequate food and shelter, and susceptible to serious *injury*.

- *A* 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*, resulting in discharge to an unsafe setting*. 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 Severity Level 3 Noncompliance: Actual Harm that is not Immediate Jeopardy include, but are not limited to:

- The facility failed to allow a resident to remain in the facility after his skilled rehabilitation ended and while his application for Medical Assistance was pending. The resident consequently was discharged to another facility that was located further from the resident's family, resulting in the resident expressing persistent sadness and withdrawal from social activities.

- A facility discharge*d* a resident after the resident attempted to hit a staff member during morning care over several days. The facility discharged the resident claiming the resident was a danger to others. Upon investigation of a complaint, it was determined the facility had been failing to provide the resident with *their prescribed* medication prior to morning care in accordance with the care plan. Evidence also showed the resident had never attempted to hit staff when pain was managed according to the care plan, therefore the resident was not actually a danger to others. There was also no documentation of the facility's attempts to meet the resident's needs or what services the new receiving facility had in order to meet the resident's needs. During an interview with the resident, the surveyor found the resident was not happy in the new facility and was no longer participating in activities or therapy, resulting in a significant decreased ability to

perform ADLs.

- Facility failed to allow a resident to return to an available bed in the same location of the composite distinct part in which they resided previously. The new location was not on the same campus where the resident previously resided, and was farther from the resident's family, resulting in the resident expressing sustained and persistent sadness and withdrawal.

- After transfer to a*n acute care facility*, a facility failed to allow a resident to return to the facility where the resident had lived for several months *saying they could not meet the resident's needs. Review of the resident's records did not show the resident had any new needs after hospitalization that could not be met by the facility. As a* result, the resident *was* transferred from the hospital to a different nursing home 40 minutes away, where he did not know anyone, and where he developed increased anxiety and depression.

- 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 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:

- A facility transferred a resident to the hospital emergently due to a change in condition. The facility failed to provide the hospital with contact information for the practitioner responsible for the resident's care leading to a delay in admitting the resident.

- 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.

An example of Severity Level 1 noncompliance:

- The failure to permit the resident to remain in the facility, document the resident's transfer or discharge, and communicate necessary information to the receiving provider places the resident at risk for more than minimal harm. Therefore, Severity Level 1 does not apply for this regulatory requirement.

F628

(Rev. 229; Issued: 04-25-25; Effective: 04-25-25; Implementation: 04-28-25)

§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.

(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.

§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 Long-Term Care Ombudsman;

(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.

§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).

§483.15(d) Notice of bed-hold 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.

§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.

§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).

INTENT

The intent of this tag is to ensure the facility adheres to all of the applicable components of the process for transferring or discharging a resident which include documentation and information conveyed to the receiving provider, the notice of transfer or discharge, notice of bed-hold policy, and completing the discharge summary.

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).

"Bed-hold": Holding or reserving a resident's bed while the resident is absent from the facility for therapeutic leave or hospitalization.

"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.

"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.

"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 facility. (See §483.5) Specifically, transfer refers to the movement of a resident from a bed in one facility to a bed in another 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 facility or other location in the community, when

return to the original facility is not expected.

GUIDANCE

§483.15(c)(2) **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;
- All special instructions and/or precautions for ongoing care, as appropriate such as:
    - Treatments and devices (oxygen, implants, IVs, tubes/catheters);
    - Transmission-based precautions such as contact, droplet, or airborne;
    - 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 other 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 a copy of the required information found at §483.21(c)(2) Discharge Summary, as applicable. 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.

§483.15(c)(3) **Notice of Transfer or Discharge and Ombudsman Notification**
When a facility transfers or discharges a resident, prior to the transfer or discharge, 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 transferred or 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. The facility must maintain evidence that the notice was sent to the Ombudsman. While Ombudsman Programs vary from state to state, facilities should know the process for ombudsman notification in their state.

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 before the discharge, 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.

For any other types of 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 a notice of transfer must be provided to the resident and resident representative as soon as practicable before the transfer, 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, as long as the list meets all requirements for content of such notices at §483.15(c)(5).

§483.15(c)(5) **Contents of the Notice**

The facility's notice must include all of the following at the time notice is provided:

- The specific reason for the transfer or discharge, including the basis under §§483.15(c)(1)(i)(A)-(F);
- The effective date of the transfer or discharge;
- The specific location (such as the name of the new provider or description and/or address if the location is a residence) to which the resident is to be transferred or discharged;
- An explanation of the right to appeal the transfer or discharge to the State;
- The name, address (mail and email), and telephone number of the State entity which receives such appeal hearing requests;
- Information on how to obtain an appeal form;
- Information on obtaining assistance in completing and submitting the appeal hearing request; and
- The name, address (mailing and email), and phone number of the representative of the Office of the State Long-Term Care ombudsman.

For nursing facility residents with intellectual and developmental disabilities (or related disabilities) or with mental illness (or related disabilities), the notice must include the name, mailing and e-mail addresses and phone number of the state agency responsible for the protection and advocacy for these populations.

§483.15(c)(4) **Timing of the Notice**

Generally, this notice must be provided at least 30 days prior to the transfer or discharge of the resident. Exceptions to the 30-day requirement apply when the transfer or discharge is affected because:

- The health and/or safety of individuals in the facility would be endangered due to the clinical or behavioral status of the resident;
- The resident's health improves sufficiently to allow a more immediate transfer or discharge;
- An immediate transfer or discharge is required by the resident's urgent medical needs; or
- A resident has not resided in the facility for 30 days.

In these exceptional cases, the notice must be provided to the resident, resident's representative if appropriate, and LTC ombudsman as soon as practicable before the transfer or discharge.

§483.15(c)(6) **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 transfer or discharge 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 and permit adequate time for discharge planning. Surveyors should be aware that if a change in destination indicates that the original basis for discharge has changed, a new notice is required and additional appeal rights may exist for the resident. This situation may require further investigation to determine whether the facility is in compliance with the Transfer and Discharge requirements at 42 CFR 483.15(c).

Example: A facility determines it cannot meet a resident's needs and arranges for discharge to another nursing home which can meet the resident's needs. Before the discharge occurs, the receiving facility declines to take the resident and the

discharging facility changes the destination to a setting that does not appear to meet the resident's ongoing medical needs. This could indicate that the basis for discharge has changed and would require further investigation.

NOTE: Federal regulations at 42 CFR Part 431, Subpart E, Fair Hearings for Applicants and Beneficiaries, address the requirements for States to implement a fair hearing process.

§483.15(c)(8) **Notice in Advance of Facility Closure:**

Refer to §483.70(l), F845 for guidance related to evaluating Notice in Advance of Facility Closure.

§483.15(d) **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.

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, *regulations at* §483.15(e)(1) 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 discharging the resident *against their wishes or stated goals*.

§483.21(c)(2) Discharge Summary

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 or physicians/practitioners to whom the discharge summary is provided.

Content of the Discharge Summary

§483.21(c)(2)(i) **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.

§483.21(c)(2)(ii) **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.

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.

§483.21(c)(2)(iii) **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.

DEFICIENCY CATEGORIZATION

An example 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 a *blood thinning medication*. 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 *their blood thinning medication*.

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 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). *The recapitulation contained all other required components.* This resulted in no negative impact to the resident.

F637

(Rev. 229; Issued: 04-25-25; Effective: 04-25-25; Implementation: 04-28-25)

§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

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

"Significant Change" *refers to* 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)" *refers to* 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)" *refers to* 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.

GUIDANCE

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 *partial/moderate assist, substantial/maximal assistance, dependent, resident refused, or not attempted* 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, Setup or clean-up assistance, or Supervision or touching 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

- Did the facility identify, 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?

F641

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§483.20(g) Accuracy of Assessments.
The assessment must accurately reflect the resident's status.

§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

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

"Accuracy of Assessment" means that the appropriate, 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) (*e.g.* 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.

The initial comprehensive assessment provides starting point data for ongoing assessment of resident progress.

Inaccurate MDS Diagnosis Coding

CMS is aware of situations where residents are given a diagnois of schizophrenia without sufficient supporting documentation that meets the criteria in the current version of the DSM

for diagnosing schizophrenia. For these situations, determine if non-compliance exists for the facility's completion of an accurate assessment. This practice may also require referrals by the facility and/or the survey team to State Medical Boards or Boards of Nursing.

Surveyors should investigate this concern through record review and interviews with staff who completed the assessment. Surveyors are not questioning the physician's medical judgement, but rather, they are evaluating whether the medical record contains supporting documentation for the diagnosis to verify the accuracy of the resident assessment.

If the facility is unable to provide documentation which supports the MDS coding of the new diagnosis in question, then noncompliance exists at §483.20(g) and (i)(2). Supporting documentation should include, but is not limited to, evaluation(s) of the resident's physical, behavioral, mental, psychosocial status, and comorbid conditions, ruling out physiological effects of a substance (e.g., medication or drugs) or other medical conditions, indications of distress, changes in functional status, resident complaints, behaviors, symptoms, and/or state Preadmission Screening and Resident Review (PASARR) evaluation.

One or two assessments with inaccurate MDS diagnosis coding should be cited as isolated. If the surveyor identifies a pattern (i.e., three or more) of inaccurate coding for any new diagnosis (such as schizophrenia) with no supporting documentation by a physician, the surveyor should cite the scope of the non-compliance at a minimum of pattern or widespread as appropriate, make a referral to the State Board of Nursing, and see the guidance below in Investigative Procedures for making a referral to the Office of the Inspector General.

When concerns related to a diagnosis that lacks sufficient supporting documentation are identified, surveyors should review:

- *F658: to determine if the documentation supports a diagnosis in accordance with standards of practice.*
- *F644: to determine if the facility made a referral to the state designated authority when a newly evident or possible serious mental disorder was identified.*
- *F605: to evaluate psychotropic medication use based on a comprehensive assessment.*
- *F841: to evaluate the medical director's oversight of medical care.*

Certification of Accuracy and Completion

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.

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 termsof 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 Patient Driven Payment Model (PDPM) scores, untriggering Care Area Assessments (CAAs) or unflagging Quality Measures (QMs), 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 internet Quality Improvement Evaluation System (iQIES) 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 iQIES system.*

INVESTIGATIVE PROCEDURES

Use the Resident Assessment Critical Element Pathway a) when MDS concerns are noted but you are not using a care area pathway (i.e., the care area did not require further investigation), or b) for concerns about the facility's MDS data completion or submission activities, along with the above guidance, when determining if the facility meets the requirements for, or investigating concerns related to resident assessment.

Surveyors are expected to focus on MDS coding accuracy but are not expected to investigate possible falsification of the resident assessment instrument.

If the surveyor identifies a pattern (i.e., three or more residents) of inaccurate MDS coding by staff who completed, signed, and certified to the accuracy of the portion of the assessment they completed, and there are indications or concerns that the individual who completed the section(s) in question knew the coding was inaccurate, a referral should be made to the Office of Inspector General for investigation of falsification per §483.20(j). See the Submit a Hotline Complaint section, under the Fraud tab, on the Department of Health & Human Services Office of the Inspector General's Office webpage at https://oig.hhs.gov/fraud/report-fraud/index.asp.

PROBES

- Based on your total review of the resident, observations, interviews and record reviews, does each portion of the MDS assessment accurately 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?

- *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?*

F658

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§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

To assure that *ALL* services*, as outlined by the comprehensive care plan,* being provided meet professional standards of quality.

GUIDANCE

"Professional standards of quality" means that care and *all* 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.
- Current professional journal articles.

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.

Mental Disorders are diagnosed by a practitioner, using evidence-based criteria and professional standards, such as the current version of the Diagnostic and Statistical Manual of Mental Disorders (DSM), and are supported by documentation in the resident's medical record. Supporting documentation should include, but is not limited to, evaluation of the resident's physical, behavioral, mental, psychosocial status, and comorbid conditions, ruling out physiological effects of a substance (e.g., medication or drugs) or other medical conditions, indications of distress, changes in functional status, resident complaints, behaviors, symptoms, and/or state Preadmission Screening and Resident Review (PASARR) evaluation.

Examples of insufficient documentation to support a mental health diagnosis would include:

- *A situation where schizophrenia or another diagnosis is only mentioned as an indication in medication orders without supporting documentation.*
- *The addition of, or request by the facility to a practitioner for, a diagnosis of schizophrenia or another diagnosis without documentation supporting the diagnosis.*
- *A practitioner's note or transfer summary from a previous provider stating "history of schizophrenia," "schizophrenia," or another diagnosis without supporting documentation confirming the diagnosis with a previous practitioner or family, and the facility failed to to provide evidence that a practitioner conducted a comprehensive evaluation after admission.*
- *A diagnosis list stating schizophrenia or another diagnosis without supporting documentation.*
- *A note of schizophrenia or another diagnosis in an electronic health record (EHR) without supporting documentation which populates throughout the EHR.*
- *A note of schizophrenia or another diagnosis in the medical record by a nurse without supporting documentation by the practitoner.*

Insufficient documentation for a new mental health diagnosis means that the resident's medical record does not contain the following:

- *Documentation (e.g., nurses' notes) indicating the resident has had symptoms, disturbances, or behaviors consistent with those listed in the DSM criteria, **and** for the period of time in accordance with the DSM criteria.*

- *Documentation from the diagnosing practitioner indicating that the diagnosis was given based on a comprehensive assessment, such as notes from a practitioner's visit.*

- *Documentation from the diagnosing practitioner indicating that the symptons, disturbances, or behaviors are not attributable to (i.e., ruled out) the effects of a substance (e.g., a drug of abuse, a medication) or another medical condition (e.g., UTI or high ammonia levels).*
- *Documentation regarding the effect the disturbance is having on the resident's function, such as interpersonal relationships, or self-care, in comparison to their level of function prior to the onset of disturbance.*

*The medical record must include documentation of **ALL** of these items, if not, this would constitute insufficient documentation.*

CMS is aware of situations where residents are given a diagnois of schizophrenia without sufficient supporting documentation that meets the criteria in the current version of the DSM for diagnosing schizophrenia. For these situations, determine if non-compliance exists related to the practitioner not adhering to professional standards of *practice* for assessing and diagnosing a resident.

Surveyors should investigate this concern through record review and interviews with the practitioner(s), facility medical director, and other appropriate nursing home staff, as well as consult with the state agency medical director as needed. Surveyors are not questioning the practitioner's medical judgement, but rather, they are evaluating whether the medical record contains supporting documentation for the diagnosis to verify the accuracy of the resident assessment.

If the facility is unable to provide practitioner documentation which supports the new psychiatric diagnosis in question, then non-compliance exists. For example, if a new diagnosis of schizophrenia is noted in the medical record, the surveyor should verify the documentation supports the use of accepted standards of practice (e.g. current DSM criteria) for the diagnosis.

Below are excerpts from the DSM (current as of the date of this publication)[1] which describe diagnostic criteria for schizophrenia, schizophreniform disorder, and schizoaffective disorder. This list is not all-inclusive and should not be used as a checklist but rather as a guide when reviewing supporting documentation.

SCHIZOPHRENIA

Diagnostic Criteria

A. Two (or more) of the following, each present for a significant portion of time during a 1-month period (or less if successfully treated). At least one of these must be (1), (2), or (3):

1. Delusions.

2. Hallucinations.

3. Disorganized speech (e.g., frequent derailment or incoherence).

4. Grossly disorganized or catatonic behavior.

5. Negative symptoms (i.e., diminished emotional expression or avolition).

B. For a significant portion of the time since the onset of the disturbance, level of functioning in one or more major areas, such as work, interpersonal relations, or self-care, is markedly below the level achieved prior to the onset (or when the onset is in childhood or adolescence, there is failure to achieve expected level of interpersonal, academic, or occupational functioning).

C. Continuous signs of the disturbance persist for at least 6 months. This 6-month period must include at least 1 month of symptoms (or less if successfully treated) that meet Criterion A (i.e., active-phase symptoms) and may include periods of prodromal or residual symptoms. During these prodromal or residual periods, the signs of the disturbance may be manifested by only negative symptoms or by two or more symptoms listed in Criterion A present in an attenuated form (e.g., odd beliefs, unusual perceptual experiences).

D. Schizoaffective disorder and depressive or bipolar disorder with psychotic features have been ruled out because either 1) no major depressive or manic episodes have occurred concurrently with the active-phase symptoms, or 2) if mood episodes have occurred during active-phase symptoms, they have been present for a minority of the total duration of the active and residual periods of the illness.

E. The disturbance is not attributable to the physiological effects of a substance (e.g., a drug of abuse, a medication) or another medical condition.

F. If there is a history of autism spectrum disorder or a communication disorder of childhood onset, the additional diagnosis of schizophrenia is made only if prominent delusions or hallucinations, in addition to the other required symptoms of schizophrenia, are also present for at least 1 month (or less successfully treated).

SCHIZOPHRENIFORM

Schizophreniform disorder is characterized by a symptomatic presentation equivalent to that of schizophrenia except for its duration (less than 6 months) and the absence of a requirement for a

decline in functioning.

Diagnostic Criteria

A. Two (or more) of the following, each present for a significant portion of time during a 1-month period (or less if successfully treated). At least one of these must be (1), (2), or (3):

1. Delusions.

2. Hallucinations.

3. Disorganized speech (e.g., frequent derailment or incoherence).

4. Grossly disorganized or catatonic behavior.

5. Negative symptoms (i.e., diminished emotional expression or avolition).

B. An episode of the disorder lasts at least 1 month but less than 6 months. When the diagnosis must be made without waiting for recovery, it should be qualified as "provisional."

C. Schizoaffective disorder and depressive or bipolar disorder with psychotic features have been ruled out because either 1) no major depressive or manic episodes have occurred concurrently with the active-phase symptoms, or 2) if mood episodes have occurred during active-phase symptoms, they have been present for a minority of the total duration of the active and residual periods of the illness.

D. The disturbance is not attributable to the physiological effects of a substance (e.g., a drug of abuse, a medication) or another medical condition.

SCHIZOAFFECTIVE DISORDER

Diagnostic Criteria

A. An ninterrupted period of illness during which there is a major mood episode (major depressive or manic) concurrent with Criterion A of schizophrenia.

Note: The major depressive episode must include Criterion A1: Depressed mood.

B. Delusions or hallucinations for 2 or more weeks in the absence of a major mood episode (depressive or manic) during the lifetime duration of the illness.

C. Symptoms that meet criteria for a major mood episode are present for the majority of the total duration of the active and residual portions of the illness.

D. The disturbance is not attributable to the effects of a substance (e.g., a drug of abuse, a medication) or another medical condition.

When residents are admitted to the facility with a mental health diagnosis, *supporting documentation should include, but is not limited to:*

- *The PASARR evaluation and determination report from the State Mental Health Authority;*
- *Facility attempts to obtain documentation regarding the mental health diagnosis from the previous provider(s);*
- *Validation of the resident's mental health diagnosis by the practitioner in accordance with professional standards of practice, such as reviewing information available in the medical record, including information from the previous provider(s), discussions about the diagnosis and history with the resident or resident representative, conducting a comprehensive evaluation, the need for a psychiatric or other consultations if necessary, and their determination of the resident's diagnosis.*

INVESTIGATIVE PROCEDURES

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).

PROBES

- 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 *and/or physician*, up to date, and accurate for the service being delivered?

- *Does the documentation show how the physician arrived at the diagnosis based on the DSM criteria? For example, for a new diagnosis of schizophrenia, does the medical record contain notes (e.g., from nursing or medical providers) of symptoms or behaviors consistent with the symptoms from criterion A, and for the period of time in criterion C as listed in the DSM?*

- *Is there documentation of a physician's visit assessing the resident and concluding a diagnosis of schizophrenia?*

The following questions may be used to assist the surveyor in discussing a resident's diagnosis with a physician:

- *Who established the mental health diagnosis?*

- *How did you arrive at the diagnosis according to standards of practice (DSM), and where is this documented? (Documentation should include information on the DSM criteria specified above such as symptoms and behaviors and their duration.)*

- *Were other underlying conditions excluded, such as medical or psychiatric conditions, progression of an existing condition such as dementia, medication side effects, delirium, etc., prior to diagnosing the resident with schizophrenia?*

DEFICIENCY CATEGORIZATION

If the surveyor identifies a pattern (e.g., three or more) of residents who have a new diagnosis which lacks sufficient supporting documentation, the surveyor should cite the scope of the non-compliance at a minimum scope of pattern (e.g., level 2 = "E," Level 3 = "H," or Level 4 = "K"), Additionally, the surveyor should discuss the findings with their state agency to consider referringl a physician, nurse practitioner, clinical nurse specialist, or physician assistant to their respective state board (e.g., state medical board, state nursing board, etc.).

A medical record which lacks sufficient documentation, such as a comprehensive evaluation and behavioral documentation, to support a new diagnosis of schizophrenia by a practitioner would represent non-compliance at F658. If the resident is receiving an antipsychotic medication and experienced negative side effects, evaluate compliance with other requirements such as F605. For example:

- *While receiving the antipsychotic medication, the resident withdrew from social activities because of difficulty concentrating and carrying on conversations and spends their day isolated in their room, or engages minimally with staff and their family since starting the antipsychotic medication. A lack of documentation to support a practitioner's diagnosis of schizoaffective*

*disorder **and** the use of an antipsychotic medication without an adequate clinical indication represents Immediate Jeopardy at F658 and F605.*

- *Because of a practitioner diagnosed schizophrenia in a resident (without supporting documentation), the facility did not attempt a gradual dose reduction (GDR) or demonstrate the GDR was contraindicated. There was no indication of a change in the resident's behavior or function,but the potential for more than minimal harm exists. Therefore, use of the antipsychotic medication without a gradual dose reduction unless contraindicated an adequate clinical indication and lack of documentation to support the diagnosis would be Level 2 at F658 and F605.*

- *A resident was diagnosed with schizophrenia after admission to the nursing home and an antipsychotic medication was initiated for agitation and aggressive behaviors. The resident had no prior history of schizophrenia and the medical record did not contain a comprehensive evaluation to support the new schizophrenia diagnosis by the practitioner and the symptoms for which the antipsychotic was prescribed did not align with schizophrenia symptoms. The medical record demonstrated failed attempts of non-pharmacological interventions, appropriate monitoring of the antipsychotic medication and an attempted gradual dose reduction. The lack of documentation to support the schizophrenia diagnosis represents level 2 noncompliance at F658 only.*

When concerns related to a diagnosis of a resident which lacks sufficient supporting documentation are identified, surveyors should also review:

- *F605: to evaluate administration of psychotropic medications based on a comprehensive assessment.*

- *F641: to determine if the facility completed an assessment which accurately reflects the resident's status.*

- *F644: to determine if the facility made a referral to the state designated authority when a newly evident or possible serious mental disorder was identified (PASARR).*

- *F841: to evaluate the medical director's oversight of medical care.*

Surveyors should consider other tags as appropriate depending on the outcome to the resident.

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 *(including diagnosing a resident)* 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

F677

(Rev. 229; Issued: 04-25-25; Effective: 04-25-25; Implementation: 04-28-25)

§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: if the resident completes the activity by themself with no assistance from a helper.*

- *Setup or clean-up assistance: if the helper sets up or cleans up; resident completes activity. Helper assists only prior to or following the activity, but not during the activity. For example, the resident requires assistance cutting up food or opening container or requires setup of hygiene item(s) or assistive device(s).*

- *Supervision or touching assistance: if the helper provides verbal cues or touching/steadying/contact guard assistance as resident completes activity.*

- *Assistance may be provided throughout the activity or intermittently.*

- *Partial/moderate assistance: if the helper does LESS THAN HALF the effort. Helper lifts, holds, or supports trunk or limbs, but provides less than half the effort.*

- *Substantial/maximal assistance: if the helper does MORE THAN HALF the effort. Helper lifts or holds trunk or limbs and provides more than half the effort.*

- *Dependent: if the helper does ALL of the effort. Resident does none of the effort to complete the activity; or the assistance of two or more helpers is required for the resident to complete the activity.*

PROCEDURES

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, as 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

(Rev. 229; Issued: 04-25-25; Effective: 04-25-25; Implementation: 04-28-25)

§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

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

"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, activation of the emergency response system, early cardiopulmonary resuscitation, and rapid defibrillation with an automated 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

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 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.

CPR Certification

Staff must maintain current CPR certification for Healthcare Providers through a CPR provider whose training includes *a* hands-on *session either in a physical or*

virtual instructor-led setting in accordance with accepted national standards.
For concerns related to *CPR certification that meets accepted professional standards* the survey team should consider §483.21(b)(3)(ii), Services Provided by Qualified Persons, F659 and/or *§483.70(b) Compliance with Federal, State, and Local Laws and Professional Standards. F836.*

INVESTIGATIVE *PROCEDURES*:

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 directives, 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;

NOTE: In addition to actual or potential physical harm, always *observe for visual cues of psychosocial distress and* consider whether psychosocial harm has occurred when determining severity level. (See *guidance on Severity and Scope Levels and* Psychosocial Outcome Severity Guide *found in the Survey Resources zip file located at https://www.cms.gov/medicare/provider-enrollment-and-certification/guidanceforlawsandregulations/nursing-homes*).

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 *in accordance with the accepted national standards.* through a CPR provider whose training includes hands-on practice and in-person skills assessment.

DEFICIENCY CATEGORIZATION

Examples of Severity Level 4 ***immediate jeopardy to resident health and 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*, 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.

