# CMS Manual System

## Pub. 100-07 State Operations Provider Certification

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

**Transmittal 225** **Date: August 8, 2024**

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

**I. SUMMARY OF CHANGES:** Updated regulations and guidance as a result of approved the Facility Assessment rule.

**NEW/REVISED MATERIAL - EFFECTIVE DATE**: August 8, 2024
**IMPLEMENTATION DATE:** August 8, 2024

***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.*)**

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

**IV. ATTACHMENTS:**

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***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. 225; Issued: 08-08-24)***

**Transmittals for Appendix PP**

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

## F540

***(Rev. 225; Issued: 08-08-24; Effective: 08-08-24; Implementation: 08-08-24)***

## §483.5 Definitions.

**As used in this subpart, the following