An example of Level 2, no actual harm, with potential for more than minimal harm, that is not immediate jeopardy includes, but are not limited to:
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.

- 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*, 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 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.

F684

(Rev. 229; Issued: 04-25-25; Effective: 04-25-25; Implementation: 04-28-25)

§ 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 residents 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-centered 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 psychosocial 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 F*605 Chemical Restraints/Unnecessary* 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(*g*) Medical Director, or for the written agreement, to F849, §483.70(*n*) 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.

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), *F628.*

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: Surveyors should refer the following concerns, as a complaint, to the State agency responsible for oversight of hospice for residents receiving Medicare-certified hospice services;

- Hospice failure to address and resolve concerns made known to them by the nursing facility which are related to coordination of care or implementation of appropriate services; and/or

- Hospice failure to provide services in accordance with the coordinated plan of care regardless of notice from the facility.

  In addition, 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 nursing home/hospice written agreement to determine whether there is a failure by the nursing home related to the implementation of the agreement at F849.

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.

Summary of Investigative Procedure

Briefly review the most recent comprehensive assessments, 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).

NOTE: *In addition to actual or potential physical harm,* always observe for visual cues of psychosocial distress and harm *and consider whether psychosocial harm has occurred when determining severity level* (see Appendix P, Guidance on Severity and Scope Levels and Psychosocial Outcome Severity Guide *located in the Survey Resources zip file located at* https://www.cms.gov/medicare/provider-enrollment-and-certification/guidanceforlawsandregulations/nursing-homes).

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, developed 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

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.

F686

(Rev. 229; Issued: 04-25-25; Effective: 04-25-25; Implementation: 04-28-25)

§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 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 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. Soft tissue damage related to 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.

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. Determining whether damage to the skin and underlying tissue is a PI or PU depends on the staging of the damaged tissue. See stages below.

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 and services to heal it and to prevent infection and 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.

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.

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 quarterly 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.

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 developing 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 could 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 State 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.

1. 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.

2. 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.

3. 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.

4. 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 §483.25, F684, Quality of Care, for definition and description of injury types other than PU/PIs.

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/PI should 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.

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 PU/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.

NOTE: In addition to actual or potential physical harm, always *observe for visual cues of psychosocial distress and* consider whether psychosocial harm has occurred when determining severity level (See *guidance on Severity and Scope Levels and* Psychosocial Outcome Severity Guide *located in the Survey Resources zip file located at https://www.cms.gov/medicare/provider-enrollment-and-certification/guidanceforlawsandregulations/nursing-homes*).

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

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 IV 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, the resident developed Stage III or IV pressure ulcers with associated soft tissue or systemic infection. (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 III pressure injury.

- 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 I 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 I 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.

- 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 F686, 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, §483.70 Administration, and §483.75 QAPI.

F688

(Rev. 229; Issued: 04-25-25; Effective: 04-25-25; Implementation: 04-28-25)

§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)

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.

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.

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: *In addition to actual or potential physical harm, a*lways observe for visual cues of psychosocial distress and *consider whether psychosocial* harm *has occurred when determining severity level* (*See g*uidance on Severity and Scope Levels and Psychosocial Outcome Severity Guide *located in the Survey Resources zip file located at https://www.cms.gov/medicare/provider-enrollment-and-certification/guidanceforlawsandregulations/nursing-homes*).

F690

(Rev. 229; Issued: 04-25-25; Effective: 04-25-25; Implementation: 04-28-25)

§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 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;

- An indwelling catheter is not used unless there is valid medical justification for catheterization and the catheter is discontinued as soon as clinically warranted;

- A resident, with or without an indwelling catheter, receives the appropriate care and services to prevent urinary tract infections to the extent possible;

- 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 fecal incontinence is identified, assessed and provided appropriate treatment and services to restore as much normal bowel function as possible, unless it is not clinically possible;

NOTE: F690 includes the appropriate treatment and services to restore bowel function for a resident with fecal incontinence, however, for concerns related to bowel management (such as constipation, fecal impaction), refer to F684 – Quality of care

DEFINITIONS

"Bacteremia" is the presence of bacteria in the bloodstream.

"Bacteriuria" is defined as the presence of bacteria in the urine.

"Continence" refers 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. 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

Sections 483.25(e)(2)(i) and (ii), 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 the ongoing assessment for the resident who currently has a catheter, including the removal of the catheter as soon as possible 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.

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: 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.

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 and/or 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 and 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

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 above 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. 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 criteria 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. 2. For residents who do not have an indwelling catheter, minimum criteria for initiating antibiotics include: $>10^5$ 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: $>10^5$ 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."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]

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.

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: https://www.niddk.nih.gov/health-information/digestive-diseases/bowel-control-problems-fecal-incontinence/

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 and;
- 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: In addition to actual or potential physical harm, always *observe for visual cues of psychosocial distress and* consider whether psychosocial harm has occurred when determining severity level (See *guidance on Severity and Scope Levels and* Psychosocial Outcome Severity Guide *located in the Survey Resources zip file located at https://www.cms.gov/medicare/provider-enrollment-and-certification/guidanceforlawsandregulations/nursing-homes*).

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 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.

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:

- +https://www.vumc.org/cqa/sites/vumc.org.cqa/files/public_files/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
- http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2614622/

F692

(Rev. 229; Issued: 04-25-25; Effective: 04-25-25; Implementation: 04-28-25)

§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.

"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, 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, cognitive status, 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.. 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, the 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.[1] 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.[2]

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. 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. 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.[3]

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.[4] Many factors influence whether a swallowing abnormality eventually results in clinically significant complications, such as aspiration pneumonia. 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.[5] 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.[6,7]

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. 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 monitoring of care planned interventions is necessary for all residents. On-going monitoring 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: In addition to actual or potential physical harm, always *observe for visual cues of psychosocial distress and* consider whether psychosocial harm has occurred when determining severity level (See *guidance on Severity and Scope Levels and* Psychosocial Outcome Severity Guide *located in the Survey Resources zip file located at https://www.cms.gov/medicare/provider-enrollment-and-certification/guidanceforlawsandregulations/nursing-homes*).

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

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 fluids, 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 poor 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 F692, 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.

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[7] Mamun, K., & Lim, J. (2005). Role of nasogastric tube in preventing aspiration pneumonia in patients with dysphagia. Singapore Medical Journal, 46(11), 627-631.

F693

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§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.

"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.

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 F692. 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).

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

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 current at the date of this publication.

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.

NOTE: In addition to actual or potential physical harm, always *observe for visual cues of psychosocial distress and* consider whether psychosocial harm has occurred when determining severity level (See *guidance on Severity and Scope Levels and* Psychosocial Outcome Severity Guide *located in the Survey Resources zip file located at https://www.cms.gov/medicare/provider-enrollment-and-certification/guidanceforlawsandregulations/nursing-homes*).

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

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.

F695

(Rev. 229; Issued: 04-25-25; Effective: 04-25-25; Implementation: 04-28-25)

§483.25(i) Respiratory care, including 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 §483.25 (i)

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.

"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.

"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 acute respiratory distress syndrome (ARDS), 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(*g*) 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.

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 and/or Tracheostomy/Tracheotomy Care

The guidance related to care of residents receiving mechanical ventilation applies to facilities who provide this type of 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 *consider whether psychosocial harm has occurred when determining severity level* (*See guidance* on Severity and Scope Levels and Psychosocial Outcome Severity Guide *located in the Survey Resources zip file located at https://www.cms.gov/medicare/provider-enrollment-and-certification/guidanceforlawsandregulations/nursing-homes*).

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 §483.25(i)

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.

DEFICIENCY CATEGORIZATION §483.25(i)

Examples of Severity Level 4 Noncompliance: Immediate Jeopardy to Resident Health or Safety includes but is 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.

F697

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§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

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

"Acute Pain" *refers to pain that is usually sudden in onset and time-limited with a duration of less than 1 month and often is caused by injury, trauma, or medical treatments such as surgery. (From the Centers for Disease Control and Prevention (CDC)).*

"Adjuvant Medication" *refers to* any medication with a primary indication other than pain management but with analgesic properties in some painful conditions.[2]

"Adverse Consequence" *refers to* 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).

*"**Chronic Pain**" refers to pain that typically lasts greater than 3 months and can be the result of an underlying medical disease or condition, injury, medical treatment, inflammation, or unknown cause. (From the CDC).*

"Medication Assisted Treatment" (MAT) *refers to* the use of medications, in combination with counseling and behavioral therapies, to provide a "whole-patient" approach to the treatment of substance use disorders. (From the Substance Abuse and Mental Health Services Administration (SAMHSA)).

"Opioid Use Disorder" (OUD) *refers to* a problematic pattern of opioid use leading to clinically significant impairment or distress. Additional criteria used to assess and diagnose OUD can be found in the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5).

*"**Subacute Pain**" refers to pain that has been present for 1–3 months. (From the CDC).*

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

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.

Use of Opioids for Pain Management—Prescribing practitioners may find that opioid medications are the most appropriate treatment for acute pain, *subacute pain, and* chronic pain in some residents. *Opioid treatment for pain needs to be appropriately assessed and individualized for each resident*. However, because of increasing opioid addiction, abuse, and overdoses, prescribers should use caution when prescribing opioids, and consider using alternative pain management approaches, when appropriate. When opioids are used, the lowest possible effective dosage should be prescribed for the shortest amount of time possible after considering all medical needs and the resident should be monitored for effectiveness and any adverse effects. *When starting opioid therapy for acute, subacute, or chronic pain, clinicians may consider prescribing immediate-release opioids instead of extended-release and long-acting.*

Due to the risk of fatal respiratory depression, combining opioids and benzodiazepines should be avoided unless clinically indicated for an individual resident. Risks related to combining these medications are even greater for adults aged 65 and older and include falls and hip fractures, cognitive impairment/confusion, daytime fatigue, and delirium. If concurrent use of opioids and benzodiazepines is clinically indicated for an individual resident, the resident should be closely monitored for adverse consequences.

Medication regimens for residents receiving end of life, palliative, or hospice care may include opioids alone or combining opioids and benzodiazepines; their use must be consistent with accepted standards of practice for this specialty of care.

When treating pain in a resident with an addiction history or opioid use disorder (OUD), strategies must be used to relieve pain while also considering the OUD or addiction history. These strategies may include continuation of medication assisted treatment (MAT), if appropriate, non-opioid pain medications, and non-pharmacological approaches.

***NOTE**: Requirements at 483.10(c)(5) describe the resident's right to be informed of the risks and benefits of the proposed treatment. For concerns related to informing the resident or resident representative of the risks of opioid use for pain, refer to F552.*

For additional information, refer to:

- *Exposure-Response Association Between Concurrent Opioid and Benzodiazepine Use and Risk of Opioid-Related Overdose in Medicare Part D Beneficiaries, https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2685628.*

- *National Institute on Drug Abuse Benzodiazepines and Opioids, https://nida.nih.gov/research-topics/opioids/benzodiazepines-opioids*
- *Geriatricpain.org, Resources and Tools for Quality Pain Care, https://geriatricpain.org/*
- *The Society for Post-Acute and Long-Term Care Medicine (AMDA) opioid The Society for Post-Acute and Long-Term Care Medicine (AMDA) Opioids in Nursing Homes , https://paltc.org/opioids%20in%20nursing%20homes*
- *Centers for Disease Control Clinical Practice Guidelines for Prescribing Opioids for Pain https://www.cdc.gov/opioids/patients/guideline.html*

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 *https://geriatricpain.org/clinicians/pain-assessment-information.*

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);

- History of addiction, past and/or ongoing and related treatment for OUD;
- 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 including medication assisted treatment for OUD; 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.

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.

Additionally, a facility should evaluate whether there is a time or day pattern to a resident's reports or signs of increased pain to ensure that the problem is not

due to drug diversion.

The CDC describes a number of side effects which prescription opioids can cause even when given as directed. Some side effects for which residents should be monitored include:

- Tolerance, meaning more medication may be needed to achieve the same level of pain relief;
- Physical dependence which causes symptoms of withdrawal when opioid medication is stopped, or a dose is held or missed;
- Increased sensitivity to pain;
- Constipation;
- Nausea, vomiting, and dry mouth;
- Sleepiness, dizziness, and/or confusion;
- Depression; and
- Itching and sweating.

According to the Substance Abuse and Mental Health Administration (SAMHSA), opioid overdose deaths can be prevented by administering naloxone, a medication approved by the Food and Drug Administration to reverse the effects of opioids. The United States Surgeon General has recommended that naloxone be kept on hand where there is a risk for an opioid overdose. Facilities should have a written policy to address opioid overdoses.

The SAMHSA website houses a number of resources related to opioid management including this document intended for prescribers which addresses appropriate prescribing, monitoring for adverse effects, and treating overdoses: SAMHSA Opioid Overdose Prevention Toolkit:
Information for Prescribers, https://www.samhsa.gov/resource/ebp/opioid-overdose-prevention-toolkit.

For concerns related to staff monitoring for adverse effects of opioid use, see F757, Unnecessary Medications.

INVESTIGATIVE *PROCEDURES*

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.

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 Guidance on Severity and Scope Levels and Psychosocial Outcome Severity Guide).

KEY ELEMENTS OF NONCOMPLIANCE

To cite deficient practice at F697, the surveyor's investigation will generally show that the facility failed to do *any* 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.

DEFICIENCY CATEGORIZATION

An example of Level 4*, 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, holding her hip area, moaning and crying out, sweating, and striking out when staff attempted to move her.

An example of Level 3*, actual harm* that is not *i*mmediate *j*eopardy 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 *Level 2, 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.

Level 1*, no* actual harm with potential for minimal harm:

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.

F698

(Rev. 229; Issued: 04-25-25; Effective: 04-25-25; Implementation: 04-28-25)

§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: §483.25(l)

"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.

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.

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 CFR §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.

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:

- C**ontinuous 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 *consider whether psychosocial harm has occurred when determining severity level* (*S*ee *g*uidance on Severity and Scope Levels and Psychosocial Outcome Severity Guide *located in the Survey Resources zip file located at https://www.cms.gov/medicare/provider-enrollment-and-certification/guidanceforlawsandregulations/nursing-homes*). 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);

DEFICIENCY CATEGORIZATION

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.

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.

F700

(Rev. 229; Issued: 04-25-25; Effective: 04-25-25; Implementation: 04-28-25)

§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 or use of bed rails, the facility attempts to use alternatives. If the attempted alternatives 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 first attempted to use appropriate 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 review possible risks and benefits of bed rails prior to installation or use. 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); and
- Risk of falling.

In addition, the resident assessment must include an evaluation of the alternatives that were attempted prior to the installation or use of a bed rail 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 examples of the potential risks with 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 that 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 and is varied 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 appropriate alternatives have been attempted and prior to installation, the facility must obtain informed consent from the resident or 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 should 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 the resident representative, so that it could be understood and that consent can be given voluntarily, free from coercion.

Appropriate Alternatives

Facilities must attempt to use appropriate alternatives prior to installing or using bed rails. CMS encourages facilities to refer to published information from recognized authorities such as the Food and Drug Administration, which has identified the following alternatives to bed rail use: "Alternatives include: roll guards, foam bumpers, lowering the bed and using concave mattresses that can help reduce rolling off the bed."
This and more information may be found at*https://www.fda.gov/medical-devices/adult-portable-bed-rail-safety/recommendations-consumers-and-caregivers-about-adult-portable-bed-rails*. This webpage was last updated in *February, 2023*.

See also, Clinical Guidance for Assessment and Implementation of Bed Rails in Hospitals, Long Term Care Facilities, and Home Care Settings:

https://www.fda.gov/media/88765/download

Recommendations for Health Care Providers about bed rails; https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/ConsumerProducts/BedRailSafety/ucm362848.htm

Additionally, alternatives that are attempted should be appropriate for the resident, safe and address the medical conditions, symptoms or behavioral patterns for which a bed rail was considered. For example, a low bed or concave mattress may not be an appropriate alternative to enable movement in bed for a resident receiving therapy for hip-replacement. If no appropriate alternative was identified, the medical record would have to include evidence of the following:

- purpose for which the bed rail was intended and evidence that alternatives were tried and were not successful

- assessment of the resident, the bed, the mattress, and rail for entrapment risk (which would include ensuring bed dimensions are appropriate for resident size/weight), and

- risks and benefits were reviewed with the resident or resident representative, and informed consent was given before installation or use.

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, which could lead to falling over bed rails.

- When installing and using bed rails, the facility should:

o 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 and specifications 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.

CMS recognizes that there are many different types of beds, some with bed rails pre-installed, or bed rails with the call button and lights incorporated into the rail, and others without bed rails pre-installed for which a separate rail could be installed.

Facilities should have a process for determining whether beds, including mattresses and rails, are appropriate and safe for their residents. For beds with rails that are incorporated or pre-installed, the facility must determine whether or not disabling the bed rail poses a risk for the resident. Some considerations would include, but are not limited to, the following:

- Could the rail simply be moved to the down position and tucked under the bed frame?
- When in the down position, does it pose a tripping or entrapment hazard?
- Would it have to be physically removed to eliminate a tripping or entrapment hazard?

Facilities should follow manufacturers' recommendations/instructions regarding disabling or tying rails down. CMS regulations do not specify that bed rails must be removed or disabled when not in use. However, if bed rails are not appropriate for the resident and the facility chooses to keep the bed rail on the bed, but in the down position, raising the rail even for episodic use during care would be considered noncompliance if all of the requirements (assessment, informed consent, appropriateness of bed, and inspection and maintenance) are not met prior to the episodic bedrail use for the resident.

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 to the resident in accordance with professional standards of practice and the resident's choices. This should be evidenced in the resident's records, including their care plan, including, but not limited to, the following information:

- 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 §483.25(n)

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 or using a side or bed rail;

- Assess the resident for risk of entrapment prior to installing or using a bed rail;

- Assess the risk versus benefits of using a bed rail and review them with the resident or the resident's representative;

- Obtain informed consent for the installation and use of bed rails prior to use.
- 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

- Ensure scheduled maintenance of any bed rail in use according to the manufacturer's recommendations and specifications.

NOTE: If a facility is unable to identify the manufacturer and access the manufacturer information and guidance for bed rails that they use, they would not meet requirements to follow the manufacturers' recommendations and specifications for installing and maintaining bed rails at 483.25(n)(4).

INVESTIGATIVE PROTOCOL §483.25(n)

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.

PROCEDURES §483.25(n)

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 or used 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 raises and lowers 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 or used,

- 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 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 §483.25(n)

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 *substantial/maximal* 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.

Example 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 or using 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.

Examples of Severity Level 1 Noncompliance No Actual Harm with Potential for Minimal Harm include, but are not limited to: 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 https://ncoa.org/professionals/health/center-for-healthy-aging/national-falls-prevention-resource-center

Centers for Disease Control and Prevention at https://www.cdc.gov/falls/index.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fhomeandrecreationalsafety%2Ffalls%2Findex.html

World Health Organization Fall Prevention in Older Age at https://www.who.int/publications/i/item/9789241563536

National Institute of Health- Senior Health at https://www.nia.nih.gov/health/topics/falls-and-falls-prevention.

Wandering and Elopement Resources
U.S. Department of Veterans Affairs VHA National Center for Patient Safety at https://patientsafety.va.gov/A_Toolkit_Patients_At_Risk_for_Wandering.asp

F725

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§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 §483.71.

§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 (*f*) 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 (*f*) of this section, the facility must designate a licensed nurse to serve as a charge nurse on each tour of duty.

INTENT

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

"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.

"Licensed Nurse" *means any nurse that requires the successful completion of a National Council Licensure Examination (NCLEX-PN or NCLEX-RN). At a minimum this would include a Licensed Practical Nurse (LPN) or a Registered Nurse (RN). Licenses and titles are defined and protected by the Nurse Practice Act (NPA) for usage in the public. They are privileged and granted by the Board of Nursing (BON) after meeting the requirements of graduating from accredited nursing educational programs, passing professional board examinations, background checks, and paying applicable fees.*[1]

"Charge Nurse" *is a licensed nurse with specific responsibilities designated by the*

facility that may include staff supervision, emergency coordinator, physician liaison, as well as direct resident care.

"Scope of Practice" *describes the services that a qualified health professional is deemed competent to perform and permitted to undertake – in keeping with the terms of their professional license.*[2]

GUIDANCE

As required under Administration at F838, §483.71 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 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 *contributes to the identification of* 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 *on any given day.*

The facility is required to provide licensed nursing staff 24-hours a day, along with other nursing personnel, including but not limited to nurse aides. The facility must also designate a licensed nurse to serve as a charge nurse on each tour of duty.

Concerns such as falls, weight loss, dehydration, pressure ulcers, elopement and resident altercations can also offer insight into potential insufficient numbers of staff available in the facility. Surveyors must discuss these concerns during team meetings and investigate how or if these adverse outcomes are related to sufficient staffing.

Compliance with State staffing standards does not necessarily determine compliance with Federal staffing standards that require a sufficient number of staff to meet all of the residents' basic and individualized care needs. If a facility does not meet state regulations for staffing, do NOT cite that as a deficiency here, but refer to Administration, F836, §483.70(b).

Cite this F-Tag only if there is non-compliance related to a facility not providing services by sufficient number of nursing personnel (licensed and non-licensed), not providing licensed nursing staff 24-hours a day, and/or does not have a licensed charge nurse on each tour of duty.

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 at §483.12, Quality of Life at §483.24, and/or Quality of Care at §483.25.*

INVESTIGATIVE PROCEDURES

Use the Sufficient and Competent Nurse Staffing Critical Element Pathway, along with the above interpretive guidance, and the procedures below, when determining if the facility meets the requirements for, or investigating concerns related to sufficient staffing.

The facility is responsible for submitting staffing data through the CMS Payroll-Based Journal (PBJ) system (Refer to F851, §483.70(p)). *When completing the offsite preparation for a recertification survey, the team coordinator must obtain the PBJ Staffing Data Report and evaluate PBJ data submitted by the facility.* This data *is available through PBJ reports that* can be obtained through *CMS' survey system*. This *report, titled* PBJ Staffing Data Report, *must be utilized by surveyors on at least every recertification survey. The report* contains information about overall direct care staffing levels *as well as licensed nurse staffing.*

While many factors may need to be considered when determining if 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, the PBJ Staffing Data Report provides very clear and distinct areas that could identify deficient practices. The steps below must be followed to determine the facility's compliance with F725, using the PBJ Staffing Data Report as a starting point.

The PBJ Staffing Data Report identifies if the facility:

1. *Reported no RN hours (F727);*
2. *Failed to have Licensed Nursing Coverage 24-hours/day (F725);*
3. *Reported excessively low weekend staffing (F725);*
4. *Has a one-star Staffing Rating (F725); and*
5. *Failed to submit PBJ data for the quarter (F851).*

The staffing domain of the Five Star Quality Rating system is based on six specific measurements that are derived from the PBJ data submitted by the facility. (Five Star Quality Rating System User's Guide).

Furthermore, the PBJ Staffing Data Report identifies specific infraction dates for when a facility reported they had no RN hours and failed to have a licensed nurse on duty for 24-hours in a day.

1. *Review the PBJ Staffing Data Report during offsite prep for every recertification survey or as applicable for abbreviated surveys.*

a. *For every recertification survey, the Team Coordinator (TC) must document in the Long-Term Care Survey Process (LTCSP) software application offsite preparation screen, any discrepancies identified in the PBJ Staffing Data Report to inform all team members of staffing concerns prior to the team entering the facility.*
   ***Note: CMS expects every team member to be aware of the offsite preparation information prior to entering the facility**.*

2. *Identify if the facility is triggered for reporting **NO licensed nursing** coverage 24-hours/day**.** If this metric is triggered on the PBJ Staffing Data Report:*

   a. *During the entrance conference, the TC must inform the facility of these infraction dates and that a citation at F725 will be issued unless evidence is provided that shows the facility had licensed nursing coverage 24-hours/day on those infraction dates. Acceptable evidence is timecards, timesheets, or payroll information that clearly shows licensed nurse coverage on the dates in question. A schedule of who was supposed to work is **NOT** acceptable.*

   b. *If the facility does not provide acceptable evidence, a citation at **F725** must be cited at a **minimum of scope and severity of "F".** The scope and severity may be increased based on further investigation throughout the survey. If the facility does provide the evidence that there was 24-hour licensed nursing coverage, surveyors must continue to conduct investigations as described below to assess compliance with the requirements for facilities to have sufficient nurse staffing.*

***Note:** If the facility failed to have licensed nursing coverage 24-hours/day, (e.g., four or more days as indicated by the PBJ Staffing Data Report or for even just one day as indicated through general investigations), **F725 must be cited**.*

If the surveyor is aware of the absence of licensed nurse (LN) coverage on one or more days use the following questions to provide insight into severity that may have already been identified, such as incidents that caused harm or placed residents in immediate jeopardy (IJ) for serious harm when a licensed nurse was not available.

Director of Nursing or Administrator

- *How often are there days with no LN onsite available to provide care for residents?*
- *What types of services or care are not provided when there is no LN staff in a 24-hour period?*

Front line staff (e.g., nurse aides, LPN/LVN, RN)

- *Are you aware when there isn't a LN available to provide services to the residents?*

- *Are you aware of any residents who needed LN services (i.e., medications or treatments) and did not receive it due to no available licensed nurse? If so, please explain.*

- *Who do you notify in the event of an emergency when there is no licensed nurse available?*

    - *If the staff member is not aware of who to notify, ask if they've ever experienced this situation and what actions did they take? Was any resident harmed?*

    - *If the staff member is aware of who to notify, what direction were they given? Was any resident harmed?*

If the facility did not trigger for any of the 3-staffing metrics on the PBJ Staffing Data Report pertaining to F725, (Failed to have Licensed Nurse Coverage 24-hours/day, Reported Excessively Low Weekend Staffing, or Has a One-star Rating Ratio) then the surveyor must ask generalized questions about the facility's ability to provide sufficient staffing. Refer to those probes provided in the LTCSP software application.

After the Initial Pool and finalized sample of the recertification survey, and as needed during abbreviated surveys, surveyors should follow the interview and observation probes included on the ***Sufficient and Competent Nurse Staffing Critical Element Pathway*** *while finalizing investigations related to QoL and QoC as well as sufficient staffing, some of which are listed below.*

Staff Interviews for triggered PBJ Staffing Data Report areas

If the facility triggered for ***One Star Staffing Rating,*** *surveyors must interview at least two additional front-line staff (e.g., housekeeping, dietary, and/or maintenance) with focused questions such as:*

- *Have you noticed the facility not having enough staff, especially during the last six months?*

- *Have you observed the facility not having enough staff to meet residents' needs, such as residents waiting a long time for someone to help them? How often does this happen?*

- *Do you ever smell bad odors when you are walking through the facility, for example, when a resident did not receive toileting or incontinence assistance in a timely manner?*

- *Do you ever hear residents or their friends and family complain about not enough staff to provide the care needed?*

*If the facility triggered for **Excessively Low Weekend Staffing,** surveyors must interview at least two additional front-line staff (housekeeping, dietary, and/or maintenance) with focused questions such as:*

- *Are there ever times when there are not enough staff to take care of the residents on the weekends? For example, are any residents calling for assistance for extended periods of time? If so, can you describe what happened to any residents affected?*
    - *If there have not been enough staff during those times, do you know who you can alert to ensure that the residents needs are met?*
    - *If you have ever notified that person, what was their response?*
- *Have weekend activities ever been canceled due to lack of staffing to get residents up and dressed to attend (e.g., church services or day trips)?*
- *Are beds left unmade and rooms messy on the weekend?*

Additionally, if the facility triggered for Excessively Low Weekend Staffing, then review the Facility Assessment to evaluate if the facility assessed resident needs and acuity to determine the number of qualified staff needed to meet each resident's needs (see §483.71).

Interview questions for use whether or not the facility triggered any of the PBJ areas

Facility Residents and/or Resident Representatives

- *Has the facility informed you that care could not be provided because there wasn't a LN available?*

Nursing Staff

During interactions with staff, ask if they feel they have enough staff to meet resident needs and the training/skills needed to provide the care required. If no, additionally interview staff using the probes below to further evaluate staff sufficiency.

- *Do you have enough time to complete your required assignments each day? If not, why, and what assignments are you not able to complete? Who do you report this to?*
- *Are you able to participate in care planning, attend team meetings and trainings, take meal breaks and provide the care residents need?*

- *How often are you asked to stay late, come in early, or work overtime? Tip: this assists in determining the frequency of open shifts, which provides insight into the extent of any staffing issues in the facility.*

- *Are you aware of who is the designated charge nurse on each shift?*

Dietary/Kitchen/Dining Staff

Interview staff if concerns related to resident food, weight loss, or nutrition are identified and are potentially related to nurse staffing.

- *Do you hear residents complain about their food getting cold while they wait to be assisted by nursing staff?*

- *Do you see food trays come back untouched that might indicate insufficient nursing staff?*

- *Are you aware of any residents that might be absent because nursing staff was not available to assist them to the dining room?*

Observations

Upon entrance to the facility, during the initial pool of the recertification survey, per the LTCSP, and throughout various times of day, surveyors should immediately and independently tour the facility and document any of the following:

- *Are there offensive odors? If so, what is the source?*

- *Do residents receive timely assistance with care needs, such as toileting and eating?*

- *Are residents still in bed and not dressed mid-morning or remain unkempt or unclean for extended periods of time?*

- *Are residents' care activities consistent with the time of day/night and their individual personal preferences, rather than at a time that is convenient for staff (e.g., bathing residents during normal hours of sleep)?*

- *Do staff rush when providing resident care (e.g., neglecting to explain what they are doing when assisting residents)?*

- *Are call devices and alarms responded to timely? If concerns about staff responsiveness exist, monitor when the resident's call device is activated and record the response time of the staff.*

- *Are residents yelling out, crying, sitting around the nurse's station or in hallways without staff intervention, or wandering unsupervised and at risk?*

- *Are residents showing signs of sedation making it easier (i.e., convenient) for staff to care for or monitor residents, indicating the potential use of unnecessary psychotropic medications/chemical restraints?*

- *Are devices or practices in use that restrict freedom of movement (e.g., position change alarms or reclining chairs) making it easier for staff to care for or monitor residents, indicating the potential use of physical restraints?*

- *Are there delays in residents receiving their medications timely?*

- *When observing care or services provided by nursing staff, do they demonstrate competency according to professional standards?*

During the resident council interview surveyors must ask residents if they receive the help and care they need without waiting a long time. If concerns are identified, the surveyor is directed to the ***Sufficient and Competent Nurse Staffing Critical Element Pathway*** *where they would follow pertinent probes to verify any non-compliance with sufficient staffing in the facility.*

As surveyors are finalizing investigations into the facility's ability to provide sufficient staffing to meet the resident's needs for quality of life and quality of care, interview the DON and Administrator to identify the facility's process used to ensure resident needs are met during difficult staffing occurrences.

Negative findings would be an indicator of noncompliance. CMS expects the survey team to discuss any negative findings regarding sufficient staffing as a team during team meetings. For example, the LTCSP Procedure Guide requires the survey team to discuss potential staffing concerns at the end of the first day and at least the end of each subsequent day the team is onsite for the recertification survey.

POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION

- *F741, for any staff caring for residents with dementia or a history of trauma and/or post-traumatic stress disorder;*

- *F801, for Food and Nutrition staff;*

- *F826, for Specialized rehabilitative services;*

- *F839, for Administration for any other staff not referenced above; and*

- *F838, for Facility Assessment.*

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 basic needs and individual needs as required by the resident's diagnoses, medical condition, or plan of care; **or**

- Ensure licensed nurse coverage 24 hours a day, except when waived; *this must be done by utilizing the PBJ Staffing Data Report. If the facility triggers on the report under the category of "No Licensed Staff," a citation at F725 should be issued at a minimum severity and scope of "F;"* **or**

- Ensure a licensed nurse is designated to serve as a charge nurse on each tour of duty, except when waived.

DEFICIENCY CATEGORIZATION

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 *one* week 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 created the likelihood for serious injury, harm, impairment or death for the resident.
- A resident complained of chest pain and shortness of breath after eating their evening meal. The nursing assistant stated they would inform the licensed nurse. The nursing assistant was informed there would be no licensed nurse available onsite. At 10:00 p.m. the resident was found unresponsive with minimal respirations. Because there was no licensed nurse on duty at that time, the nursing assistant called 911 and the resident was sent to the emergency room.

- *The PBJ Staffing Data Report reviewed during offsite preparation for the recertification survey indicated the facility had 4 days in the previous quarter when there were no licensed nurses in the facility for all 24-hours of each day. The facility failed to provide evidence that there were licensed nurses in the facility on all of these days. The facility had many residents in each unit in the facility with complex medical needs such as tracheostomies, feeding tubes, pressure ulcers requiring multiple treatments daily, and residents who were identified as high-risk for falls. After a thorough investigation, the team determined the absence of a licensed nurse in the facility created the likelihood of serious injury, harm, impairment or death for many residents throughout the facility (widespread) therefore, the scope and severity was determined to be at "L".*

Examples of Level 3, actual harm that is not immediate jeopardy include, 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 for additional direction.
- A resident was admitted to the facility with a recently repaired hip fracture and required assistance with ambulation. The resident used the calling device to request assistance to the bathroom. *No* help arrived *before* the resident attempted to ambulate with a walker to the bathroom without assistance. The resident subsequently fell and was found by nursing assistants. The resident was assisted back to bed by the nursing assistants and complained of pain in the area of the recently repaired hip fracture. The licensed nurse on duty was unable to assess the resident for any injuries or provide medication for pain. During interview, the licensed nurse stated she was occupied with urgent needs from other residents. The next morning the resident complained of increased pain in the area of the repaired hip fracture. After assessment by the day shift licensed nurse, the resident was sent to the hospital. The resident was admitted *with a fracture to the same hip* and required surgery to repair the re-fractured hip.
- *The PBJ Staffing Data Report reviewed during offsite preparation for the survey showed there were no licensed nurses in the facility for a total of seven days that quarter. This was verified with the facility during the survey. The survey software displayed there was one off-site selected resident with the MDS indicators of major infection of pneumonia and one re-hospitalization. The resident was part of*

the survey sample, and the surveyor's investigation confirmed that leading up to the re-hospitalization, the resident was to have received an intravenous antibiotic once a day for three days for a respiratory infection. Interviews and record review confirmed the resident missed the third dose because the Certified Medication Aide could not administer it within their scope of practice. A licensed nurse was not present that day and the medicine was omitted. Although that day was not one of the PBJ-Staffing Data Report specific infraction dates, it was determined by record review that the facility failed to have Licensed Nursing Coverage 24-hours/day on that day as well.

The PBJ Staffing Data Report supported citation of a facility under tag F725 at a widespread scope of non-compliance with no actual harm, but that has a potential for more than minimal harm, that is not immediate jeopardy. However, the onsite survey found a resident had experienced harm due to a significant medication error and subsequent hospitalization for the treatment of pneumonia due to the facility failing to have Licensed Nursing Coverage 24-hours/day. Due to these survey findings regarding harm to one resident and the PBJ Staffing Data Report demonstrating widespread noncompliance, the facility was cited at the severity level of actual harm that is not immediate jeopardy for failure to have Licensed Nursing Coverage 24-hours/day.

Examples of Level 2, no actual harm, with potential for more than minimal harm, that is not immediate jeopardy include, 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 resulted in the resident occasionally missing occupational therapy. There has been no recent documented 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. Review of staffing data submitted via the PBJ system revealed the facility had a one-star staffing quality rating. Follow up interviews with the staffing coordinator revealed that only one CNA was available to provide showers, and therefore residents' preferences for timing of showering could not be met caus*ing* anxiety. Refer to the Psychosocial Outcome Guide for additional direction.
- *The PBJ Staffing Data Report revealed a facility did not have 24-hours of licensed nurses for at least four days, as submitted by the facility to the PBJ system. The facility failed to provide evidence, such as through timecards or payroll information, showing that licensed nurses were onsite during all the dates listed on the report. The survey did not find evidence of harm or immediate jeopardy to residents. Therefore, the facility is cited*

at a scope and severity of "F," due to the potential for causing more than minimal harm for any resident in the facility.

Severity Level 1: ***no actual harm with potential for minimal harm***

- The failure of the facility to provide sufficient staffing including licensed nurses creates a risk that is more than minimal harm. Therefore, Severity Level 1 does not apply for this regulatory requirement.

F726

(Rev. 229; Issued: 04-25-25; Effective: 04-25-25; Implementation: 04-28-25)

§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 §483.71.

§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.

§483.35(*d*) 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

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

"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

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(e), 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.

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, §483.71, 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 (§483.71), 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

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 §483.71. 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

If there are concerns with staff skills and competencies it may be necessary to review the facility's assessment as required at F838, §483.71 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.

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.

F727

(Rev. 229; Issued: 04-25-25; Effective: 04-25-25; Implementation: 04-28-25)

Social Security Act §1919 [42 U.S.C. 1396r]

§1919(b)(4)(C) Required nursing care; facility waivers.—

§1919(b)(4)(C)(i) General requirements.—With respect to nursing facility services provided on or after October 1, 1990, a nursing facility—

> *(II) except as provided in clause (ii),* **must use the services of a registered professional nurse for at least 8 consecutive hours a day, 7 days a week.**

Social Security Act §1819 [42 U.S.C. 1395i–3]

§1819(b)(4)(C) REQUIRED NURSING CARE.—

§1819(b)(4)(C)(i) IN GENERAL.—Except as provided in clause (ii), a skilled nursing facility … **must use the services of a registered professional nurse at least 8 consecutive hours a day, 7 days a week.**

§483.35(*c*)(*3*) Except when waived under paragraph (*f*) or (*g*) of this section, the facility must designate a registered nurse to serve as the director of nursing on a full time basis.

§483.35(*c*)(*4*) 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

"Full-time" is defined as working 40 or more hours a week.

"Charge Nurse" is a licensed nurse with specific responsibilities designated by the facility that may include staff supervision, emergency coordinator, physician liaison, as well as direct resident care.

"Scope of Practice" *describes the services that a qualified health professional is deemed competent to perform and permitted to undertake in keeping with the terms of their professional license.*[1]

GUIDANCE

Nurse staffing in nursing homes has a substantial impact on the quality of care and outcomes that residents experience. A registered nurse (RN) is typically responsible for overseeing the care provided to nursing home residents by other staff such as Licensed Practical Nurses (LPN) or Certified Nurse Aides (CNA). The RN is generally responsible for more advanced care activities such as resident assessments, *developing and evaluating plans of care,* consulting with physicians, and administering intravenous fluids or medications.

Facilities are responsible for ensuring they have an RN providing services at least 8 consecutive hours a day, 7 days a week. However, per Facility Assessment requirements at F838, §483.71, facilities are expected to identify when they may require the services of an RN for more than 8 hours a day based on the acuity level of the resident population. *For example, the facility may serve a population of residents that require more frequent assessment, as well as care plan development and evaluation of interventions that may not be delegated to the LPN or other healthcare professional.* If it is determined the services of an RN are required for more than 8 hours a day, refer to the guidance at F725 related to sufficient nurse staffing for further investigation.

Facilities may choose to have differing tours of duty (e.g., 8 hour- or 12-hour shifts) for their licensed nursing staff. Regardless of the approach, the facility is responsible for ensuring the 8 hours worked by the RN are consecutive within each 24-hour period. *The requirement for 8 consecutive hours of RN services can be met by any RN or multiples of RNs. The hours worked by the DON would be considered applicable towards the requirement.*

The facility must designate a registered nurse (RN) to serve as the DON on a full-time basis. *Additionally, the* facility may permit the DON to serve as a charge nurse only when the facility has an average daily occupancy of 60 or fewer residents.

INVESTIGATIVE PROCEDURES

Use the Sufficient and Competent Nurse Staffing Critical Element Pathway, along with the above interpretive guidance, and procedures below, when determining if the facility meets the requirements for, or investigating concerns related to Nursing Services.

During the entrance conference of a survey, the team will request confirmation of a full-time DON. If at any time during the survey, the team identifies concerns with the availability of a full-time DON, further investigation would be warranted (utilize the probes noted below).

Probes related to the full-time DON requirements:

- *Who does the facility designate as an RN to serve as the DON on a full-time basis?*
    - *If the facility does not provide the name of the person who serves as the DON on a full-time basis,* ***F727*** *must be cited at a* ***minimum of scope and of "F."***
- *If the facility's average daily census is greater than 60 residents, does the DON serve as the charge nurse?*
    - *If the facility's average daily census is greater than 60 residents, and the facility indicates that the DON does serve as the charge nurse,* ***F727*** *must be cited at a* ***minimum of scope and severity of "F."***

Use of the Payroll Based Journal (PBJ) Staffing Data Report in determining non-compliance:

The facility is responsible for submitting staffing data through the PBJ (Refer to F851, §483.70(p)). *When completing the offsite preparation for a recertification survey, the team coordinator must obtain the PBJ Staffing Data Report and evaluate PBJ data submitted by the facility.* This data is available through facility*'s* PBJ *Staffing Data Report* that can be obtained through *CMS' survey system. This* reports *must* be utilized by surveyors *on at least every recertification survey. The report* contains information about overall direct care staffing levels as well as if an RN was onsite for 8 hours a day. *If concerns were identified on this report, as well as from other sources, refer to the Sufficient and Competent Nurse Staffing Critical Element Pathway and the probes noted below.*

The PBJ Staffing Data Report identifies if the facility:

1. *Reported no RN hours (F727);*
2. *Reported not having Licensed Nursing Coverage 24 hours/day (F725);*
3. *Reported excessively low weekend staffing (F725);*
4. *Has a one-star Staffing Rating (F725); and*
5. *Failed to submit PBJ data for the quarter (F851).*

Furthermore, the PBJ Staffing Data Report provides specific infraction dates for when the facility reported they had no RN hours and failed to have a licensed nurse on duty for 24 hours in a day.

The surveyor must follow the steps below:

1. *Review the PBJ Staffing Data Report during offsite prep for every standard survey or as applicable for abbreviated surveys.*
2. *If the facility did NOT trigger for lack of RN Hours, surveyors are expected to investigate concerns with compliance that might arise as part of investigations into other, more specific Quality of Life/Quality of Care concerns.*
3. *If the facility triggered for reporting **No RN Hours**:*
    a. *During the entrance conference, the Team Coordinator (TC) must inform the facility of the infraction dates from the PBJ Staffing Data Report and that a citation at F727 will be issued unless evidence is provided that shows the facility had an RN onsite for 8 consecutive hours a day on those infraction dates. Acceptable evidence is timecards, timesheets, or payroll information that clearly shows RN coverage on the dates in question. A schedule of who was supposed to work is **NOT** acceptable.*
    b. *If the facility does not provide the acceptable evidence that an RN was onsite for at least 8 consecutive hours for the dates indicated on the PBJ Staffing Data Report, **F727** must be cited at a **minimum of severity and scope of "F,"** unless the facility has a waiver of the RN requirement per §483.35(f) or (g). For information on this waiver, see Chapter 7 of the State Operations Manual (SOM).*

If the surveyor identifies non-compliance, a level of severity must then be determined. Once the surveyor identifies noncompliance based on the data from the PBJ Staffing Data Report, or the probes for the DON

requirements as described above, the surveyor needs to determine if the scope and severity of the noncompliance must be raised above an "F" level citation for F727. The surveyor should utilize the Sufficient and Competent Staffing CE Pathway, and the probes below to identify higher levels of severity at F727. If a higher level of severity is identified, the surveyor may need to reduce the scope of the non-compliance.

For example, if the facility failed to provide the services of an RN for at least 8 consecutive hours a day, a citation of F727 at a severity and scope of F (potential for more than minimal harm that is widespread) would be issued. However, if it is discovered a resident was harmed due to the facility's failure to provide the services of an RN, the citation of F727 would be cited at a severity and scope of G (harm that is isolated).

Note: *This could assist identifying incidents that occurred directly related to non-compliance with RN staffing requirements, which would warrant an increase in the level of severity of the citation.*

If concerns were identified on this report, as well as from other sources, refer to the Sufficient and Competent Nurse Staffing Critical Element Pathway, and the probes noted below.

Interviews

If there is no RN coverage for at least 8 consecutive hours each day, (e.g., four or more days with no RN hours as indicated by the PBJ Staffing Data Report), or for even just one day if identified through other investigations), conduct the following interviews:

Facility Residents and Resident Representatives

- *Has the facility informed you that care could not be provided because there wasn't an RN available (e.g., IV medication)?*

Front Line Staff *(i.e., nurse aides, LPNs/LVNs):*

Interviewing front line staff is a good way to determine how well facility administration and supervisors communicate staffing patterns or needs to other members of staff.

- *Are you aware if the RN is on duty for at least 8 consecutive hours a day?*
- *Are you aware of a resident who needed care or services that only an RN can provide (i.e., intravenous medications, assessment) and did not receive it? If so, please explain.*

Director of Nursing or Administrator

- *How often are there days with no RN available to provide care for residents*?
- *What types of services or care are not provided when there is not an RN onsite for 8 hours a day?*

DEFICIENCY CATEGORIZATION

An example of Level 4, immediate jeopardy to resident health and safety includes, but is no limited to:

- The annual recertification survey of a facility indicates that it provides care for residents with high acuity needs including residents that receive medications and fluids via central intravenous lines (IV) and ventilator dependent residents. The *PBJ Staffing Data Report triggered an* investigation *that* revealed an RN was not onsite for at least 8 consecutive hours during the day. During the period when there was no RN, the LPN had to perform assessments and maintain central line (IV) infusions, which is out of the scope of practice for an LPN in the absence of supervision of the RN. The facility's failure to have an RN on duty for at least 8 consecutive hours a day as required by the regulation, created the likelihood for serious injury, harm, impairment or death. Specifically, the RN was not present to meet the critical needs of these high acuity residents.

Examples of Level 3, actual harm that is not immediate jeopardy include, but is not limited to:

- Investigation of falls occurring in the facility with a census greater than 60 residents revealed the monthly fall evaluation for one resident was not completed with the interdisciplinary team after the resident experienced 2 falls. Interview with the Director of Nursing (DON) revealed this was the DON's responsibility; however, because she had been serving as the charge nurse, there was no time to complete the evaluation for this resident who experienced another fall resulting in a sprained wrist. Record review revealed that the resident experienced a fall after the DON failed to complete the fall evaluation in response to the two initial falls. Staff ultimately determined the resident was falling due to a change in the resident's condition (deteriorating eyesight) that was not timely identified because of the DON's failure to complete a monthly fall evaluation.
- *During the offsite preparation of a recertification survey, the team coordinator identified the facility triggered for "No RN" when reviewing the PBJ Staffing Data Report. Further review of the report revealed a listing of 6 dates throughout the last quarter the facility did not report an RN on duty. During investigations the team identified that the lack of an available RN to perform assessments and develop or revise interventions to prevent falls, contributed to resident falls. Two of those falls resulted in injury, one with a hematoma to the wrist and one with a sprained finger.*

Examples of Level 2, no actual harm, with potential for more than minimal harm, that is not immediate jeopardy include, but are not limited to:

- Review of the PBJ Staffing Data Report revealed concerns related to the facility's requirement to have a Registered Nurse on duty for at least 8 consecutive hours a day. The *facility failed to provide evidence through timecards or payroll information that an RN was onsite for 8* consecutive hours *on the dates noted on the PBJ Staffing Data Report.* No actual harm *or immediate jeopardy for serious harm* to residents was identified. *The scope of the deficiency is considered widespread ("F") as all residents in the facility were at risk for more than minimal harm.*
- Review of the PBJ Staffing Data Report, other staffing documentation, and staff interviews revealed that the Director of Nursing routinely served as a charge nurse when the facility had an average daily occupancy of between 65-70 residents. No actual harm to residents was identified. However, there was a potential for more than minimal harm resulting from the Registered Nurse's dual role in simultaneously serving as both the Director of Nursing and the Charge Nurse for greater than 60 residents.

Severity Level 1: ***no actual harm with potential for minimal harm***

- The failure of the facility to provide an RN creates a risk that is more than minimal harm. Therefore, Severity Level 1 does not apply for this regulatory requirement.

F728

(Rev. 229; Issued: 04-25-25; Effective: 04-25-25; Implementation: 04-28-25)

§483.35(*e*) Requirement for facility hiring and use of nurse aides-

§483.35(*e*)(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(*e*)(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 (*e*)(1)(i) and (ii) of this section.

§483.35(*e*)(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

A "**permanent employee**" is defined as any employee the facility expects to continue working on an ongoing basis.

GUIDANCE

Any 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.

If 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

- 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

(Rev. 229; Issued: 04-25-25; Effective: 04-25-25; Implementation: 04-28-25)

§483.35(*e*)(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.

§483.35(*e*)(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.

§483.35(*e*)(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

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, for monetary compensation. 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.

PROCEDURE

If concerns are identified with Nurse Aide Services at F725 and F726, review a minimum of five nurse aide personnel files including any specific staff members with whom concerns were identified.

- Review the nurse aide personnel folder to determine if the facility received registry verification that the individual has met competency evaluation requirements before the employee's start date unless an exception applies as noted in §483.35(*e*)(4).

- Review the nurse aide personnel folder to determine if the facility verified information from every State registry that the facility believes will include information concerning that individual before the employee's start date.

- If records reveal a nurse aide has not provided nursing related services for monetary compensation over a 24-month period, did the individual complete a new training and competency evaluation program?

F730

(Rev. 229; Issued: 04-25-25; Effective: 04-25-25; Implementation: 04-28-25)

§483.35(*e*)(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

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

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 their 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

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 reviewing 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

(Rev. 229; Issued: 04-25-25; Effective: 04-25-25; Implementation: 04-28-25)

§483.35(*f*) Nursing facilities

Waiver of requirement to provide licensed nurses *and a registered nurse* on a 24-hour basis.

To the extent that a facility is unable to meet the requirements of paragraphs (a)(*1*) and (b)(1)*(i) and (c)(1)* of this section, a State may waive such requirements with respect to the facility if—

§483.35(*f*)(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;

§483.35(*f*)(2) The State determines that a waiver of the requirement will not endanger the health or safety of individuals staying in the facility;

§483.35(*f*)(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;

§483.35(*f*)(4) A waiver granted under the conditions listed in paragraph (e) of this section is subject to annual State review;

§483.35(*f*)(5) In granting or renewing a waiver, a facility may be required by the State to use other qualified, licensed personnel;

§483.35(*f*)(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

§483.35(*f*)(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(*g*) SNFs
Waiver of the requirement to provide services of a registered nurse for *at least 112* hours a week.

§483.35(*g*)(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 (*c*) 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.

§483.35(*g*)(2) A waiver of the registered nurse requirement under paragraph (*g*)(1) of this section is subject to annual renewal by the Secretary.

INTENT

To give the facility flexibility, in limited circumstances, when the facility cannot meet nurse staffing requirements.

GUIDANCE

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

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 *Location* with information needed to grant this continuation.

- Does the SNF meet all requirements necessary for continuation of the waiver?

PROCEDURES

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 F727;
    - For NFs that have a waiver of the 24-hour licensed nursing requirement, cite F725, 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 F731.

If the facility has an approved nurse staffing waiver, it is **not** considered a deficiency. The facility does not need to submit a Plan of Correction.

F732

(Rev. 229; Issued: 04-25-25; Effective: 04-25-25; Implementation: 04-28-25)

§483.35(*i*) Nurse Staffing Information.

§483.35(*i*)(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.

§483.35(*i*)(2) Posting requirements.

(i) The facility must post the nurse staffing data specified in paragraph (*i*)(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, *staff*, and visitors.

§483.35(*i*)(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(*i*)(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

To make nurse staffing information readily available in a readable format to residents and visitors at any given time.

GUIDANCE

The facility's staffing data "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 that is readily accessible to residents, *staff,* 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 is not required to include in the posting the data for staff who are 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.

PROCEDURES AND PROBES

Surveyors must determine through information obtained by observations and verified by record reviews the following:

- The facility posts the following information on a daily basis:

    1. Facility name

    2. The current date

    3. The total number and actual hours worked by the following categories of licensed and unlicensed nursing staff directly responsible for resident care per shift: registered nurses, licensed practical nurses or licensed vocational nurses, and certified nurse aides.

    4. Resident census

- The facility must post the nurse staffing data mentioned above on a daily basis at the beginning of each shift.

- The data must be posted in a clear and readable format and in a prominent place readily accessible to residents and visitors.

- 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.

- 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.

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, *staff,* 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**

- Make daily staffing available to the public for review upon request: **or**

Maintain the posted daily nurse staffing data for a minimum of 18 months, or as required by State law, whichever is greater.

F740

(Rev. 229; Issued: 04-25-25; Effective: 04-25-25; Implementation: 04-28-25)

§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.

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. Mental disorders are usually associated with significant distress or disability in social, occupational, or other important activities.

American Psychiatric Association. "Diagnostic and Statistical Manual of Mental Disorders - Fifth edition." 2013.

"Substance use disorder" ("SUD") is defined as recurrent use of alcohol and/or drugs that causes clinically and functionally significant impairment, such as health problems, disability, and failure to meet major responsibilities at work, school, or home.

Adapted from Substance Abuse and Mental Health Services Administration (SAMHSA). "Mental Health and Substance Use Disorders." Accessed March 2, 2021. https://www.samhsa.gov/find-help/disorders.

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 behavioral health care needs of those with a SUD or other serious mental disorder should be part of the facility assessment under §483.*71* (F838) and the facility should determine if they have the capacity, services, and staff skills to meet the requirements as discussed in F741.

Surveyors should be aware that all residents are screened for possible serious mental disorders or intellectual disabilities and related conditions prior to admission to determine if specialized services under Preadmission Screening and Resident Review (PASARR) requirements are necessary. If a resident qualifies for specialized Level II services under PASARR, please refer to §483.20(k) (F645), as well as §483.20(e) (F644). 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 type(s) of service(s) needed is clearly identified based on the individual assessment, care plan and strategies to arrange such services.

Behavioral health care and services could 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. Residents living with mental health and SUDs may require different activities than other nursing home residents. Facilities must ensure that activities are provided to meet the needs of their residents.

  NOTE: For concerns related to the facility's activity program, or activities which do not address the needs of the resident, refer to §483.24(c), F679, Activities Meet Interest /Needs of Each Resident.

- 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.

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.

For residents with an assessed history of a mental disorder or SUD, the care plan must address the individualized needs the resident may have related to the mental disorder or the SUD. Some facilities may use behavioral contracts as part of the individualized care plan to address behaviors which could endanger the resident, other residents and staff. Behavioral contracts may be a method for encouraging residents to follow their plan of care. However, in some circumstances, using them to impose a system of rewards and/or punishments could be construed as meeting the definition of abuse which includes the willful infliction of punishment and/or the deprivation of goods and services. Please refer to §483.5 for the definition of abuse and §483.12 for requirements pertaining to abuse, neglect, and exploitation.

Additionally, behavioral contracts are only intended to be used for residents who have the capacity to understand them. The contract cannot conflict with resident rights or other requirements of participation (i.e., requirements at §483.15 related to admission, transfer, and discharge), but may address issues such as:

- Residents with mental disorder and/or SUD may be at increased risk for leaving the facility without facility knowledge (which could be considered an elopement) at various times throughout their treatment, or if going through active withdrawal. The facility should explain the resident's right to have a leave of absence and also explain the health and safety risks of

leaving without facility knowledge or leaving against medical advice (AMA). The facility cannot restrict a resident's right to leave the facility, but a contract can distinguish between a leave of absence, elopement, and leaving AMA. (For concerns related to inadequate supervision resulting in elopement, see F689 - Free of Accidents Hazards/Supervision/Devices);

- Facility efforts to help residents with mental disorder and/or SUD, such as individual counseling services, access to group counseling, or access to a Medication Assisted Treatment program, if applicable;

- Steps the facility may take if substance use is suspected, which may include:

    - Increased monitoring and supervision in the facility to maintain the health and safety of the resident suspected of substance use, as well as all residents;
    - Restricted or supervised visitation, if the resident's visitor(s) are deemed to be a danger to the resident, other residents, and/or staff (See F563 - Right to receive/deny visitors);

    - Voluntary drug testing if there are concerns that suspected drug use could adversely affect the resident's condition;

    - Voluntary inspections, if there is reasonable suspicion of possession of illegal drugs, weapons or other unauthorized items which could endanger the resident or others (See F557- Respect, Dignity/Right to have Personal Property); and

- Referral to local law enforcement for suspicion of a crime in accordance with state laws, such as possession of illegal substances, paraphernalia or weapons (See F557- Respect, Dignity/Right to have Personal Property).

Refusal to accept or non-adherence to the terms of a behavioral contract cannot be the sole basis for a denial of admission, a transfer or discharge. A facility may only transfer or discharge a resident for one of the reasons listed in F627, §483.15(c)(1)(i)(A)-(F). Rather, non-adherence to the contract should be treated like any care plan intervention that needs attention or needs to be altered to meet the needs of the resident. The IDT should work with the resident and resident representative to revise the care plan and contract.

The following section discusses general information pertaining to 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 (major depressive disorder or clinical depression) is a common and serious mood disorder. Symptoms may include fatigue, sleep and appetite disturbances, agitation, and expressions of guilt, difficulty concentrating, apathy, withdrawal, and suicidal ideation. Depression is not a natural part of aging, however, older adults in the nursing home setting are more at risk than older adults in the community. 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.

Adapted from the American Psychiatric Association. "Diagnostic and Statistical Manual of Mental Disorders - Fifth edition." 2013.

Anxiety and Anxiety Disorders

Anxiety is a common reaction to stress that involves occasional worry about circumstantial events. Anxiety disorders, however, could include symptoms such as excessive fear, intense anxiety, significant distress, 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 depression and dementia in older adults, and care must be taken to ensure that other disorders are not inadvertently misdiagnosed as an anxiety disorder (or vice versa). There are many types of anxiety disorders, each with different symptoms. The most common types of anxiety disorders include Generalized Anxiety Disorder, Social Anxiety Disorder, Panic Disorder, Phobias and Post-traumatic Stress Disorder.

Adapted from the American Psychiatric Association. "Diagnostic and Statistical Manual of Mental Disorders - Fifth edition." 2013.

Schizophrenia

Schizophrenia is a serious mental disorder that may interfere with a person's

ability to think clearly, manage emotions, make decisions and relate to others. It is uncommon for schizophrenia to be diagnosed in a person younger than 12 or older than 40. Schizophrenia must be diagnosed by a qualified practitioner, using evidence-based criteria and professional standards, such as the Diagnostic and Statistical Manual of Mental Disorders - Fifth edition (DSM-5), and documented in the resident's medical record. Symptoms of Schizophrenia include delusions, hallucinations, disorganized speech (e.g., frequent derailment or incoherence), grossly disorganized or catatonic behavior, and diminished expression or initiative. Delusions refer to false beliefs that don't change even when the person who holds them is presented with new ideas or facts. Hallucinations include a person hearing voices, seeing things, or smelling things others can't perceive.

Adapted from the:

- National Alliance on Mental Illness (NAMI). "Schizophrenia." Accessed March 2, 2021. https://www.nami.org/Learn-More/Mental-Health-Conditions/Schizophrenia.

- American Psychiatric Association. "Diagnostic and Statistical Manual of Mental Disorders - Fifth edition." 2013.

Bipolar Disorder

Bipolar disorder is a mental disorder that causes dramatic shifts in a person's mood or energy, and may affect the ability to think clearly. People with bipolar experience high and low moods—known as mania and depression—which differ from the typical ups-and-downs most people experience. Symptoms and their severity can vary. A person with bipolar disorder may have distinct manic or depressed states but may also have extended periods—sometimes years—without symptoms. A person can also experience both extremes simultaneously or in rapid sequence.

Adapted from NAMI. "Bipolar Disorder." Accessed March 2, 2021. https://www.nami.org/Learn-More/Mental-Health-Conditions/Bipolar-Disorder.

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, meets each resident's needs, and includes 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. For additional guidance, see also the Psychosocial Severity Outcome Guide at the CMS Nursing Homes Survey Resources website that can be accessed by visiting https://www.cms.gov/files/zip/survey-resources-10262022.zip.

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:

- A resident was admitted to the facility one month ago with diagnoses of major depression, SUD, and a history of a suicide attempt. After admission, the resident continuously expressed wanting to die and often yelled and cursed at staff members. The attending physician ordered a psychological evaluation, an antidepressant, and 30 minute checks which were implemented by the facility. Record review showed that the psychological evaluation recommended the use of several non-pharmacological behavioral health interventions, which were not implemented. During additional record review and an interview with the nurse it was revealed that the resident was found hanging from his closet bar with a sheet tied around his neck, and no pulse. CPR was started and the resident was resuscitated.

The facility failed to adequately meet a resident's mental health needs when it did not address non-pharmacological approaches to care.

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.

Examples of Severity Level 2: No Actual Harm with Likelihood for More Than Minimal Harm that is Not Immediate Jeopardy, include:

- 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 at the CMS Nursing Homes Survey Resources website that can be accessed by visiting https://www.cms.gov/files/zip/survey-resources-10262022.zip.

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.

Some resources pertaining to behavioral health care and services can be found by visiting:

- SAMHSA. Accessed March 2, 2021. http://www.samhsa.gov/.
  This website provides numerous resources with the mission to reduce the impact of substance abuse and mental illness on America's communities.

- NAMI. Accessed March 2, 2021. https://www.nami.org/.
  This website provides resources dedicated to building better lives for the millions of Americans affected by mental illness.

- National Institute of Mental Health (NIMH). Accessed November 9, 2022.https://www.nimh.nih.gov/.
  This website provides resources for the understanding and treatment of mental illnesses.

- National Long-term Care Ombudsman Resource Center. Accessed March 2, 2021. https://ltcombudsman.org/.
  This website is filled with information, resources, and news from Ombudsman programs to support and inform programs across the country.

- MentalHealth.gov. Accessed March 2, 2021.
  https://www.mentalhealth.gov/.
  This website provides one-stop access to U.S. government mental health and mental health problems information.

- SAMSHA. "Anger Management for Substance Use Disorder and Mental Health Clients: Participant Workbook." Accessed March 2, 2021.
  https://store.samhsa.gov/sites/default/files/d7/priv/anger_management_workbook_508_compliant.pdf.

  This workbook is designed for people living with a mental illness and/or substance use disorder who participate in group cognitive behavioral therapy sessions pertaining to anger management. It summarizes core concepts for each session, and includes worksheets and homework assignments.

- NIMH. "Schizophrenia." Accessed November 9, 2022.
  https://www.nimh.nih.gov/health/topics/schizophrenia.

This brochure describes symptoms, causes, and treatments for schizophrenia with information on ways to get help and cope effectively.

- NIMH. "Bipolar Disorder." Accessed November 9, 2022. https://www.nimh.nih.gov/health/topics/bipolar-disorder.
  This brochure describes symptoms, causes, and treatments for bipolar disorder with information on ways to get help and cope effectively.

- NIMH. "Post-Traumatic Stress Disorder." Accessed November 9, 2022. https://www.nimh.nih.gov/health/topics/post-traumatic-stress-disorder-ptsd.
  This brochure describes symptoms, causes, and treatments for post-traumatic stress disorder with information on ways to get help and cope effectively.

- NIMH. "Anxiety Disorders." Accessed November 9, 2022.
  - https://www.nimh.nih.gov/health/topics/anxiety-disorders.
  This brochure describes symptoms, causes, and treatments for anxiety disorders with information on ways to get help and cope effectively.

- NIMH. "Depression." Accessed November 9, 2022. https://www.nimh.nih.gov/health/topics/depression.
  This brochure describes symptoms, causes, and treatments for depression with information on ways to get help and cope effectively.

- NIMH."Generalized Anxiety Disorder (GAD): When Worry Gets Out of Control." Accessed November 9, 2022. https://www.nimh.nih.gov/health/publications/generalized-anxiety-disorder-gad.

  This brochure discusses signs and symptoms, diagnosis, and treatment options for GAD

  References to non-CMS sources 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.

F741

(Rev. 229; Issued: 04-25-25; Effective: 04-25-25; Implementation: 04-28-25)

§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 §483.71. 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 §483.71, and

§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 §483.71. This includes residents with mental disorders, psychosocial disorders, or substance use disorders (SUDs), and those with a history of trauma and/or post-traumatic stress disorder (PTSD), as reflected in the facility assessment. Facility staff members must implement person-centered care approaches designed to meet the individual goals and 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 Nursing Staff and §483.35(a)(3) (F726), Competent Nursing 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. Mental disorders are usually associated with significant distress or disability in social, occupational, or other

important activities.
American Psychiatric Association. "Diagnostic and Statistical Manual of Mental Disorders - Fifth edition. 2013.

"Substance use disorder" ("SUD") is defined as recurrent use of alcohol and/or drugs that causes clinically and functionally significant impairment, such as health problems, disability, and failure to meet major responsibilities at work, school, or home. Adapted from Substance Abuse and Mental Health Services Administration (SAMHSA). "Mental Health and Substance Use Disorders." Accessed March 2, 2021. https://www.samhsa.gov/find-help/disorders.

"Trauma" results from an event, series of events, or set of circumstances that is experienced by an individual as physically or emotionally harmful or life threatening and that has lasting adverse effects on the individual's functioning and mental, physical, social, emotional, or spiritual well-being.

SAMHSA."SAMHSA's Concept of Trauma and Guidance for a Trauma-Informed Approach."July 2014. Accessed February 25, 2021. https://ncsacw.samhsa.gov/userfiles/files/SAMHSA_Trauma.pdf.

"Post-traumatic stress disorder" occurs in some individuals who have encountered a shocking, scary, or dangerous situation. Symptoms usually begin early, within three months of the traumatic incident, but sometimes they begin years afterward. Symptoms must last more than a month and be severe enough to interfere with relationships or work to be considered PTSD.

National Institute of Mental Health. "Post-Traumatic Stress Disorder." Accessed November 9, 2022, https://www.nimh.nih.gov/health/topics/post-traumatic-stress-disorder-ptsd. This brochure describes symptoms, causes, and treatments for post-traumatic stress disorder with information on ways to get help and cope effectively.

"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.*71* (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, SUDs, as well as residents with a history of trauma and/or PTSD.

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, psychosocial disorders, SUDs, a history of trauma, and/or PTSD). Staff need to be knowledgeable about implementing non-pharmacological interventions. The skills and competencies needed to care for residents should be identified through the facility assessment. The facility assessment must include an evaluation of the overall number of facility staff needed to ensure that a sufficient number of qualified staff are available to meet each resident's needs. Furthermore, the assessment should 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.

Once the necessary skills and competencies are identified, staff must be aware of those disease processes and disorders (e.g. SUDs) that are relevant to each

resident to enhance the resident's 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.

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, and should involve the interdisciplinary team (IDT), the resident, resident's family, and/or representative(s). The IDT should be aware of potential underlying causes and/or triggers that may lead to expressions or indications of distress and/or re-traumatization. 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 goals and 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 of all ages 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, goals, 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);

- Assisting the resident outdoors in the sunshine and fresh air (e.g. in a non-smoking area for a non-smoking resident);

- Providing access to pets or animals for the resident who enjoys pets (e.g. a cat for a resident who used to have a cat of their own);

- Assisting the resident to participate in activities that support their spiritual needs;

- Assisting with the opportunity for meditation and associated physical activity (e.g. chair yoga);

- Focusing the resident on activities that decrease stress and increase awareness of actual surroundings, such as familiar activities; offering verbal reassurance, especially in terms of keeping the resident safe; and acknowledging that the resident's experience is real to her/him;

- Utilizing techniques such as music, art, electronics/computer technology systems, massage, essential oils, reminiscing;

- Assisting residents with SUDs to access counseling (e.g., individual or group counseling services, 12-step programs, and support groups) to the fullest degree possible;

- Assisting residents with access to therapies, such as psychotherapy, behavior modification, cognitive behavioral therapy, and problem solving therapy; and

- Providing support with skills related to verbal de-escalation, coping skills, and stress management.

For additional guidance and examples of individualized non-pharmacological interventions, see §483.24(c) (F679), 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) (F*605*), *Chemical Restraints/Unnecessary* 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 SUDs, as well as residents with a history of trauma and/or PTSD who lack care plan interventions to address their individual goals, 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 §483.71 (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;

- Identify the signs and symptoms of substance use in a resident with SUD;

- Provide care, in accordance with the individualized care plan, that meets the needs of residents with mental disorders, substance use disorders, a history of past trauma, 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 plan of care, 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; or

- Attempt alternate approaches to care for the resident's assessed behavioral health needs, if necessary.

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:

- The facility failed to have sufficient numbers of staff who had the skills and competencies to monitor a resident with SUD and who had just returned from a leave of absence (LOA). The resident had a history of substance abuse when on LOA, and had care plan interventions indicating to monitor every 15 minutes for signs and symptoms of substance use, which included changes in behavior, slowed respirations and somnolence.

Upon interview of the nurse's aide assigned to monitor this resident, the aide did not know what somnolence was, and could not state what a normal respiratory rate was. The aide also stated that he or she had never been assigned to this resident before and was unaware of what the resident's baseline behaviors were. Therefore, the aide could not state if he or she had observed any changes in the resident's behaviors. This was the only aide working the unit when the resident returned from LOA.

- 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 the CMS Nursing Homes Survey Resources website that can be accessed by visiting https://www.cms.gov/files/zip/survey-resources-10262022.zip.

References to non-CMS sources 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.

F744

(Rev. 229; Issued: 04-25-25; Effective: 04-25-25; Implementation: 04-28-25)

§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 *Medications,* and §483.45(e) *and 483.12(a)(2) (F605)*, *Chemical Restraints/Unnecessary* Psychotropic *Medications*.

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 at the CMS Nursing Homes Survey Resources website that can be accessed by visiting https://www.cms.gov/files/zip/survey-resources-10262022.zip.

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 at the CMS Nursing Homes Survey Resources website that can be accessed by visiting https://www.cms.gov/files/zip/survey-resources-10262022.zip.

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.]

F756

(Rev. 229; Issued: 04-25-25; Effective: 04-25-25; Implementation: 04-28-25)

§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, 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.

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

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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, *Chemical Restraints/*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.

NOTE: In addition to actual or potential physical harm, always *observe for visual cues of psychosocial distress and* consider whether psychosocial harm has occurred when determining severity level (*See guidance on Severity and Scope Levels and* Psychosocial Outcome Severity Guide *located in the Survey Resources zip file located at https://www.cms.gov/medicare/provider-enrollment-and-certification/guidanceforlawsandregulations/nursing-homes*).

DEFICIENCY CATEGORIZATION

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

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), F*605*, 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(*g*), 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

(Rev. 229; Issued: 04-25-25; Effective: 04-25-25; Implementation: 04-28-25)

§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

§483.45(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.

INTENT

The intent of these requirements is to ensure 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.

NOTE:

- ***For concerns related to psychotropic medications only, including the unnecessary medication requirements, surveyors should assess compliance with §483.10(e), §483.12(a), and §§483.45(c) and (e), F605.***

- ***This guidance uses the terms "medications," and, "drugs," interchangeably.***

- ***For purposes of this guidance, references to "the pharmacist" mean the facility's licensed pharmacist, whether employed directly by the facility or under arrangement.***

The regulations and guidance are not intended to supplant the judgment of a practitioner in consultation with facility staff, the resident, and his/her representatives and in accordance with professional standards of practice. However, surveyors are expected to investigate the basis for decisions and interventions affecting residents. For example, a resident's medical record should contain documentation that demonstrates how the practitioner arrived at their decision(s) in accordance with the professional standards of practice.

DEFINITIONS

***"Adequate Indications for use"** refers to the identified, documented clinical rationale for administering a medication that is based upon an assessment of the resident's*

condition and therapeutic goals, and after any safer treatments have been deemed clinically contraindicated. Also, adequate indication for use means that the medication administered 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.

"Adverse consequence" *refers to unwanted, unintended, 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" *refers to* 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.

"Neuroleptic Malignant Syndrome (NMS)" *refers to* a syndrome related to the use of medications, 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.

"Serotonin Syndrome" *refers to* 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.

GUIDANCE

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.

Comprehensive Assessment

The indications for initiating, maintaining, or discontinuing medication(s) are determined by evaluating the resident's physical, behavioral, mental, and psychosocial signs and symptoms in order to identify and rule out any underlying medical conditions, including the assessment of relative benefits and risks, and the preferences and goals for treatment. The resident's medical record should include documentation of this evaluation and the rationale for chosen treatment options.

Additionally, the facility should ensure that the initiation or change in a medication is not:

- *Due to a medical condition or problem (e.g., pain, fluid or electrolyte imbalance, infection, obstipation, medication side effect or polypharmacy) that can be expected to improve or resolve as the underlying condition is treated or the offending medication(s) are discontinued;*

- *Due to environmental stressors alone, that can be addressed to improve the symptoms; and*

- *Due to psychological stressors alone, that can be expected to improve or resolve as the situation is addressed.*

Circumstances that warrant evaluation of a resident's underlying medical condition and medication(s) include:

- *Admission or re-admission: Some residents may be admitted to the facility on medications that were started in the hospital or the community without a clear documented indication for why the medication was begun or should be continued.*

The prescribing practitioner and the IDT should subsequently determine if continuing the medication is justified by conducting a comprehensive evaluation;

- *A new or worsening change in condition/status;*
- *An irregularity identified in the pharmacist's medication regimen review. See F756 for guidance related to the medication regimen review; and*
- *New medication order as an emergency measure – When a resident is experiencing an acute medical problem or emergency and the acute phase has stabilized, the staff and prescriber should consider whether medications are still relevant.*

Determining the Necessity for use of Medications

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 have serious side effects, such as changes in vital signs/lab values, confusion, immobility, falls, and hip fractures, which can be especially dangerous for elderly residents, in addition to an increased risk of death. American Geriatrics Society 2023 updated AGS Beers Criteria® for Potentially Inappropriate Medication Use in Older Adults provides information on safely prescribing medications for older adults,
https://agsjournals.onlinelibrary.wiley.com/doi/full/10.1111/jgs.18372.

NOTE: *Instances of prescribing antibiotics unnecessarily should be cited at §483.45(d), F757. The findings may support citing F881 as well, in which case the surveyor must also show that the facility is not implementing part or all of the Antibiotic Stewardship Program (e.g., antibiotic use protocols that utilize an infection assessment tool, monitoring of antibiotic use, or feedback and education to prescribing providers).*

Resident's Right to be Informed

In accordance with the requirements at §483.10(c), residents have the right to be informed of and participate in their treatment. Prior to initiating or increasing a medication, the resident, family, and/or resident representative must be informed of the benefits, risks, and alternatives for the medication, in advance of such initatiation or increase. The resident has the right to accept or decline the initiation or increase of a medication. To demonstrate compliance, the resident's medical record must include documentation that the resident or resident representative was informed in advance of the risks and benefits of the proposed care, the treatment alternatives or other options and

was able to choose the option he or she preferred. A written consent form may serve as evidence of a resident's consent to medication, but other types of documentation are also acceptable. If a medication has been initiated or increased, and there is not documentation demonstrating compliance with the resident's right to be informed and participate in their treatment, noncompliance with §483.10(c) exists and F552 must be cited.

Dose and Duration

The dose and duration of medications, in accordance with §483.45(d)(1) and (d)(2), are 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 Interdisciplinary Team (IDT) about the resident, including the resident's preferences and goals, the type of medication(s), and therapeutic goals being considered or used.

***Dose** refers to 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.*

***Polypharmacy** refers to the use of five or more medications for an individual which can increase the risk of adverse outcomes such as falls, frailty, disability, and mortality in older adults. Polypharmacy also increases the possibility of prescribing cascades when additional drugs are prescribed to treat the adverse effects of one of the current medications.*

***Duplicate therapy** refers to two or more medications of the same pharmacological class/category without a clear distinction of when one medication should be administered over another. 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 medication containing the same ingredient, use of more than one drugs within the same class, or medications from different therapeutic categories with similar effects or properties.*

The risk for polypharmacy and duplicate therapy 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 each medication and the approach to monitor the benefits and any adverse consequences.

***Excessive dose** refers to 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.

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..*

The clinical rationale for continued use of a medication(s) should be documented in the medical record. Examples of inappropriate duration that should be cited for non-compliance may include:

- *A medication was initiated because of a time-limited condition (for example, delirium, pain, infection, nausea and vomiting, cold and cough symptoms, or itching). However, failure to review whether the underlying cause has resolved led to excessive duration, because the medication was not discontinued when the condition resolved or there was no documentation indicating why continued use was still relevant.*

- *A medication was administered beyond the stop date established by the prescriber, without evidence of clinical indication for continued use of the medication.*

Monitoring and Adverse Consequences

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, in accordance with §483.45(d)(3) and (d)(5), as well as documenting medication management steps. Monitoring and accurate documentation of the resident's response to any treatment (such as, lab results, vital signs, progress notes, behavior flow sheets, medication administration records and the consultant pharmacist's drug regimen review) is essential to evaluate the ongoing effectiveness, benefits as well as risks of medications.

Note: *The facility's pharmacist is a valuable source of information about medications. The pharmacist and attending physician must adhere to the requirements for reporting and responding to identified irregularities (See F756 Drug Regimen Review).*

When there are multiple prescribers, 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 be clinically indicated and documented in the resident's medical record. If it is determined through monitoring that changes in the resident's treatment plan need to be made, surveyors must review the medical record to determine whether the prescribing practitioner provided a rationale for continued use or discontinuation. Without a rationale, the use of the medication(s) may be unnecessary and therefore, noncompliant.

The surveyor must review documentation to confirm that residents are being adequately monitored and re-evaluated for adverse consequences and the need for tapering. Adverse consequences related to medications are common enough to warrant serious attention and close monitoring, and can range from minimal harm to functional decline, hospitalization, permanent injury, and death.

One of the existing mechanisms to warn prescribers about risks associated with medications is the Food and Drug Administration (FDA) requirement that manufacturers include 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: https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program or search for "FDA Safety Alerts for Human Medical Products." Manufacturers are required to place statements about serious problems or contraindications in a prominently displayed box ("black box") in the medication labelling. The boxed warning is reserved for prescription drugs that pose a significant risk of serious or life-threatening adverse effects, based on medical studies. 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 in determining whether a facility has systems and processes in place to minimize risk factors and mitigate harm to residents. This tool and other resources are available on the CMS Adverse Events in Nursing Homes website, https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/QAPI/Adverse-Events-NHs. Additionally, as part of a facility's QAPI program, a facility may track its use of certain classes of medications through reports from the long-term care pharmacist which could identify trends and reduce adverse events.

INVESTIGATIVE PROCEDURES

Use the Unnecessary Medications, Chemical Restraints/Psychotropic Medications, and Medication Regimen Review Critical Element (CE) Pathway, along with the above interpretive guidance, when determining if the facility meets the requirements or when investigating concerns.

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
• 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).
	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
	• Monitoring for and reporting of:
	  ○ Response to medications and progress toward therapeutic goals and resident's goals
	  ○ Emergence of medication-related adverse consequences
	• Adverse consequences, if present and potentially medication-related, note if there was:
	  ○ Recognition, evaluation, reporting, and management by the IDT
	  ○ Physician action regarding potential

SYMPTOMS, SIGNS, AND CONDITIONS THAT MAY BE ASSOCIATED WITH MEDICATIONS	REVIEW FOR HOW THE IDT MANAGED MEDICATIONS FOR THE RESIDENT
• 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.	medication-related adverse consequences • The resident's 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 and any possible side effects in the *facility*. Evaluate if the resident may have experienced psychosocial harm related to side effects of medications.

For a resident who is unable to communicate psychosocial outcomes related to medication side effects, the surveyor should consider how a reasonable person *in the resident's condition* would experience the changes caused by medication side effects as explained in the Psychosocial Outcome Severity Guide, on the CMS Nursing Homes Survey Resources website.

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.

POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION

- *F552, Right to be Informed/Make Treatment Decisions*
- *F553, Right to Participate Planning Care*
- *F580, Notification of Changes*
- *F656, Develop/Implement Comprehensive Care Plan*

- *F710, Physician Supervision*
- *F756, Drug Regimen Review*
- *F841, Medical Director*
- *F881, Antibiotic Stewardship Program*

DEFICIENCY CATEGORIZATION

Examples of Level 4, immediate jeopardy to resident health and safety include, but are not limited to:

- Facility failure to take appropriate action (e.g., suspending administration of the anticoagulant) in response to an elevated International Normalized Ratio (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.

Examples of Level 3, actual harm that are not immediate jeopardy include, but are not limited to:

- The facility failed to monitor the side effects of a resident's new medication regimen as the source of a resident's recent nausea. Instead of

adjusting the current regimen, the prescriber added a medication to treat the nausea, which caused agitation and insomnia.

- *A resident had been sick and taking in less fluids. Staff failed to monitor the resident's blood pressure when the resident mentioned feeling lightheaded. The resident continued to receive prescribed blood pressure medications without adequate monitoring which led to a low blood pressure causing the resident to fall and sustain a serious injury.*

Examples of Level 2, *no* actual harm, with potential for more than minimal harm, that is not immediate jeopardy, 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.

- 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:

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. 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).

- 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

- *Post-Acute and Long-Term Care Medical Association, https://paltmed.org/*

- American Society of Consultant Pharmacists, *https://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. *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.*

F761

(Rev. 229; Issued: 04-25-25; Effective: 04-25-25; Implementation: 04-28-25)

§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

§483.45(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.

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.

NOTE: In addition to actual or potential physical harm, always *observe for visual cues of psychosocial distress and* consider whether psychosocial harm has occurred when determining severity level (*See guidance on Severity and Scope Levels and* Psychosocial Outcome Severity Guide *located in the Survey Resources zip file located at https://www.cms.gov/medicare/provider-enrollment-and-certification/guidanceforlawsandregulations/nursing-homes*).

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

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

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.

F771

(Rev. 229; Issued: 04-25-25; Effective: 04-25-25; Implementation: 04-28-25)

§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.**

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(*e*);
- 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.

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 CMS *Location* 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(*g*) 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:

- Provide transfusion services in accordance with the requirements for laboratories specified in part §493 to meet the needs of the residents.

§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 *Location* for appropriate follow-up by CLIA surveyors.

F772

(Rev. 229; Issued: 04-25-25; Effective: 04-25-25; Implementation: 04-28-25)

§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 *Location* 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.

F776

(Rev. 229; Issued: 04-25-25; Effective: 04-25-25; Implementation: 04-28-25)

§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 *Location* 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(*f*) - 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.

F812

(Rev. 229; Issued: 04-25-25; Effective: 04-25-25; Implementation: 04-28-25)

§483.60(i) Food safety requirements.

The facility must –

§483.60(i)(1) - Procure food from sources approved or considered satisfactory by federal, state 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) - To 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.

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.[1]

"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. [2]

"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.

"Food 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 meals to residents' rooms or dining areas, etc. When meals are assembled in the kitchen and then delivered to residents' rooms or dining areas to be distributed, covering foods is appropriate, either individually or in a mobile food cart.

"Food Service" means the processes involved in actively serving food to the resident. When actively serving residents in a dining room or outside a resident's room where trained staff are serving food/beverage choices directly from a mobile food cart or steam table, there is no need for food to be covered. However, food should be covered when traveling a distance (i.e., down a hallway, to a different unit or floor).

"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)

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;

- U.S. FDA Food Code *web* site at *https://www.fda.gov/food/retail-food-protection/fda-food-code*

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 *current recommendations of the U.S. FDA 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/food/retail-food-protection/fda-food-code*

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** - Employees, 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).

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

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, distribution and serving 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.

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 – According to the current standards of practice such as the Food Code of the FDA, food service staff must wear hair restraints (e.g., hairnet, hat, and/or beard restraint) to prevent hair from contacting food.

According to the Food Code, food service staff must wear hairnets when cooking, preparing, or assembling food, such as stirring pots or assembling the ingredients of a salad. However, staff do not need to wear hairnets when distributing foods to residents at the dining table(s) or when assisting residents to dine.

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. According to the Food Code, gloves are necessary when directly touching ready-to-eat food. Additionally, per infection control guidance, gloves are necessary when serving residents who are on transmission-based precautions (See F880 for additional information on transmission-based precautions). However, staff do not need to wear gloves when distributing foods to residents at the dining table(s) or when assisting residents to dine, unless touching ready-to-eat 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.

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.

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:
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  - 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.

- **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 Distribution - Various systems are available for distributing food items to residents. These include but are not limited to tray lines, portable steam tables transported to dining areas, or mobile food carts that maintain food in the proper temperature and out of the Danger Zone. 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 time food leaves the kitchen, to transport and distribution to prevent contamination (e.g., covering food items). Timely distribution is essential to ensure food and beverages are served at the proper temperature.

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 on other floors or areas of the building.

Food Service - Meal service 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 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;

- Handling food with bare hands or improperly handling equipment and utensils;

- Staff distributing meals without first properly washing their hands; and

- Serving food to residents after collecting soiled plates and food waste, without proper hand washing.

The temperature of PHF/TCS 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.

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.

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 refrigerators 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, *FDA* 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, distributed, and served 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 *Mealtimes*:

- 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, mobile 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.

F836

(Rev. 229; Issued: 04-25-25; Effective: 04-25-25; Implementation: 04-28-25)

§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). Violations of such other provisions may result in a finding of non-compliance with this paragraph.

DEFINITIONS

"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.

GUIDANCE

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:

Facility licenses, 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 CMS *Location* will assist you to contact the appropriate Federal agency to refer your concerns. 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.

F841

(Rev. 229; Issued: 04-25-25; Effective: 04-25-25; Implementation: 04-28-25)

§483.70(g) Medical director.

§483.70(g)(1) The facility must designate a physician to serve as medical director.

§483.70(g)(2) The medical director is responsible for—

(i) Implementation of resident care policies; and
(ii) The coordination of medical care in the facility.

DEFINITIONS

"Medical director" *refers to* 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) *refers to* 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

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(e) 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 *that* 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.

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.

- *Implementation of resident care policies, such as ensuring physicians and other practitioners adhere to facility policies on diagnosing and prescribing medications and intervening with a health care practitioner regarding medical care that is inconsistent with current professional standards of care.*

- Participation in the Quality Assessment and Assurance (QAA) committee or assign a designee to represent him/her. (Refer to F86*8*).

- *Addressing i*ssues related to the coordination of medical care *and implementation of resident care policies identified* through the facility's quality assessment and assurance committee and other activities.

- *Active involvement in the process of conducting the facility assessment (Refer to F838).*

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:

- *Administrative decisions including recommending, developing and approving facility policies related to resident care. Resident care includes the resident's physical, mental and psychosocial well-being;*

- 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*s* 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 expectations 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*, for example, physicians assigning new psychiatric diagnoses and/or prescribing psychotropic medications without following professional standards of practice; 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.

INVESTIGATIVE PROCEDURES

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 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 *one* 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.

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, *a*ctual harm 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 *to* the medical director's failure to ensure implementation of resident care policies, the potential for more than minimal harm existed.
- *The medical director, who is responsible for overseeing the medical care in the facility, was made aware of residents newly diagnosed with schizophrenia by their physician and/or other practitioner and their medical records did not contain documentation to support the new diagnoses. The medical director did not review the medical records for these residents nor did he/she discuss the new diagnoses with the residents' physician and/or diagnosing practitioner. This practice resulted in residents being potentially misdiagnosed with schizophrenia and receiving antipsychotic medications. None of the residents experienced harm, but they were at risk for harm by receiving treatment, including antipsychotic medications, when they may not have been clinically indicated. Note: If this occurred on three or more residents, at minimum, this would be cited at a scope of pattern (e.g., "E").*

Level 1 - Severity 1 does not apply for this regulatory requirement

F842

(Rev. 229; Issued: 04-25-25; Effective: 04-25-25; Implementation: 04-28-25)

§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(*h*) Medical records.

§483.70(*h*)(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(*h*)(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(*h*)(3) The facility must safeguard medical record information against loss, destruction, or unauthorized use.

§483.70(*h*)(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.

§483.70(*h*)(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

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.

The medical record must contain an accurate representation of the actual experiences of the resident and include enough information to provide a picture of the resident's progress, including his/her response to treatments 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(*h*)(2) and (*h*)(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(*h*)

When reviewing a resident's medical record, determine if the record, including any archived information, is accessible to and provides 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

There are no requirements for the use of Electronic Health Record (EHR) systems, 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.

The 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 *Location* 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(h)(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.

F843

(Rev. 229; Issued: 04-25-25; Effective: 04-25-25; Implementation: 04-28-25)

§483.70(*i*) Transfer agreement.

§483.70(*i*)(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(*i*)(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(*i*)

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)*(7),* F627 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), *(F628),* 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.

F845

(Rev. 229; Issued: 04-25-25; Effective: 04-25-25; Implementation: 04-28-25)

§483.70(k) Facility closure-Administrator.

Any individual who is the administrator of the facility must:

§483.70(k)(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(k)(2) Ensure that the facility does not admit any new residents on or after the date on which such written notification is submitted; and

§483.70(k)(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(k)

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(*l*).

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 *Location* 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.

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 *Location* ; 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

(Rev. 229; Issued: 04-25-25; Effective: 04-25-25; Implementation: 04-28-25)

§483.70(l) 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(l)

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(*k*) The policies and procedures must address:

- The administrator's duties and responsibilities as required per §483.70(*k*) 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 *Location,* 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(l)

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.

F847 Entering Into Binding Arbitration Agreements

(Rev. 229; Issued: 04-25-25; Effective: 04-25-25; Implementation: 04-28-25)

§483.70(m) Binding Arbitration Agreements

If a facility chooses to ask a resident or his or her representative to enter into an agreement for binding arbitration, the facility must comply with all of the requirements in this section.

§483.70(m)(1) The facility must not require any resident or his or her

representative to sign an agreement for binding arbitration as a condition of admission to, or as a requirement to continue to receive care at, the facility and must explicitly inform the resident or his or her representative of his or her right not to sign the agreement as a condition of admission to, or as a requirement to continue to receive care at, the facility.

§483.70(m)(2) The facility must ensure that:

> **(i) The agreement is explained to the resident and his or her representative in a form and manner that he or she understands, including in a language the resident and his or her representative understands;**
>
> **(ii) The resident or his or her representative acknowledges that he or she understands the agreement…**

§483.70(m)(3) The agreement must explicitly grant the resident or his or her representative the right to rescind the agreement within 30 calendar days of signing it.

§483.70(m)(4) The agreement must explicitly state that neither the resident nor his or her representative is required to sign an agreement for binding arbitration as a condition of admission to, or as a requirement to continue to receive care at, the facility.

§483.70(m)(5) The agreement may not contain any language that prohibits or discourages the resident or anyone else from communicating with federal, state, or local officials, including but not limited to, federal and state surveyors, other federal or state health department employees, and representative of the Office of the State Long-Term Care Ombudsman, in accordance with §483.10(k). . .

NOTE: The requirements at 483.70(m) went into effect on September 16, 2019. This guidance is intended for the review of arbitration agreements entered into on or after September 16, 2019.

INTENT

To ensure that long-term care facilities inform residents or their representatives of the nature and implications of any proposed binding arbitration agreement, to inform their decision on whether or not to enter into such agreements.

The requirements at F847emphasize the residents' or their representatives' right to make informed decisions and choices about important aspects of residents' health, safety and welfare. Facilities may present residents or their representatives the opportunity to utilize a binding arbitration agreement to resolve disputes at

any time during a resident's stay as long as the agreement complies with the regulations at §483.70(m)(1)-(5).

DEFINITIONS

Arbitration: a private process where disputing parties agree that one or several other individuals can make a decision about the dispute after receiving evidence and hearing arguments. [1]

Binding Arbitration Agreement (Arbitration Agreement or Agreement): a binding agreement by the parties to submit to arbitration all or certain disputes which have arisen or may arise between them in respect of a defined legal relationship, whether contractual or not. The decision is final, can be enforced by a court, and can only be appealed on very narrow grounds. [2]

Pre-dispute binding arbitration agreement (pre-dispute arbitration agreement or pre-dispute agreement): A binding agreement to resolve a future unknown dispute with an arbitrator prior to any issue or dispute arising.

Post-dispute binding arbitration agreement (post-dispute arbitration agreement, or post-dispute agreement): A binding agreement signed after the circumstances of the dispute have occurred to resolve the dispute with an arbitrator.

Dispute: A disagreement, controversy, or claim amongst parties where one party claims to have been harmed.

Judicial Proceedings: any action by a judge (i.e., trials, hearings, petitions, or other matters) formally before the court.

GUIDANCE §483.70(m)(1)(2)(i)(ii)(3)-(5)

Over the years, long-term care facilities and residents have used arbitration to resolve many disputes. Parties subject to arbitration give up their right to have some or all claims heard in court (The arbitration epidemic: Mandatory arbitration deprives workers and consumers of their rights, https://www.epi.org/publication/the-arbitration-epidemic/, Accessed 1/6/2021). The results of arbitration decisions are typically not disclosed to the public and arbitrators' decisions are generally final and binding with little or no opportunity to initiate judicial proceedings that challenge unfavorable decisions.

Concerns have been raised about the fairness and transparency related to both the means by which these agreements are created and the fairness of the arbitration processes themselves in the specific context of long-term care facilities. For

example, an individual is often admitted to a long-term care facility directly from the hospital after a decline in their health. These individuals are often quite ill and are not in a position to engage in meaningful negotiations over the terms of an arbitration agreement or to coordinate care at another facility. As a result, this is quite often an extremely stressful situation with limited time to review documents before signing them. During this time, long-term care facilities have often required individuals to sign pre-dispute arbitration agreements to obtain health care. These factors, among others, impede individuals' ability to obtain care and simultaneously make it extremely difficult for residents or their representatives to make an informed decision about arbitration. Therefore, asking individuals to commit to binding arbitration agreement in these situations may not represent the best option in terms of advancing the health care of residents.

Use of a binding arbitration agreement must be voluntary and must be clearly communicated to the residents or their representatives as optional and not required as a condition of admission or to continue to receive care at the facility. The agreement must be explained so that the resident or his or her representative understands the terms of the agreement. This should include an explanation that the resident may be giving up his or her right to have a dispute decided in a court proceeding. And residents and their representatives must be provided 30 days after signing to fully review and potentially rescind any agreement that was not understood at the time of admission.

Pre- and Post-dispute Arbitration Agreements: Binding arbitration agreements may be offered either before (pre-dispute) or after (post-dispute) a dispute arises. A pre-dispute binding arbitration agreement is an agreement to resolve an unspecified future dispute(s) through arbitration. Disputes may vary from a non-life threatening situation such as a financial disagreement, up to and including significant concerns such as abuse, neglect, and/or wrongful injury or death of a resident. By entering into a pre-dispute binding arbitration agreement, the parties are not settling an existing dispute but deciding, in advance, the forum in which any future disputes would be resolved. For example, if a resident enters into a pre-dispute arbitration agreement when admitted to a facility, and a few months later the facility is alleged to have wrongfully caused a type of harm covered by the agreement, such as abuse, the resident cannot seek legal action through the traditional court system. Rather, they must resolve the dispute through the agreed-upon arbitration proceeding.

Facilities wishing to utilize pre-dispute binding arbitration agreements will generally offer these arrangements prior to, or early in the admission process. Facilities must not require residents or their representatives to enter into a binding pre-dispute arbitration agreement as a condition of being admitted to the facility or as a requirement for continued care.

Post-dispute arbitration agreements involve the use of the arbitration process after a dispute occurs, which would otherwise be resolved in a court proceeding. In such cases, following an issue which gives rise to a dispute, the facility may propose using an arbitrator to resolve the dispute, rather than engage in litigation in court. When the facility wishes to use a post-dispute binding arbitration agreement, existing legal authorities generally provide that the facility must not compel, pressure, or coerce a resident or his or her representative to enter into a binding arbitration agreement, and the regulation provides that the facility must not require arbitration as a condition of receiving continued care at the facility.

Requirements for Arbitration Agreements - Transparency in the Arbitration Process: The requirements at §483.70(m)(2)(i) specify that the arbitration **"agreement is explained to the resident and his or her representative in a form and manner that he or she understands, including in a language the resident and his or her representative understands."** It is important that the arbitration process is transparent. This means that facilities should take every step to meet the resident's needs or special accommodations (e.g. literacy level, font size, format, language, etc.) when explaining the arbitration agreement. When explaining the agreement, facilities must identify and use the resident's or their representative's preferred communication method, including language, to ensure understanding of the arbitration agreement. The terms and conditions of arbitration agreements must be clearly explained to the resident or his or her representative.

The requirement at §483.70(m)(2)(ii) specifies that **"the resident or his or her representative acknowledges that he or she understands the agreement."** After the arbitration agreement is explained in a manner and form the resident or their representative understands, the facility must ensure there is evidence that the resident or their representative has acknowledged understanding of the agreement. In some cases, the binding arbitration agreement may specify that the resident or his or her representative acknowledges understanding by signing the document. When a signature is used to acknowledge understanding, additional evidence may be needed to establish that in fact the resident or their representative understood what he or she was signing. It may not be sufficient that the resident or their representative signed the document. It is also important that facilities clarify when a signature is used to acknowledge understanding, when it indicates consent to enter into an agreement, or is used for both purposes.

Surveyors should determine how the facility ensures residents or their representatives understood the terms of the binding arbitration agreement, and how this understanding is acknowledged. Surveyors must verify through

interview and record review, that the resident or their representative understood what they were signing. In situations where the resident may have cognitive impairment, surveyors should refer to the medical record to identify the resident's health care decision-making capacity at the time the agreement was offered, explained, and entered into.

Arbitration Agreements Embedded within other Contracts or Agreements: Binding arbitration agreements may not necessarily be a stand-alone document. Facilities may choose to offer pre-dispute arbitration agreements at the time of admission. Some facilities may embed the arbitration agreement within the admission agreement, contract, or other documents. In these cases, all of the requirements related to arbitration agreements still apply. For example, the facility must explain that the admissions agreement includes a binding arbitration agreement, and inform the resident of all of their rights related to this agreement in a form and manner that they understand. Additionally, the facility should clearly distinguish the arbitration agreement from the admission agreement, so that, residents or their representatives have a clear understanding of each agreement, and are able to enter into or decline the arbitration agreement. In other words, residents must be allowed to sign an admissions agreement without consenting to the facility's arbitration agreement. Surveyors should determine how the facility ensures residents or their representatives are made aware of arbitration agreements which are embedded within another document. Surveyors should also obtain copies of any documents or agreements that include information about arbitration. For example, if a facility's admission agreement has a paragraph referencing arbitration, but also has a separate arbitration agreement, the surveyor will need to examine both documents to ensure compliance.

Requirements for Arbitration Agreements – Language: The requirements at §483.70(m)(1), (3)-(5) identify specific terms and conditions which must be "explicitly" stated in any arbitration agreement between a resident or their representative, and a Medicare and/or Medicaid certified facility. Explicitly means clearly and without any vagueness or ambiguity. Thus, these terms and conditions must be disclosed in the agreement in a clear and detailed manner, leaving no room for confusion. For further arbitration agreement language to be included, refer to F848, specifically §483.70(m)(2)(iii), (iv).

§483.70(m)(1): The arbitration agreement **"…must explicitly inform the resident or his or her representative of his or her right not to sign the agreement as a condition of admission to, or as a requirement to continue to receive care at, the facility."** This means that the agreement must clearly explain that the resident or their representative has the right to refuse to enter into the arbitration agreement without fear of:

- Not being admitted; or

- Being transferred or discharged as a result of refusing to enter into an arbitration agreement.

Facilities cannot refuse to admit any resident who has, or whose representative has, declined to enter into an arbitration agreement. Additionally, facilities must not discharge any resident for failure to use arbitration to settle a dispute.

NOTE: Surveyors should thoroughly investigate the basis for transfer or discharge for any resident who has refused to enter into a binding arbitration agreement, and has been, or will be subsequently transferred or discharged. For additional information, refer to the guidance at §483.15(c) - F627, Transfer and Discharge Requirements.

§483.70(m)(3): The arbitration **"agreement must explicitly grant the resident or his or her representative the right to rescind this agreement within 30 calendar days of signing it.**" This means the agreement must clearly explain that the resident or his or her representative has 30 calendar days to withdraw from or terminate the agreement, should he or she change their mind. This ensures that residents or their representatives have time to reconsider the decision to use arbitration to settle a dispute with the facility. This also allows time for them to seek legal advice, if he or she chooses to do so.

Facilities should have a process, that is also explained to the resident or their representative, which ensures timely communication to the appropriate facility staff of a resident's or resident representative's desire to withdraw from, or terminate the arbitration agreement. Otherwise, miscommunications or delays could deny the resident or representative the right to withdraw from the agreement within the 30-day period.

§483.70(m)(4): The arbitration agreement "**must explicitly state neither the resident nor his or her representative is required to sign this agreement as a condition of admission to, or as a requirement to continue to receive care at the facility.**" This means the agreement itself must contain clear language that neither the resident nor the representative are required to enter into the agreement as a condition of admission or to continue to reside at the facility. As stated above at §483.70(m)(1), this must be clearly conveyed without any ambiguity, thereby ensuring that no resident or his or her representative will have to choose between signing an arbitration agreement and receiving care at the facility.

§483.70(m)(5): The arbitration **"agreement may not contain any language that prohibits or discourages the resident or anyone else from communicating with**

federal, state, or local officials, including but not limited to, federal and state surveyors, other federal or state health department employees, and representative of the Office of the State Long-Term Care Ombudsman, in accordance with §483.10(k)." Residents or their representatives have the right to unrestricted communication with officials from federal agencies, as well as with state and local officials, including representatives from the State Survey Agency, State Health department, and representatives from the Office of the State Long-Term Care Ombudsman. In addition to prohibition of language in the agreement which discourages such contact or communication, this also means that there should be no attempt by facility staff to discourage this communication verbally.

Surveyors should verify through interview that the resident or his or her representative were not discouraged in any way from contacting federal, state, or local officials, which includes and is not limited to surveyors and ombudsmen, when entering into a binding arbitration agreement. For additional information, refer to the guidance at §483.10(k) - F586, Contact with External Entities.

PROCEDURES AND PROBES §483.70(m)(1)(2)(i)(ii)(3)-(5)

Surveyors should verify with the facility whether arbitration agreements are used to resolve disputes. If so, determine compliance with F847 through interview of sampled residents, resident representatives, resident council/family council (if one exists), Long-Term Care Ombudsman, facility staff; and record review, which includes reviewing the agreement and other relevant documentation. For facilities that offer arbitration agreements, the following are interview questions that may assist Surveyors in their investigation. Surveyors are not required to ask all of the below interview questions, but instead use these example questions as a guide during interviews.

NOTE: These provisions are not intended to, "supersede or interfere with state laws or other state contract and consumer protection laws . . . except to the extent any such laws are actually in conflict with this regulation." 84 Fed. Reg. 34718, 34721 (July 18, 2019).

Interviews

a. **Resident and/or his or her Representative:** For residents who have arbitration agreements, determine the extent to which the arbitration agreement was explained to the resident or representative by asking:

- What is your understanding of the arbitration process when a dispute arises?

- Do you understand that you are giving up your right to litigation in a court proceeding?

- Were you told that the facility could not require you to enter into an arbitration agreement in order to be admitted, or in order to remain in the facility?

- Were you told that you had the right to terminate or withdraw from the agreement within 30 days of signing? If yes, were you told how to do so?

- Did you feel you were obligated, required, forced or pressured to sign the binding arbitration agreement? If yes, how so?

- Have you filed any complaint(s) or grievance(s) with the facility and/or state survey agency about the arbitration agreement?

- Is there anything you would have liked to have known before signing the arbitration agreement?

- Was the arbitration agreement explained in a way that you understood?

- If the arbitration agreement was included within another document, were you told first that you had the right to decline the agreement; and second, how to exercise this right (crossing out, etc.)?

b. Resident Council/ Family Council: For facilities having resident and/or family councils, and that have elected to utilize arbitration agreements, determine if there are general concerns with arbitration agreements. If concerns are identified, surveyors should arrange to meet individually with the resident to discuss their personal/private concerns related to arbitration agreements (for individual interview probes, see resident/representative interview questions above). Ask the following:

- Has the Resident's Council ever voiced any concerns to the facility about arbitration agreements, such as the way they are explained, pressure or being forced into signing them, or concerns with the process for withdrawing or terminating an agreement?

- Do you know if residents feel forced (coerced) to sign the arbitration agreement? If yes, how so?

- Whom from the facility discusses or reviews the binding arbitration agreement with residents or their representatives?

c. Facility staff: Interview facility staff responsible for explaining the arbitration agreement to residents or their representatives. Determine how the facility staff ensure the resident or his or her representative understands the agreement by asking:

When, and under what circumstances, do you request that a resident or his or her representative agree to an arbitration agreement?

- How do you ensure the resident or representative understands the terms of the arbitration agreement?

- How do you ensure the arbitration agreement is explained in a form and manner that accommodates the resident or his or her representative's needs?

- How do you make sure the resident understands their rights with regard to the arbitration agreement, such as their right to refuse to enter into it, and their right to rescind it within 30 days?

- What is the process in your facility for allowing residents or their representatives to terminate, or withdraw from an arbitration agreement in the first 30 days?

- Do you know any resident(s) whom your facility refused admission to, or discharged due to refusal to sign a binding arbitration agreement?

- Have any residents filed a complaint or grievances with the facility regarding the use of an arbitration agreement?

- How do you determine if the resident's physical condition and his/her cognitive status may be contributing factors in understanding of the binding arbitration agreement, including their ability to make an informed and appropriate decision?

d. State Long-Term Care Ombudsman (if available):

- Did any resident or his or her representative report that he/she felt forced or pressured into signing the binding arbitration agreements as a condition of admission or as a requirement to continue receiving care at the facility?

- Do you know any resident whom the facility may have refused admission to, or who was discharged, due to refusal to sign a binding arbitration agreement?

- Are you aware of any issues that have been raised regarding binding arbitration agreements?

- Are you aware of any residents or representatives who sought to rescind a binding arbitration agreement? If yes, how did the facility respond to the rescission request?

Record Review: Review the resident record, as well as the arbitration agreement to ensure:

The binding arbitration agreement clearly states that the resident or his or her representative is not required to enter into the agreement as a condition of admission to the facility, or as a requirement to continue to receive care.

- The binding arbitration agreement does not include language, which prohibits or discourages the resident or representative from communicating with federal, state, or local officials.

- There is evidence the binding arbitration agreement was explained in a form, manner and language that the resident or his or her representative understands.

- There is evidence that the resident had the cognitive ability to understand the terms of the agreement, and evidence the resident acknowledged this understanding.

- The binding arbitration agreement gives the resident or his or her representative the right to rescind the agreement within 30 calendar days of signing it.

- For residents who have a representative, there is evidence the representative has the legal authority to sign the binding arbitration agreement.

POTENTIAL TAGS FOR ADDITIONAL CONSIDERATION

If there are concerns regarding communication with external entities such as federal and state surveyors, other federal or state health department employees, and representative of the Office of the State Long-Term Care Ombudsman, surveyors should further investigate and review regulatory requirements at §483.10(k), F586, Contact with External Entities.

If there are concerns regarding admission agreement, surveyors should further investigate and review regulatory requirement at §483.15(a), F620, Admissions Policy.

If there are concerns regarding the basis for transfer and discharge for any resident who has refused to enter into a binding arbitration agreement and has been, or will be subsequently transferred or discharged, surveyors should further investigate and review regulatory requirements at §483.15(c), F627 Transfer and Discharge.

KEY ELEMENTS OF NONCOMPLIANCE

To cite deficient practice at F847, the surveyors' investigation will generally show: The facility failed to:

- Explain the terms of the agreement to the resident or his or her representative in a form and manner (including language) that he or she understands; and/or

- Inform the resident or his or her representative they are not required to enter into a binding arbitration agreement as a condition of admission, or as a condition to continue to receive care at the facility; or

- Inform the resident or representative they have the right to rescind or terminate the agreement within 30 calendar days of signing.

The agreement itself:

- Contains language that prohibits or discourages the resident or his or her representative from communicating with federal, state, or local officials, including:

    - Federal and state surveyors, and/or

    - Other federal or state health department employees, and/or

    - Representative of the Office of the State Long-Term Care Ombudsman; or

- Fails to contain language which clearly informs the resident or their representative they are not required to sign the agreement as a condition of admission to, or as a requirement to continue to receive care at the facility.

Guidance on Identifying Noncompliance at F847: In some cases, a resident or his or her representative may not be able to recall the specifics of a conversation explaining arbitration agreements held during admission or at some point previous to the survey. It is not uncommon for an individual to not remember all the technical details of something they signed in the past (e.g., six months ago). If a resident or their representative cannot recall the conversation explaining arbitration agreements, or details of the terms of the agreement, this alone may not necessarily indicate noncompliance. However, if several residents do not recall being advised of their rights related to arbitration agreements, the surveyor should conduct further investigation.

Conversely, if a resident or his or her representative actively asserts or complains that they remember the admissions conversation, and can affirm that the facility staff member did not inform them of their rights related to arbitration, this **may** indicate noncompliance. In either case, surveyors are expected to verify noncompliance through further investigation with the resident or representative, as well as other residents, staff members, and resident council.

Guidance on Determining Severity of Noncompliance at F847: When determining the severity of noncompliance at F847, surveyors must always consider what impact the identified noncompliance had on the affected resident(s). However, unlike noncompliance at other tags, such as Abuse or Quality of Care, which may result in physical, mental, and/or psychosocial outcomes, noncompliance at F847 will almost exclusively have a psychosocial impact or outcome. Surveyors must gather sufficient evidence through interviews, record review and observation to demonstrate what the psychosocial impact was to the resident. In some cases, the surveyor may have to use the reasonable person concept to determine severity. Refer to the Psychosocial Severity Outcome Guide for further information.

The failure of the facility to meet the requirements at F847 is more than minimal harm. Therefore, Severity Level 1 does not apply for this regulatory requirement.

Absent evidence of actual harm, noncompliance at F847 would likely be cited at severity level 2, No Actual Harm with Potential for More than Minimal Harm that is not Immediate Jeopardy.

However, if the surveyor identifies that noncompliance at F847 has caused psychosocial **harm** to the resident (per the Psychosocial Severity Outcome Guide), this should be cited at severity level 3, Actual Harm that is not Immediate Jeopardy.

In order to cite Immediate Jeopardy, the surveyor's investigation would have to show that noncompliance resulted in the likelihood for serious psychosocial injury or harm, or caused actual serious psychosocial injury or harm, and required immediate action to prevent further serious psychosocial injury or harm from occurring or recurring. Refer to Appendix Q for further information.

Guidance on Correcting Noncompliance at F847: When noncompliance exists at F847, the Plan of Correction (POC) is expected to include the required elements as identified at State Operations Manual, Chapter 7, §7317 – Acceptable Plan of Correction. These include:

- Address how corrective action will be accomplished for those residents found to have been affected by the deficient practice;

- Address how the facility will identify other residents having the potential to be affected by the same deficient practice;

- Address what measures will be put into place or systemic changes made to ensure that the deficient practice will not recur;

- Indicate how the facility plans to monitor its performance to make sure that solutions are sustained; and

- Include dates when corrective action will be completed.

When the surveyor's investigation shows systemic noncompliance, indicating a complete disregard or unawareness of the requirements, such as the standard use of arbitration agreements containing language which violates the requirements at F847, evidence that the facility has made no attempt to explain arbitration agreements, or evidence of overt attempts to conceal arbitration agreements within other documents, in addition to the requirements for POCs listed above, CMS has the following expectations with regard to the accepted POC:

- The POC must ensure that any new or revised arbitration agreements in use in the facility complies with the requirements at F847 – Surveyors must review the revised agreements and confirm that they comply with F847;

- If a resident or their representative has signed a non-compliant agreement, the facility must ensure that the resident or their representative is promptly notified that the agreement does not comply with §483.70(m), and it must promptly offer the resident or their representative a compliant agreement;

- The facility must explain the terms of the new agreement to the residents or their representatives, and do so in terms the residents or their representatives can understand; and

- All other requirements at F847 are met.

F849

(Rev. 229; Issued: 04-25-25; Effective: 04-25-25; Implementation: 04-28-25)

§483.70(n) Hospice services.

§483.70(n)(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(n)(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(n)(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(n)(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.

DEFINITIONS §483.70(n)

"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(n)

Provision of Hospice Services In A Nursing Home
As described in §483.70(n)(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.

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(n)(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(n)(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(n)(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(n)(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(n)(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(n)(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(n)(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(n)(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(n)(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(n)(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(n)(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(n)(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(n)(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(n)(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(n)(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(n)(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(n)(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: *In addition to actual or potential physical harm, a*lways observe for visual cues of psychosocial distress and *consider whether psychosocial harm has occurred when determining severity level* (*S*ee Guidance on Severity and Scope Levels and Psychosocial Outcome Severity Guide *located in the Survey Resources zip file located at https://www.cms.gov/medicare/provider-enrollment-and-certification/guidanceforlawsandregulations/nursing-homes*).

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(n) - 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(*g*), F841, Medical Director;
- 42 CFR §483.70(h)(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.

F851

(Rev. 229; Issued: 04-25-25; Effective: 04-25-25; Implementation: 04-28-25)

§483.70(p) 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(p)(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(p)(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(p)(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(p)(4) Data format.

The facility must submit direct care staffing information in the uniform format specified by CMS.

§483.70(p)(5) Submission schedule.

The facility must submit direct care staffing information on the schedule specified by CMS, but no less frequently than quarterly.

INTENT

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

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.

INVESTIGATIVE PROCEDURES

When completing the offsite preparation for all recertification surveys, the team coordinator must obtain the most recent quarter data from the PBJ Staffing Data Report and evaluate PBJ data submitted by the facility. This report can be found by accessing the Certification And Survey Provider Enhanced Reports (CASPER). The report does allow for previous quarters of submitted data to be obtained. This may be beneficial for the investigation of complaints or Facility Report Incidents (FRI). See the LTCSP Procedure Guide for details.

The facility's failure to submit PBJ data as required will be reflected on their CASPER report and result in a deficiency citation.

The team coordinator must follow the steps below:

1. *Obtain the PBJ Staffing Data Report.*

2. *Identify if the facility triggered for "Failed to Submit Data for the Quarter."*
    a. *If the facility failed to submit the required PBJ Staffing Data, F851 must be cited as a Severity and Scope of "F".*

NOTE: *It should be an* ***extremely rare*** *circumstance when a facility is not cited if the PBJ data report indicates the facility did not submit PBJ data for the quarter. If there are questions or the team thinks the facility should not be cited, the team coordinator must email NHStaffing@cms.hhs.gov for assistance. CMS will respond by the end of the next business day and copy the CMS location.*

Additionally, if facilities have questions on submitting PBJ data, refer them 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/nursing-home-improvement/staffing-data-*

submission

For questions related to *PBJ*, providers, or other stakeholders should email NHStaffing@cms.hhs.gov.

KEY ELEMENTS OF NONCOMPLIANCE
To cite deficient practice at F851, the surveyor's investigation will generally show that the facility failed to do any one of the following:

- *Submit the required staffing information based on payroll data in a uniform format;* ***or***
- 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.

Note: Noncompliance at F851 focuses on the submission of staffing data. If the surveyor identifies concerns related to *registered nurse (RN) coverage eight hours a day, licensed nurse (LN) coverage 24-hour a day, or* sufficient staffing, surveyors *should* investigate these concerns using the Sufficient and Competent Staff Critical Element Pathway, and guidance at §483.35 Nursing Services (F725 & F727).

F867
(Rev. 229; Issued: 04-25-25; Effective: 04-25-25; Implementation: 04-28-25)

§483.75(c) Program feedback, data systems and monitoring.
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.

§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.*71* 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.

§483.75(d) Program systematic analysis and systemic action.

§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)(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 §483.71. Improvement projects must include at least annually a project that focuses on high risk or 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:

(i) 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.

INTENT

These provisions are intended to ensure facilities obtain feedback, use data, and take action to conduct structured, systematic investigations and analysis of underlying causes or contributing factors of problems affecting facility-wide processes that impact quality of care, quality of life, and resident safety.

DEFINITIONS

"Adverse Event" is defined in §483.5 as an untoward, undesirable, and usually unanticipated event that causes death or serious injury, or the risk thereof.

"Corrective Action" *refers to* 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.

"Health equity" *refers to* ***t****he attainment of the highest level of health for all people, where everyone has a fair and just opportunity to attain their optimal health regardless of race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, preferred language, or other factors that affect access to care and health outcomes. From the CMS Framework for Health Equity, April 2022, https://www.cms.gov/about-cms/agency-information/omh/health-equity-programs/cms-framework-for-health-equity.*

"High-risk areas" *r*efers**:** Refers to care or service areas associated with significant risk to the health or safety of residents. Errors in these care areas have the potential to cause adverse events resulting in pain, suffering, and/or death. Examples include tracheostomy care; pressure injury prevention; administration of high-risk medications such as anticoagulants, insulin, and opioids.

"High-volume areas" *r*efers**:**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.

"Incidence" *refers to* a measure of the number of new cases of a characteristic that develop in a population in a specified time period. National Institute of Mental Health (NIMH) (https://www.nimh.nih.gov/health/statistics/what-is-prevalence.shtml, accessed 12/21/2020).

"Indicator" *refers to* measurement of performance related to a particular care area or service delivered. Used to evaluate the success of a particular activity in achieving goals or thresholds.

"Medical Error" *refers to* a deviation from the process of care, which may or may not cause harm to the resident.

"Near Miss" *refers to* a serious error or mishap that has the potential to cause an adverse event but fails to do so because of chance or because it is intercepted. It is also called a potential adverse event.

"Prevalence" *refers to* the proportion of a population who have a specific characteristic in a given time period. NIMH (https://www.nimh.nih.gov/health/statistics/what-is-prevalence.shtml, accessed 12/21/2020).

"Problem-prone areas" refers to care or service areas that have historically had repeated problems, e.g., call bell response times; staff turnover; lost laundry.

"Quality Assurance and Performance Improvement (QAPI)" *refers to* 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)** *refers to* 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) *refers to* 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)" *refers to 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 *needing* 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 noncompliance deficiency cited by surveyors, but may include issues related to deficiencies cited on annual or complaint surveys.

"Systematic" *refers to* a step by step process that is structured, so that it can be replicated.

"Systemic" *refers to* embedded within, and affecting a system or process.

GUIDANCE

As required in §483.75(a) (F865), the facility must develop and implement systems that ensure the care and services it delivers meet acceptable standards of

quality in accordance with recognized standards of practice. This is accomplished, in part, by identifying, collecting, analyzing and monitoring data which reflects the functions of each department and outcomes to residents.

Feedback

Feedback is one of many data sources which provide valuable information the facility must incorporate into an effective QAPI program. Each facility must establish and implement written policies and procedures for feedback.

Feedback must be obtained from direct care staff, other staff, residents and resident representatives, as well as other sources, and be used to identify problems that are high-risk, high-volume, and/or problem-prone, as well as opportunities for improvement. Feedback from residents is necessary to understand what quality concerns are important to them, their perspectives, values and priorities, as well as the impact of the facility's daily routines on their physical, mental, and psychosocial well-being. Staff can also provide valuable input into understanding care and service delivery processes. *Facilities should consider feedback related to concerns about health equity. For example, does the facility address the needs of individuals with disabilities, limited English proficiency, with different cultural or ethnic preferences, or other health equity concerns? Additional information on addressing health equity can be found at the CMS Framework for Health Equity site, https://www.cms.gov/about-cms/agency-information/omh/health-equity-programs/cms-framework-for-health-equity.*

A facility should choose the best mechanism for feedback to support their QAPI program. Examples of mechanisms for obtaining resident and staff feedback may include, but are not limited to:

- Satisfaction surveys and questionnaires;
- Routine meetings, e.g., care plan meetings, resident council, safety team, town hall; and
- Suggestion or comment boxes

Effective feedback systems in a QAPI program also include methods for providing feedback to direct care staff, other staff, residents and representatives. This may involve including these individuals in problem solving, various meetings or providing updates and communicating facility system changes.

Data Collection Systems and Monitoring

In order to ensure care and services are carried out consistently, accurately,

timely and according to recognized standards of quality, the facility must collect and monitor data reflecting its performance, including adverse events.

Facility policies and procedures must address how data will be identified, and the frequency and methodology for collecting and using data from all departments. The facility determines what data it will collect to represent its care areas considered to be associated with high-risk, high-volume, and/or problem-prone issues. *Facilities should also collect and monitor data related to the outcomes of sub-populations to address any health equity issues. For example, there could be higher risk or problem-prone issues related to certain sub-populations (e.g., race, sexual orientation, socioeconomic status, or preferred language) within the facility.*

Data collection can be done using several methods, such as audit tools (purchased or developed by the facility), direct observation, interview, or testing. Sources for data may include the Minimum Data Set (MDS) and Quality Measures, electronic and paper medical records, survey results, incident reports, complaints, suggestions and staffing data. CMS expects the data collection methodology to be consistent, reproducible and accurate to produce data that are valid and reliable and support all departments and the facility assessment (§483.71).

It is not necessary to collect all data at the same frequency. The facility may develop a schedule for routine data collection. For example, data related to high-risk or problem-prone issues will generally be collected more frequently (e.g. daily, weekly, or monthly) until performance is at a satisfactory level, then collected less frequently (e.g. quarterly or every six months).

Performance Indicators

The facility must have policies and procedures in place for developing, monitoring and evaluating performance indicators. The policies and procedures must also describe how and with what frequency the facility develops, monitors and evaluates its performance indicators.

A performance indicator is a measurement of from the data collected, which represents performance in a specific care or service area. Performance indicators enable the facility QAA Committee to establish performance thresholds and goals, identify deviations in performance and evaluate progress. An example of monitoring includes comparing results of facility performance over time, as well as to state or national benchmarks.

Systematic Analysis and Action

As part of its' QAPI program, each facility is responsible for having systems in place and implementing actions intended to improve performance. This includes implementation of corrective actions, measuring success, and tracking performance, to ensure improvements are achieved and sustained.

The facility must develop and implement policies and procedures which address:

- How it will use systematic approaches (such as root cause analysis, reverse tracker methodology, or health-care failure and effects analysis) to assist in determining underlying causes of problems impacting larger systems.

- 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

- How the facility will monitor the effectiveness of its performance improvement activities to ensure that improvements are sustained.

Establishing Priorities

The facility must establish priorities for performance improvement activities that focus on resident safety, health outcomes, autonomy, choice and quality of care, as well as high-risk, high-volume, and/or problem-prone areas. When determining priorities, the facility must also consider the incidence, prevalence and severity of problems or potential problems identified. *Consideration should also be given to factors that affect health equity and outcomes depending on the population of residents within the facility.*

If systemic concerns, especially repeat survey deficiencies, have not been identified or prioritized by the facility's QAA committee, this may be an indication that the committee is not performing its required functions effectively.

Medical Errors and Adverse Events

In addition to self-identified improvement activities, the facility must also track medical errors and adverse resident events. When medical errors or adverse resident events are identified, the facility must analyze the cause of the error/event, implement corrective actions to prevent future events, and conduct monitoring to ensure desired outcomes are achieved and sustained.

Nursing homes must develop and implement written policies and procedures that enable the facility to systematically identify and investigate for medical

errors and adverse events, including how the facility will analyze and use data relating to errors/events to develop activities to prevent future occurrences. *Data analysis should include an evaluation of factors known to affect health equity, such as race, sexual orientation, socioeconomic status, or preferred language.*

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	Infectious diarrhea • Clostridium difficile

Potentially Preventable Events Related to:		
	tracheostomy/ventilator care	• 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; levothyroxine; ACE inhibitors; phenytoin; lithium; valproic acid; antibiotics	Elopement	
Altered cardiac output related to use of cardiac/blood pressure medication	Instances of abuse, neglect, and misappropriation of resident property and exploitation (see §483.5)	

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%)

As part of the facility's performance improvement activities to reduce medical errors and adverse events, feedback and learning must be provided throughout the facility (483.75(e)(2)). Educating staff, residents, resident representatives and family members on medical errors and adverse events, such as what to look for

and preventive measures, are important factors in reducing and preventing medical errors and adverse resident events.

For additional information regarding QAPI training requirements see §483.95(d), (F944).

Identifying Quality Deficiencies and Corrective Actions

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. Adverse events, such as the elopement of a cognitively-impaired resident, should be considered a high risk problem for which corrective action is required.

Once a quality deficiency is identified, the QAA committee has a responsibility to oversee development of an appropriate corrective action. An appropriate corrective action is one that addresses 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 includes determining contributing causes of the problem;
- Measurable goals;
- 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 Plan-Do-Study-Act (PDSA) cycles until the desired performance goals have been met, or the facility may conduct a Performance Improvement Project.

Performance Improvement Projects (PIPs)

The facility must conduct distinct performance improvement projects, based on the scope and complexity of facility services and available resources, identified as a result of the facility assessment required at §483.71. While the number and

frequency of improvement projects may vary, each facility must conduct at least one improvement project annually that focuses on high-risk or problem-prone areas, identified by the facility through data collection and analysis.

PIPs are a process that generally involves a team making a concentrated effort over time to improve a systemic problem or improve quality in absence of a problem. PIPs often require a systematic investigation, such as a Root Cause Analysis (RCA) to identify underlying causes or factors which have contributed to or caused the problem and the development of a corrective action plan. Interventions are designed to address the underlying causes, and once implemented, the team closely monitors results to determine if changes are yielding the expected improvement or if the interventions should be revised.

The facility's action plans to address quality deficiencies and improve performance may be implemented in a variety of ways, including staff training and deployment of changes to procedures; monitoring and feedback mechanisms; and processes to revise plans that are not achieving or sustaining desired outcomes. The committee may delegate the implementation of action plans to various facility staff and/or outside consultants.

Quality assessment and assurance

Functioning under the facility's governing body, the QAA committee is responsible for:

- Developing and implementing appropriate plans of action to correct identified deficiencies;

- Regularly reviewing and analyzing data, including data collected under the QAPI program and data resulting from drug regimen reviews; and

- Acting on available data to make improvements.

For concerns related to governance and leadership and the governing body and/or executive leadership, see §483.75(f), (F865).

INVESTIGATIVE PROCEDURE

Use the Facility Task Pathway for Quality Assurance and Performance Improvement (QAPI) and Quality Assessment and Assurance (QAA) Review, along with the above interpretive *guidance* when determining if the facility meets the requirements for, or investigating concerns related to QAPI/QAA.

Surveyors should refer to the following when investigating concerns and citing non-compliance related to QAPI:

- F865: For concerns related to whether a facility has implemented and maintains a comprehensive QAPI program and plan, disclosure of records and governance and leadership.

- F867: For concerns related to how the facility obtains feedback, collects data, monitors adverse events, identifies areas for improvement, prioritizes improvement activities, implements corrective and preventive actions, and conducts performance improvement projects.
- F868: For concerns related to the composition of the QAA committee, frequency of meetings and reporting to the governing body.

KEY ELEMENTS OF NON-COMPLIANCE

To cite deficient practice at F867, the surveyor's investigation *will* must generally show that the facility failed to do any one of the following:

- Include in its policies and procedures how it obtains and uses feedback from residents, resident representatives, and staff to identify high-risk, high-volume, or problem prone issues as well as opportunities for improvement; or

- Develop and implement policies and procedures which include how it ensures data is collected, used and monitored for all departments; or

- Develop and implement policies and procedures for how the facility develops, monitors and evaluates performance indicators and the frequency for these activities; or

- Develop policies and procedures for how it will identify, report, and track, adverse events, and high risk, high volume, and/or problem-prone concerns; or

- Establish priorities for its improvement activities, that focus on high-risk, high-volume or problem-prone areas, as well as resident safety, choice, autonomy, and quality of care; or

- Ensure the QAA Committee developed and implemented action plans to correct identified quality deficiencies; or

- Measure the success of actions implemented and track performance to

ensure improvements are realized and sustained; or

- Track medical errors and adverse events, analyze their causes, and implement preventive actions and mechanisms; or

- Conduct at least one PIP annually that focuses on high-risk or problem prone areas, identified by the facility, through data collection and analysis; or

- Ensure the QAA Committee regularly reviews and analyzes data collected under the QAPI program and resulting from drug regimen reviews, and act on the data to make improvements.

DEFICIENCY CATEGORIZATION

Examples of Level 4, 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. QAPI review showed the facility failed to use (e.g. review or analyze) the data they collected for routine monitoring of hot water temperatures throughout the facility. The failure of the facility to use the data it collected, resulted in lack of action to correct the systemic, high-risk issue, which created a situation where some residents were likely to experience serious injury, harm, impairment, or death.

- 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. QAPI review showed the QAA committee was not aware of this high-risk, systemic issue, and was not monitoring facility practices related to accurate and consistent communication of residents' advance directives and code status.

***An e*xample~~s~~ of Level 3, actual harm that is not immediate jeopardy include*s*, but is not limited to:**

- 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 QAPI review showed the QAA committee was not aware of the issue and was not monitoring practices around discharge.

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:

- Facility failed to correct and monitor a quality deficiency identified on the previous survey, involving inaccurate weight measurement. This issue has the potential to cause more than minimal harm.

An example of 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.

F880

(Rev. 229; Issued: 04-25-25; Effective: 04-25-25; Implementation: 04-28-25)

§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 diseases and infections.

§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 §483.71 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.

(iv) 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

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, reporting, investigation and control of infections and communicable diseases of residents, staff, and visitors. It must include an ongoing system of surveillance designed to identify possible communicable diseases and 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 all facility staff (direct and indirect care functions), contracted staff, consultants, volunteers, others 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:

    - Define standard precautions to prevent the spread of infection and explain their application during resident care activities;

    - Define transmission-based precautions and explain how and when they 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 to follow hand hygiene practices consistent with accepted standards of practice.

- Requires staff to 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" refer to 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.[1]

"Alcohol-based hand rub (ABHR)" refers to a 60-95 percent ethanol or isopropyl alcohol-containing preparation base designed for application to the hands to reduce the number of viable microorganisms.

"C. difficile infection (CDI)" refers to an infection from a bacterium that causes colitis, an inflammation of the colon, causing diarrhea.

"Cleaning" refers to 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" refers to 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).[2] During outbreaks, healthcare staff may be assigned to a specific cohort of residents to further limit opportunities for transmission (cohorting staff). The term "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" refers to the presence of microorganisms on or within body sites without detectable host immune response, cellular damage, or clinical expression.[3]

"Communicable disease (also known as (a.k.a.) "contagious disease")" refers to 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')**"** refer to infections that are present or incubating at the time of admission and which generally develop within 72 hours of admission.

"Contact precautions" refer to 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.[4]

"Contaminated laundry" refers to laundry which has been soiled with

blood/body fluids or other potentially infectious materials or may contain sharps.

"Decontamination" refers to 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" refers to 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.[5]

"Disinfection" refers to 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).[6]

"Droplet precautions" refer to actions designed to reduce/prevent the transmission of pathogens spread through close respiratory or mucous membrane contact with respiratory secretions.

"Enhanced Barrier Precautions" (EBP) *refer to an infection control intervention designed to reduce transmission of multidrug-resistant organisms that employs targeted gown and glove use during high contact resident care activities.*

"Hand hygiene" refers to a general term that applies to hand washing, antiseptic handwash, and alcohol-based hand rub.[7]

"Hand washing" refers to washing hands with soap and water.[8]

"Healthcare-associated infection (HAI)" refers to 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" refers to being free of pathogens in sufficient numbers to cause human illness.[9]

"Infection" refers to 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.).

"Infection preventionist" refers to the person(s) designated by the facility to be responsible for the infection prevention and control program as specified in §483.80(b) (F882).

"Legionellosis" refers to two clinically and epidemiologically distinct illnesses: Legionnaires' disease, which is typically characterized by fever, myalgia, cough, and clinical or radiographic pneumonia; and Pontiac fever, a milder illness without pneumonia (e.g., fever and muscle aches). Legionellosis is caused by Legionella bacteria**.**

"Multidrug-resistant organisms (MDROs)" refer to microorganisms, predominantly bacteria that are resistant to one or more classes of antimicrobial agents. Although the names of certain MDROs describe resistance to only one agent, these pathogens are frequently resistant to most available antimicrobial agents.

"Personal protective equipment (PPE)" refers to protective items or garments worn to protect the body or clothing from hazards that can cause injury and to protect residents from cross-transmission.

"Standard precautions" refer to the infection prevention practices that apply to all residents, regardless of suspected or confirmed diagnosis or presumed infection status. Standard precautions *are* 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 resident's 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 hand hygiene, proper selection and use of personal protective equipment, safe injection practices, respiratory hygiene/cough etiquette, environmental cleaning and disinfection, and reprocessing of reusable resident medical equipment.[10, 11]

"Transmission-based precautions (a.k.a. "Isolation Precautions")" refer to 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 by the healthcare community and used in this guidance will refer to "transmission-based precautions" instead of "isolation" as these terms can be used interchangeably.

> **NOTE:** References to non-CMS sources 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 and referenced documents were current as of the date of this publication. Guidelines change, and facilities are responsible for following the most current standards.

GUIDANCE

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 accepted national standards and guidelines.

We expect facilities to tailor the emphasis of their IPCP for visitors and to work to prevent transmission of infection to the resident from the visitor using reasonable precautions and national standards.[12] For example, "screening may be passive through the use of signs to alert family members and visitors with signs and symptoms of communicable diseases not to enter. More active screening may include the completion of a screening tool or questionnaire which elicits information related to recent exposures or current symptoms. That information is reviewed by the facility staff and the visitor is either permitted to visit or is excluded."[13]

The Infection Prevention and Control Program must include, at a minimum, the following parts:

- A system for preventing, identifying, reporting, investigating, and controlling infections and communicable diseases that:
  - Covers all residents, staff, contractors, consultants, volunteers, visitors, others 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;
  - Is based on the individual facility assessment conducted under §483.71; and
  - 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) pursuant to §483.80(a)(3) (for more information on ASP requirements, see F881).

Facility Assessment

Pursuant to §483.*71* (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, among other things, a facility-based and community-based risk assessment, utilizing an all-hazards approach. See §483.*71* (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.[14]

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 infection control standards of practice based on recognized guidelines and facility assessment are incorporated in the resident care policies and procedures. These IPCP policies and procedures must include, at a minimum, the following:

- As necessary, and at least annually, review and revision of the IPCP based upon the facility assessment (according to 483.71) 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;

- Define and explain standard precautions and their application during resident care activities. Define transmission-based precautions (i.e., contact precautions, droplet precautions, airborne precautions) and explain how and when they should be utilized, as consistent with accepted national standards. The areas listed below are examples of standard and/or transmission-based precautions[15] which are further described under their respective sections:
-
    - Hand hygiene (HH) (e.g., hand washing and/or ABHR): consistent with accepted standards of practice such as the preferential use of ABHR instead of soap and water in most clinical situations except when hands are visibly soiled[16] (e.g., blood, body fluids), or after caring for a resident with known or suspected C. difficile or norovirus infection during an outbreak, or if rates of C. difficile infection (CDI) are high; in these circumstances, soap and water should be used;[17]

      NOTE: According to the Centers for Disease Control and Prevention (CDC),
      strict adherence to glove use is the most effective means of preventing hand contamination with C. difficile spores as these spores are not killed by ABHR and may be difficult to remove even with thorough hand washing. Additional information on appropriate hand hygiene practices may be found in CDC's Hand Hygiene in Healthcare Settings website at
      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;

- 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);[18]

- The process to manage a resident on transmission-based precautions when a single/private room is not available;

- Limiting the movement of a resident who is on transmission-based precautions to medically necessary purposes only;[19]

- Respiratory Hygiene/Cough Etiquette: implementing policies and procedures would include providing resources and instructions for performing HH in or near lobby areas or entrances in accordance with accepted national standards. During times of increased prevalence of respiratory infections in the community, facilities should have facemasks available and offer them to visitors and others entering the facility. In addition, the facility should post signs with instructions on visitation restrictions for those with symptoms of respiratory infection or other communicable diseases;[20] and

- Environmental cleaning and disinfection:
  - Routine cleaning and disinfection of frequently touched or visibly soiled surfaces in common areas, resident rooms, and at the time of discharge; and

    NOTE: Privacy curtains should be changed when visibly dirty and should be laundered or disinfected with an Environmental Protection Agency (EPA)-registered disinfectant per the curtain and disinfectant manufacturer's instructions.

  - Routine cleaning and 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 should address:

  - Reporting of staff illnesses and following work restrictions per nationally recognized standards and guidelines;[21, 22]

- Prohibiting contact with residents or their food when staff have potentially communicable diseases or infected skin lesions;

- Assessing risks for tuberculosis (TB) based on exposure or cases of TB in the facility. Then screen staff for TB to the extent permitted under applicable federal guidelines[23] and state law;

- Monitoring and evaluating for clusters or outbreaks of illness among staff; and

- Implementing an exposure control plan in order to address potential hazards posed by blood and body fluids (e.g., from dialysis, glucose monitoring or any other point of care testing).

- Facilities must ensure staff follow the IPCP's standards, policies and procedures. 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 PPE) while other needs are specific to particular roles, responsibilities, and situations (e.g., injection safety and point of care testing); and

- 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, the facility should determine how it will track the extent to which staff are following the facility's IPCP policies and procedures, and facilities should address any areas that need 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, the CDC's National Healthcare Safety Network (NHSN) Long Term Care Criteria to define infections or updated McGeer criteria.[24] 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.[25] 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.[26] When a resident is transferred, the information provided to the receiving provider must include special instructions or precautions (e.g., transmission-based precautions, if applicable) for ongoing care and other necessary information including a discharge summary (if discharged). 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 §483.15(c)(2)(iii), *Discharge Process, Information provided to the receiving provider* and §483.21(c)(2), Discharge Summary *at* (F62*8*) for further information on these requirements.
Additionally, as part of the overall IPCP for surveillance, the facility shall establish process and outcome surveillance.

Process Surveillance

Process surveillance is the review of practices by staff directly related to resident care.[27] 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 (e.g., objective methods for evaluation may include direct practice observation, fluorescent markers, adenosine triphosphate (ATP) bioluminescence (a method for quantifying the concentration of environmental microorganisms), or swab cultures used primarily for outbreak investigation[28]);

- 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: Additional information related to examples of nationally accepted surveillance definitions may be found at the "CDC/SHEA Position Statement: Surveillance Definitions of Infections in Long-Term Care Facilities: Revisiting the McGeer Criteria[29]" or NHSN at https://www.cdc.gov/nhsn/.

The following are some sources of data that can be utilized in outcome

surveillance for infections, and 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
- Transfer/discharge summaries for new or readmitted residents for infections.[30]

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 possible 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 of disease than expected in a given area or among a specific group of people over a particular period of time.[31] 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. 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.

NOTE: Some states have specific regulations regarding responding to and reporting outbreaks that must be included in the IPCP.

NOTE: If there are concerns that actions taken by the facility are not addressing public health authority instructions to contain and remedy the outbreak, the SA must notify the appropriate local/state public health authority. **If surveyors cite this tag for an outbreak, utilize the guidelines in Appendix Q to determine if immediate jeopardy exists.**

Water Management

The bacterium Legionella can cause a serious type of pneumonia called Legionnaires' Disease in persons at risk, such as those who are at least 50 years old, smokers, or with underlying medical conditions such as chronic lung disease or immunosuppression. Legionella can grow in parts of building water systems that are continually wet (e.g., pipes, faucets, water storage tanks, decorative

fountains), and certain devices can spread contaminated water droplets via aerosolization.

Legionellosis outbreaks are generally linked to locations where water is held or accumulates and pathogens can reproduce, including those found in long-term care facilities. Transmission from these water systems to humans occurs when the water is aerosolized (i.e., converted into a spray/mist in the air). Legionella is less commonly spread by aspiration of drinking water or ice.

Facilities must be able to demonstrate its measures to minimize the risk of Legionella and other opportunistic pathogens in building water systems such as by having a documented water management program. Water management must be based on nationally accepted standards (e.g., ASHRAE (formerly the American Society of Heating, Refrigerating, and Air Conditioning Engineers), CDC, U.S. Environmental Protection Agency or EPA) and include:

- An assessment to identify where Legionella and other opportunistic waterborne pathogens (e.g., Pseudomonas, Acinetobacter) could grow and spread; and

- Measures to prevent the growth of opportunistic waterborne pathogens (also known as control measures), and how to monitor them.

Examples of an assessment include a description of the building water systems using text and flow diagrams for identification. Additionally, control measures may include visible inspections, use of disinfectant, and temperature (that may require mixing valves to prevent scalding). Monitoring such controls include testing protocols for control measures, acceptable ranges, and documenting the results of testing. Water management should also include established ways to intervene when control limits are not met.

An industry standard calling for the development and implementation of water management programs in large or complex building water systems to reduce the risk of legionellosis was published by ASHRAE. The CDC and its partners developed a toolkit to facilitate implementation of this ASHRAE Standard.

Resources are available to develop and implement a water management program, such as:

- "The ASHRAE Standard 188- Legionellosis: Risk Management for Building Water Systems" https://www.ashrae.org;

- The CDC toolkit to facilitate implementation of the ASHRAE Standard titled "Developing a Water Management Program to Reduce Legionella Growth & Spread in Buildings: A

Practical Guide to Implementing Industry Standards" https://www.cdc.gov/legionella/wmp/toolkit/index.html; and

- The EPA's "Technologies for Legionella Control in Premise Plumbing Systems: Scientific Literature Review" is available at https://www.epa.gov/ground-water-and-drinking-water/technologies-legionella-control-premise-plumbing-systems.

At this time, CMS does not require water cultures for Legionella or other opportunistic waterborne pathogens as part of routine program validation, although there may be instances when it is needed (e.g., a case of healthcare-associated legionellosis or a potential outbreak of legionellosis in the facility).

The facility should contact the local/state public health authority if there is a case of healthcare-associated legionellosis or an outbreak of an opportunistic waterborne pathogen causing disease. The facility must follow public health authority recommendations which may include, but is not limited to, remediating the pathogen reservoir and adjusting control measures as necessary. The SA should work with local/state public health authorities, if possible, to determine if the water management program was inadequate to prevent the growth of Legionella or other opportunistic waterborne pathogens and whether the facility implemented adequate prevention and control measures once the issue was identified.

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;[32]

- The hepatitis B virus can last up to a week on inanimate surfaces;[33] 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.[34]

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.

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, staff, and visitors, and ensuring staff do not carry infectious pathogens on their hands or via equipment during resident care. As mentioned above in the definitions section, standard precautions include hand hygiene, selection and use of PPE (e.g., gloves, gowns, facemasks, respirators, eye protection), respiratory hygiene and cough etiquette, safe injection practices, environmental cleaning and disinfection, and reprocessing of reusable resident medical equipment. [35, 36]

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 involved in direct resident contact must perform hand hygiene (even if gloves are used).

Hand hygiene is performed[37]:

- 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.

Certain PPE may be required when working in the facility, such as use of facemasks or eye protection during a respiratory virus pandemic. Additionally, 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 resident care or procedures that are likely to contaminate mucous membranes, or generate splashes or sprays of blood, body fluids, secretions or excretions;

- 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.

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**: Additional information related to environmental cleaning may be found in CDC and the Healthcare Infection Control Practices Advisory Committee's (HICPAC) "Guidelines for Environmental Infection Control in Health-Care Facilities (2003)" at https://www.cdc.gov/infectioncontrol/guidelines/environmental/index.html.

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).[38]

The CDC has adopted the Spaulding classification system that identifies three risk levels associated with medical and surgical instruments: critical, semi-critical, and noncritical items.

- 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. Sterilization destroys all viable microorganisms to prevent disease transmission associated with the use of that item. 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 an 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). Non-critical items require cleaning followed by either low- or intermediate-level disinfection following manufacturers' instructions. Disinfection should be performed with an EPA-registered disinfectant labeled for use in healthcare 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).[39]

    - Low-level disinfection is traditionally defined as the destruction of all vegetative bacteria (except tubercle bacilli) and most viruses, some fungi, but not bacterial spores. Examples of low-level disinfectants include EPA-registered hospital disinfectants with an HBV and HIV label claim. Low-level disinfection is generally appropriate for most non-critical equipment.

    - Intermediate-level disinfection is traditionally defined as destruction of all vegetative bacteria, including tubercle bacilli, lipid and some nonlipid viruses, and fungi, but not bacterial spores. EPA-registered hospital disinfectants with a tuberculocidal claim are intermediate-level disinfectants. Given the broader spectrum of activity, intermediate-level disinfection should be considered for non-critical equipment that is visibly contaminated with blood. However, a low-level disinfectant with a label claim against HBV and HIV could also be used.[40,41]

Single-use disposable equipment is an alternative to reprocessing 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 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: Additional information related to disinfection and sterilization may be found in CDC's "Guideline for Disinfection and Sterilization in Healthcare Facilities (2008)" at https://www.cdc.gov/infectioncontrol/guidelines/Disinfection/index.html.

Enhanced Barrier Precautions (EBP)

EBP are used in conjunction with standard precautions and expands the use of PPE to donning of gown and gloves during high-contact resident care activities that provide opportunities for transfer of MDROs to staff hands and clothing.

EBP are indicated for residents with any of the following:

- *Infection or colonization with a CDC-targeted MDRO when Contact Precautions do not otherwise apply; or*
- *Wounds and/or indwelling medical devices even if the resident is not known to be infected or colonized with a MDRO.*

Wounds generally include chronic wounds, not shorter-lasting wounds, such as skin breaks or skin tears covered with an adhesive bandage (e.g., Band-Aid®) or similar dressing. Examples of chronic wounds include, but are not limited to, pressure ulcers, diabetic foot ulcers, unhealed surgical wounds, and venous stasis ulcers.

Indwelling medical device examples include central lines, urinary catheters, feeding tubes, and tracheostomies. A peripheral intravenous line (not a peripherally inserted central catheter) is not considered an indwelling medical device for the purpose of EBP.

EBP should be used for any residents who meet the above criteria, wherever they reside in the facility.

*Facilities **have discretion** in using EBP for residents who do not have a chronic wound or indwelling medical device and are infected or colonized with an MDRO that is not currently targeted by CDC.*

Implementing Contact versus Enhanced Barrier Precautions

This table only applies to MDROs not all pathogens that may require use of transmission-based precautions.

Resident Status	***Contact Precautions***	***Use EBP***
Infected or colonized with any MDRO and has secretions or excretions that are unable to be covered or contained	*Yes*	*No*
*Infected or colonized with a CDC-targeted MDRO **without** a wound, indwelling medical device or secretions or excretions that are unable to be covered or contained.*	*No*	*Yes*

Resident Status	***Contact Precautions***	***Use EBP***
*Infected or colonized with a non-CDC targeted MDRO **without** a wound, indwelling medical device, or secretions or excretions that are unable to be covered or contained.*	*No*	*At the discretion of the facility*
*Has a wound or indwelling medical device, **and** secretions or excretions that are unable to be covered or contained and are not known to be infected or colonized with any MDRO.*	*Yes, unless/until a specific organism is identified.*	*Yes, if they do not meet the criteria for contact precautions.*
*Has a wound or indwelling medical device, **without** secretions or excretions that are unable to be covered or contained and are not known to be infected or colonized with any MDRO.*	*No.*	*Yes.*

Examples of secretions or excretions include wound drainage, fecal incontinence or diarrhea, or other discharges from the body that cannot be contained and pose an increased potential for extensive environmental contamination and risk of transmission of a pathogen.

For residents whom EBP are indicated, EBP is employed when performing the following high-contact resident care activities:

- *Dressing*
- *Bathing/showering*
- *Transferring*
- *Providing hygiene*
- *Changing linens*
- *Changing briefs or assisting with toileting*
- *Device care or use: central line, urinary catheter, feeding tube, tracheostomy/ventilator*
- *Wound care: any skin opening requiring a dressing*

***Note**: In general, gowns and gloves would not be recommended when performing transfers in common areas such as dining or activity rooms, where contact is anticipated*

to be shorter in duration. Outside the resident's room, EBP should be followed when performing transfers or assisting during bathing in a shared/common shower room and when working with residents in the therapy gym, specifically when anticipating close physical contact while assisting with transfers and mobility.

Residents are not restricted to their rooms or limited from participation in group activities. Because EBP do not impose the same activity and room placement restrictions as Contact Precautions, they are intended to be in place for the duration of a resident's stay in the facility or until resolution of the wound or discontinuation of the indwelling medical device that placed them at higher risk.

Facilities have discretion on how to communicate to staff which residents require the use of EBP. CMS supports facilities in using creative (e.g., subtle) ways to alert staff when EBP use is necessary to help maintain a home-like environment, as long as staff are aware of which residents require the use of EBP prior to providing high-contact care activities..

Facilities should ensure PPE and alcohol-based hand rub are readily accessible to staff. Discretion may be used in the placement of supplies which may include placement near or outside the resident's room. PPE for enhanced barrier precautions is only necessary when performing high-contact care activities and may not need to be donned prior to entering the resident's room. For example, staff entering the resident's room to answer a call light, converse with a resident or provide medications ***and*** *who do* ***not*** *engage in a high-contact resident care activity would likely not need to employ EBP while interacting with the resident.*

Information regarding CDC-targeted MDROs and current recommendations on Enhanced Barrier Precautions are available on the CDC's Implementation of Personal Protective Equipment (PPE) Use in Nursing Homes to Prevent Spread of Multidrug-resistant Organisms (MDROs) webpage at https://www.cdc.gov/hai/containment/PPE-Nursing-Homes.html.

Surveyors will evaluate the use of EBP when reviewing sampled residents for whom EBP are indicated and focus their evaluation of EBP use as it relates to CDC-targeted MDROs.

Transmission-based Precautions

There are three categories of transmission-based precautions: contact precautions, droplet precautions, and airborne precautions. Transmission-based precautions are used when the route(s) of transmission is (are) not completely interrupted using standard precautions alone. For some diseases that have multiple routes of transmission, more than one transmission-based precautions category may be required. Whether used singly or in combination, they must

always be used in addition to standard precautions. The type of PPE and precautions used depends on the potential for exposure, route of transmission, and infectious organism/pathogen (or clinical syndrome if an organism is not yet identified).

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.[42, 43]

The facility should initiate transmission-based precautions for a constellation of new symptoms consistent with a communicable disease. Empirically initiated transmission-based precautions may be adjusted or discontinued when additional clinical information becomes available (e.g., confirmatory laboratory results).

Facility policies must identify the type (i.e., contact, droplet, airborne) and duration of the transmission-based precautions required, depending upon the infectious pathogen involved. Residents on transmission-based precautions should remain in their rooms except for medically necessary care.[44] 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 *are* not to be considered involuntary seclusion. However, once the resident is no longer a risk for transmitting the pathogen (e.g., duration of the illness and/or can contain secretions), removing transmission-based precautions is required in order to avoid unnecessary involuntary seclusion.

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:

- 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 based on the pathogen and method of transmission.[45]

When a resident is placed on transmission-based precautions, facility staff should implement the following:

- Clearly identify the type of precautions and the appropriate PPE to be used;

- Place signage that includes instructions for use of specific PPE in a conspicuous location outside the resident's room (e.g., on the door or on the wall next to the doorway), wing, or facility-wide. Additionally, either the CDC category of transmission-based precautions (e.g., contact, droplet, or airborne) or instructions to see the nurse before entering should be included in signage. 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 before or upon entry into the environment (e.g., room or cubicle) of a resident on transmission-based precautions (e.g., contact precautions);

- 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;[46]

- 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;[47] 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.

Resources are available for current recommendations on standard and transmission-based precautions, such as:

- "Guidelines for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings (2007)" https://www.cdc.gov/infectioncontrol/guidelines/isolation/index.html; and

- "Management of Multidrug-resistant Organisms In Healthcare Settings (2006)" https://www.cdc.gov/infectioncontrol/guidelines/mdro/index.html.

Contact Precautions

Contact precautions are intended to prevent transmission of pathogens that are spread by direct (e.g., person-to-person) or indirect contact with the resident or environment (e.g., C. difficile, norovirus, scabies), and requires the use of appropriate PPE, including a gown and gloves before or 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.

Contact precautions should also be used in situations when a resident is experiencing wound drainage, fecal incontinence or diarrhea, or other discharges from the body that cannot be contained and suggest an increased potential for extensive environmental contamination and risk of transmission of a pathogen, even before a specific organism has been identified.

MDRO Colonization and Infection

Contact precautions are used for residents infected or colonized with MDROs in the following situations:

- *Presence of acute diarrhea, draining wounds or other sites of secretions or excretions that are unable to be covered or contained;*

- *Co-infection with another organism for which Contact Precautions is recommended (e.g., norovirus);*

- *For a limited time period, as determined in consultation with public health authorities, on units or in facilities during the investigation of a suspected or confirmed MDRO outbreak; and*

- *When otherwise directed by public health authorities.*

PPE *should* be used for residents who do not meet criteria *above* for contact precautions but are infected or colonized with MDROs (or have risk factors for MDRO acquisition). *See the section on EBP in this guidance.*

NOTE: Additional information related to MDROs may be found in CDC's "Implementation of Personal Protective Equipment in Nursing Homes to Prevent Spread of Novel or Targeted Multidrug-resistant Organisms (MDROs)" at https://www.cdc.gov/hai/containment/PPE-Nursing-Homes.html.

Droplet Precautions

The use of droplet precautions applies when respiratory droplets contain pathogens which may be spread to another susceptible individual. Respiratory pathogens can enter the body via the nasal mucosa, conjunctivae and less frequently the mouth.[48] Examples of droplet-borne organisms that may cause infections include, but are not limited to Mycoplasma pneumoniae, influenza, and other respiratory viruses.

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.[49] The maximum distance for droplet transmission is currently unresolved, but the area of defined risk based on epidemiological findings is approximately 3-10 feet.[50] In contrast to airborne pathogens, droplet-borne pathogens are generally not transmitted through the air over long distances.

Facemasks should be used upon entry into a resident's room or cubicle with respiratory droplet precautions.[51] Based upon the pathogen or clinical syndrome, if there is risk of exposure of mucous membranes or substantial spraying of respiratory secretions is anticipated, gloves and gown as well as goggles (or face shield in place of goggles) should be worn.[52] The preference for a resident on droplet precautions would be to place the resident in a private room.[53] If a private room is not available, the resident could be cohorted with a resident with the same infectious agent. If it becomes necessary for a resident who requires droplet precautions to share a room with a resident who does not have the same infection, the facility should make decisions regarding resident placement on a case-by-case basis after considering infection risks to other residents in the room and available alternatives.[54] Spatial separation and drawing the curtain between resident beds is especially important for residents in multi-bed rooms with infections transmitted by the droplet route.[55] A resident who is on droplet precautions for the duration of the illness (e.g.,

influenza), should wear a facemask (e.g., surgical or procedure facemask) when leaving his/her room.

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.[56]

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.[57]

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.[58]

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).

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 SA must notify the appropriate local/state public health authority of the deficient practice.

Resources are available on fingerstick safety, such as:

"CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens"
https://www.cdc.gov/injectionsafety/fingerstick-devicesbgm.html; and

- CDC's Frequently Asked Questions (FAQs) regarding Assisted Blood Glucose Monitoring and Insulin Administration 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. FDA's "Letter to Manufacturers of Blood Glucose Monitoring Systems Listed With the FDA" can be found at:
https://public4.pagefreezer.com/browse/FDA/12-01-2022T02:57/https:/www.fda.gov/medical-devices/in-vitro-diagnostics/letter-manufacturers-blood-glucose-monitoring-systems-listed-fda

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."[59]

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 blood glucose meters per device and disinfectant manufacturer's instructions for use, they are used for more than one resident, and there is a resident with a known bloodborne pathogen in the facility, surveyors must cite noncompliance under this tag and utilize the guidelines in Appendix Q for determining immediate jeopardy. Furthermore, the SA must notify the appropriate local/state public health authority of this practice. Other instances of deficiencies may meet the definition of immediate jeopardy; utilize guidelines in Appendix Q to make this determination.

NOTE: Additional information related to point-of-care testing may be found in CDC's Infection Prevention during Blood Glucose Monitoring and Insulin Administration 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, which include but are 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 determining immediate jeopardy. The SA must notify the appropriate local/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 determining immediate jeopardy. The SA must notify the appropriate local/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 determining immediate jeopardy. The SA must notify the appropriate local/state 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: Additional information related to multi-dose vials may be found in CDC's Questions about Multi-dose vials website at

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 determining immediate jeopardy.** The SA must notify the appropriate local/state public health authority of the finding.

NOTE: Additional information related to insulin pens may be found in FDA's "Drug Safety Communication: FDA requires label warnings to prohibit sharing of multi-dose diabetes pen devices among patients" at https://www.fda.gov/drugs/drugsafety/ucm435271.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. Resources are available for current standards of practice for the care of CVCs, such as:

- CDC's "Basic Infection Control and Prevention Plan for Outpatient Oncology Settings" https://www.cdc.gov/hai/settings/outpatient/basic-infection-control-prevention-plan-2011/index.html;
- CDC's "Hemodialysis Central Venous Catheter Scrub-the-Hub Protocol" http://www.cdc.gov/dialysis/PDFs/collaborative/Hemodialysis-Central-Venous-Catheter-STH-Protocol.pdf;
- CDC's "Audit Tool: Catheter Exit Site Care Observations" http://www.cdc.gov/dialysis/PDFs/collaborative/Catheter-Exit-Site-Care-Observations.pdf; and
- CDC's "Guidelines for the Prevention of Intravascular Catheter-Related Infections (2011)" https://www.cdc.gov/infectioncontrol/guidelines/index.html/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 in accordance with §483.80(a)(4). 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

Under §483.80(e), the facility must develop and follow practices on handling, storing, processing, and transporting laundry so as to prevent the spread of infection. 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 manner.

Handling Laundry

The facility staff should handle all used laundry as potentially contaminated and use standard precautions (e.g., gloves, gowns when sorting and rinsing). The facility should use the following practices[60]:

- Contaminated laundry is bagged or contained at the point of collection (i.e., location where it was used);
- Leak-resistant containers or bags are used for linens or textiles contaminated with blood or body substances;
- Sorting and rinsing of contaminated laundry at the point of use, hallways, or other open resident care spaces is prohibited; and
- Staff should handle soiled textiles/linens with minimum agitation to avoid the contamination of air, surfaces, and persons.

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 when transporting;

- No special precautions (e.g., double bagging, melting bags) or categorizing (e.g. biohazard, color-coded) for linen originating in transmission-based precaution rooms is necessary;[61]

- 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;[62]

- Contaminated linen carts must be cleaned and disinfected whenever visibly soiled and according to a schedule developed by the facility;
- 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[63]

- 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.[64]

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);[65] and

- 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.

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 include but are not limited to the following[66]:

- Availability and use of hand hygiene products, as well as appropriate PPE (i.e., gloves and gowns) while sorting and handling contaminated linens;

- The receiving area for contaminated textiles is clearly separated from clean laundry areas. Workflow should prevent cross-contamination;

- 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);

- Laundry equipment (e.g., washing machines, dryers) is used and maintained according to the manufacturer's IFU to prevent microbial contamination of the system;

- Damp laundry is not left in machines overnight;

- Laundry detergents, rinse aids or other additives are used according to the manufacturer's IFU. **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); 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 160°F (71°C) for 25 minutes; and

    - For laundry that is not hot water compatible, low temperature washing at 71 to 77 °F (22-25 °C) plus chlorine or oxygen-activated bleach can reduce microbial contamination.

    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 practices[67] include, but are not limited to, the following:

- 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

Under §483.80(f), 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 PROCEDURES

Use the Infection Prevention, Control & Immunizations Facility Task, along with the above interpretive guidance, when determining if the facility meets the requirements for, or when investigating concerns related to, infection prevention and control. One surveyor should coordinate the review of the facility's overall 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. If potential non-compliance is identified, the surveyor should corroborate those concerns through observations, interviews, and record and/or document review.

Observations

Specific observations for the provision of infection prevention and control practices such as following standard precautions *and EBP* (e.g., hand hygiene and the appropriate use of PPE) should be made by all team members throughout the survey. Observe care of residents 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 on transmission-based precautions.

Observe laundry services throughout the survey (e.g., resident and laundry rooms) to determine whether staff handle, store, process, 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.

POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION

- F945: for concerns related to staff training on the standards, policies, and procedures of the infection prevention and control program;

- F726: for staff competency concerns related to Nursing Services;

- F741: for staff competency concerns related to Behavioral Health staff caring for residents with dementia or a history of trauma and/or post-traumatic stress disorder;

- F801: for staff competency concerns related to Food and Nutrition staff;

- F839: for staff competency concerns related to Administration for any other staff not referenced above;

- F550 and F675: for concerns related to 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;

- F603: for concerns related to possible involuntary seclusion;

- F755: for concerns related to reconciliation of data from injectable, scheduled drug tracking;

- F867: for concerns related to the QAA committee's responsibility to identify or correct quality deficiencies, which may include systemic infection control concerns;

- F841: for concerns related to the medical director's role in responsibility for care;
- F684: for concerns related to the provision of wound care;

- F686: for concerns related to the provision of pressure ulcer care;

- F690: for concerns related to the provision of urinary catheter care;

- F694: for concerns related to the administration of parenteral fluids; and

- F695: for concerns related to the provision of respiratory care.

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; or

- The IPCP must be reviewed at least annually and updated as necessary; or

- 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 §483.71] and follows accepted national standards; or

- 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; or

    - Developing and implementing a system of surveillance to identify infections or communicable diseases; or

    - How to use standard precautions (to include appropriate hand hygiene) and how and when to use transmission-based precautions (i.e., "isolation precautions"); 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; or

- Assure that staff handle, store, process and transport laundry to prevent the spread of infection; or

- Maintain a system for recording identified incidents and taking appropriate corrective actions.

DEFICIENCY CATEGORIZATION

Examples of Level 4 immediate jeopardy to resident health and 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.

- The facility failed to provide a safe and sanitary environment. Staff failed to handle linens so as to prevent the spread of infection. Staff rinsed contaminated linens in the resident's sink instead of in the facility's dedicated area. Furthermore, the staff did not clean and disinfect the bathroom sink after rinsing soiled clothing and linens in the shared bathroom sink. 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.

- The facility failed to ensure that its staff demonstrated the proper use of gloves with hand hygiene between residents to prevent the spread of infection. The registered nurse (RN) was observed wearing gloves while providing direct care to a resident who was on contact precautions for an infection with a multidrug-resistant organism. The RN left the room after removing the gloves but did not conduct hand hygiene, went to a second resident and started providing direct care. As a result, the second resident was likely exposed through indirect contact transmission to the MDRO, creating the likelihood of serious injury, serious harm, serious impairment,

or death.

- *The facility failed to initiate an outbreak investigation and implement preventative measures to address transmission of COVID-19 among residents in one unit of the facility. Subsequently, one or more residents in an adjoining unit became seriously ill with contracted COVID-19 resulting in hospitalization for some residents.*

Examples of Level 3, actual harm that is not immediate jeopardy include, but are 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.

- *The facility failed to prevent the transmission of COVID-19 between residents. Resident #1, who had COVID-19 symptoms, was not tested for COVID-19 prior to being placed in a room with a resident (Resident #2) who was not known to have COVID-19 and who did not have COVID-19 symptoms. This failure resulted in Resident #2, contracting COVID-19 and developing moderate illness.*

Examples of Level 2, 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 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 gown, and carrying the contaminated linens against his/her uniform 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.

- *During the survey, staff were observed entering a COVID-19 unit housing cognitively impaired residents through a stairwell entrance without donning necessary PPE. PPE was necessary when entering the unit because the cognitively impaired residents with COVID-19 could not be restricted to their room. Staff indicated they were unaware of the need for donning PPE prior to entering this unit. Signs were not in place at all entrances to the designated COVID-19 unit indicating the need for PPE prior to entering. Staff who entered the COVID unit without wearing PPE promptly donned the necessary PPE and no additional residents or staff developed COVID-19 in the days following the observation. The lack of signage at the stairwell entrance of the COVID-19 unit resulted in staff not donning appropriate PPE prior to entering, which caused staff to no be properly protected and increased the risk of COVID-19 transmission.*

An example of Level 1, 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.

F887
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§483.80 Infection control

§483.80(d)(3) COVID-19 immunizations. The LTC facility must develop and implement policies and procedures to ensure all the following:

(i) When COVID-19 vaccine is available to the facility, each resident and staff member is offered the COVID-19 vaccine unless the immunization is medically contraindicated or the resident or staff member has already been immunized;

(ii) Before offering COVID-19 vaccine, all staff members are provided with education regarding the benefits and risks and potential side effects associated with the vaccine;

(iii) Before offering COVID-19 vaccine, each resident or the resident representative receives education regarding the benefits and risks and potential side effects associated with the COVID-19 vaccine;

(iv) In situations where COVID-19 vaccination requires multiple doses, the resident, resident representative, or staff member is provided with current information regarding those additional doses, including any changes in the benefits or risks and potential side effects, associated with the COVID-19 vaccine, before requesting consent for administration of any additional doses.

(v) The resident or resident representative, has the opportunity to accept or refuse a COVID-19 vaccine, and change their decision; and

(vi) The resident's medical record includes documentation that indicates, at a minimum, the following:

(A) That the resident or resident representative was provided education regarding the benefits and potential risks associated with COVID-19 vaccine; and

(B) Each dose of COVID-19 vaccine administered to the resident, or

(C) If the resident did not receive the COVID-19 vaccine due to medical contraindications or refusal.

(vii) The facility maintains documentation related to staff COVID-19 vaccination that includes at a minimum, the following:

(A) That staff were provided education regarding the benefits and potential risks associated with COVID-19 vaccine;

(B) Staff were offered the COVID-19 vaccine or information on obtaining COVID-19 vaccine; and

(C) The COVID-19 vaccine status of staff and related information as indicated by the Centers for Disease Control and Prevention's National Healthcare Safety Network (NHSN).

DEFINITIONS

"Staff" *refers to those individuals who work in the facility on a regular (that is, at least once a week) basis, including individuals who may not be physically in the LTC facility for a period of time due to illness, disability, or scheduled time off, but who are expected to return to work. This also includes individuals under contract or arrangement, including hospice and dialysis staff, physical therapists, occupational therapists, mental health professionals, or volunteers, who are in the facility on a regular basis, as the vaccine is available.*

"Emergency Use Authorization (EUA)" *refers to a mechanism to facilitate the availability and use of medical countermeasures, including vaccines, during public health emergencies, such as the COVID-19 pandemic. The EUA process is a way to ensure safety while still expediting approval in emergent situations.*

GUIDANCE

In order to protect LTC residents from COVID-19, each facility must develop and implement policies and procedures that meet each resident's, resident representative's, and staff member's information needs and provides vaccines to all residents and staff that elect them.

Education

All residents and/or resident representatives and staff must be educated on the COVID-19 vaccine they are offered, in a manner they can understand, and should receive the Food and Drug Administration (FDA) COVID-19 EUA Fact Sheet for vaccines under an EUA or the CDC Vaccine Information Statement (VIS) for FDA approved vaccines, before being offered the vaccine. The FDA requires that vaccine recipients or their representative are provided with certain vaccine-specific EUA information to help make an informed decision about vaccination. EUA Fact Sheets can be found at the FDA's COVID-19 Vaccines and the CDC's COVID-19 Vaccine Emergency Use Authorization (EUA) Fact Sheets for Recipients and Caregivers website. CDC Vaccine Information Statements can be found at the CDC's Current VISs website.

Education must cover the benefits and potential side effects of the vaccine. This should include common reactions, such as aches or fever, and rare reactions such as anaphylaxis.

If the vaccination requires multiple doses of vaccine, the resident or resident representative and staff are again provided with education regarding the benefits and potential side effects of the vaccine and current information regarding those additional doses, including any changes in the benefits or potential side effects, before requesting consent for administration of any additional doses. The resident, or resident representative, must be provided the opportunity to refuse the vaccine and to change their decision about vaccination at any time.

The CDC, FDA, Immunization Action Coalition (IAC), and vaccine manufacturers have developed a variety of educational and training resources for healthcare professionals related to COVID-19 vaccines. CMS recommends that staff work with their LTC facility's Medical Director and Infection Preventionist and use the CDC and FDA resources as the source of information for their vaccination education initiatives. The CDC's Promoting COVID-19 Vaccine in Long-term Care Settings webpage has information and resources to build confidence among staff and residents.

Offering Vaccinations

LTC facilities must offer residents and staff vaccination against COVID-19 when vaccine supplies are available to the facility. Screening individuals prior to offering the vaccination for prior immunization, medical precautions and contraindications is necessary for determining whether they are appropriate candidates for vaccination at any given time. The vaccine may be offered and provided directly by the LTC facility or indirectly, such as through an arrangement with a pharmacy partner, local health department, or other appropriate health entity.

The facility is not required to educate and offer COVID-19 vaccinations to individuals who enter the facility for specific purposes and for a limited amount of time, such as delivery and repair personnel or volunteers who may enter the LTC facility infrequently (meaning less than once weekly). However, if the facility has the availability, they may offer education and vaccination to these individuals.

If a resident or staff member requests vaccination against COVID-19 but missed earlier opportunities for any reason (including recent residency or employment, changing health status, overcoming vaccine hesitancy, or any other reason), we expect the facility to offer the vaccine to that individual as soon as possible. If the vaccine is unavailable in the facility, the facility should provide information on obtaining vaccination opportunities (e.g. health department or local pharmacy) to the individual, however it is expected that the facility will provide evidence, upon request, of efforts made to make the vaccine available to its staff and residents. Similar to influenza vaccines, if there is a manufacturing delay, the facility should provide evidence of the delay, including efforts to acquire subsequent doses as necessary.

Indications and contraindications for COVID-19 vaccination are evolving and facilities should be alert to any new or revised guidelines issued by the CDC, FDA, vaccine manufacturers, or other expert stakeholders.

Vaccination Administration

For residents and staff who opt to receive the vaccine, vaccination must be conducted in accordance with CDC, ACIP, FDA, and manufacturer guidelines. All facilities must adhere to current infection prevention and control recommendations when preparing and administering vaccines.

Administration of any vaccine includes appropriate monitoring of recipients for adverse reactions, and long-term care facilities must have strategies in place to appropriately evaluate and manage post-vaccination adverse reactions among their residents and staff, per 483.45(d), F757. Particularly for COVID-19 vaccines, safety monitoring is required under the associated EUAs.

Vaccination Adverse Event Reporting

In accordance with FDA requirements, select adverse events for COVID-19 vaccines must be reported to the Vaccine Adverse Event Reporting System (VAERS), (that is, vaccine administration errors, serious adverse events, multisystem inflammatory syndrome (MIS) in children or adults, and cases of COVID-19 that result in hospitalization or death). Any revised safety reporting requirements must also be followed. For additional information see VAERS – Vaccine Adverse Event Reporting System at https://vaers.hhs.gov.

Vaccination Refusal

Residents and their representatives have the right to refuse the COVID-19 vaccine in accordance with Resident Rights requirements at 42 CFR 483.10(c)(6) and tag F578. Additionally, the regulation at §483.10(b)(2) states "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." Therefore, facilities cannot take any adverse action against a resident or representative who refuses the vaccine, including social isolation, denied visitation and involuntary discharge.

Facilities should follow state law and facility policies with respect to staff refusal of vaccination.

Documentation

The resident's medical record must include documentation that indicates, at a minimum, that the resident or resident representative was provided education regarding the benefits and potential side effects of the COVID-19 vaccine, and that the resident (or representative) either accepted and received the COVID-19 vaccine or did not receive the vaccine due to medical contraindications, prior vaccination, or refusal. If there is a contraindication to the resident having the vaccination, the appropriate documentation must be made in the resident's medical record. Documentation should include the date the education and offering took place, and the name of the representative that received the education and accepted or refused the vaccine, if the resident has a representative that makes decisions for them. Facilities should also provide samples of the educational materials that were used to educate residents.

The facility must maintain documentation that each staff member was educated on the benefits and potential side effects of the COVID-19 vaccine and offered vaccination or provided information on obtaining the vaccine unless medically contraindicated or the staff member has

already been immunized. Compliance can be demonstrated by providing a roster of staff that received education (e.g., a sign-in sheet), the date of the education, and samples of the educational materials that were used to educate staff. The facility must document the vaccination status of each staff member (i.e., immunized or not).

If a staff member is not eligible for COVID-19 vaccination because of previous immunization at another location or outside of the facility, the facility should request vaccination documentation from the staff member to confirm vaccination status.

LTC administrators and clinical leadership are encouraged to track vaccination coverage in their facilities and adjust communication with residents and staff accordingly to facilitate understanding and knowledge of the benefits of vaccination.

INVESTIGATIVE PROCEDURES

Use the Infection Prevention, Control & Immunizations Facility Task, along with the above interpretive guidance, when determining if the facility meets the requirements for, or investigating concerns related to educating and offering COVID-19 vaccines to residents and staff.

If noncompliance is identified with educating and offering residents and staff of COVID-19 vaccine, surveyors may need to expand their sample to evaluate the scope of the noncompliance. Once the review is complete, use the following to determine the scope of noncompliance:

- *One or two individuals = Isolated*
- *Three or more individuals, but not pervasive throughout the facility (e.g., less than 50% of residents and/or staff) = Pattern*
- *A large number (e.g., greater than 50%) of residents and/or staff = Widespread.*

Resources for COVID-19 Vaccines

- *COVID-19 Vaccination Training Programs and Reference Materials for Healthcare Professionals: https://www.cdc.gov/vaccines/covid-19/downloads/COVID-19-Clinical-Training-and-Resources-for-HCPs.pdf*
- *Immunization Action Coalition - for education and implementation materials https://www.immunize.org/handouts/covid19-vaccines.asp*
- *CDC's Clinical Resources for COVID-19 Vaccine https://www.cdc.gov/vaccines/covid-19/index.html*
- *General Best Practice Guidelines for Immunization: Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP) www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html*

F911

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§483.90 (e)(1) Bedrooms must

§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:

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 *Location*.

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:

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?

F918

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§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 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."

"**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.

Facilities that meet any of the below criteria must meet the requirement for having in each resident bedroom its own bathroom consisting of at least a sink and commode/toilet:

- *A facility that received approval for construction from the state or local authority after November 28, 2016;*

- *A facility that is newly certified after November 28, 2016;*

- *A facility that completes* a change of ownership under §489.18 and the new owner does not accept assignment of the existing provider agreement *resulting in* a "new initial certification" for a new provider agreement that is effective after November 28, 2016*; or*

- *A facility whose* provider agreement was terminated by CMS, and a *new* provider is working to *reenroll in the Medicare program as a newly certified facility effective after November 28, 2016.*

Facilities that meet any of the above criteria also must meet the requirements in §483.90(e)(1)(i), which requires accommodation of no more than two residents per bedroom. We note that two conjoined private bedrooms (i.e., single occupancy in each room) with a shared bathroom equipped with at least a commode and a sink (i.e., "Jack & Jill bathroom") are in compliance with §483.90(e)(1)(i) and §483.90 (f). However, if more than one resident resides in either conjoined bedroom, this would no longer be compliant with CMS regulations.

In the case where the Secretary has declared a public health emergency *and the President declares a national emergency, the Secretary is authorized at section 1135 of the Act* to waive or *modify* certain *specified* requirements under Titles XVIII, XIX, XXI, and XI under certain conditions. The *waiver* of specific requirements under section 1135 for affected facilities requesting a waiver would depend on many factors, including, *for example,* the extent of damage to the facility. New construction or reconstruction of facilities affected by a public health emergency should be discussed with the appropriate CMS *Location*.

PROCEDURES: §483.90(f)

If a facility meets any of the criteria above and does not have each resident room~~s~~ equipped with or located near toilet and bathing facilities*, then noncompliance exists.*

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[1] *American Nurses Association*

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[2] Partnership for Food Safety Education. (n.d.). Retrieved from http://www.fightbac.org.
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[67] See endnote 41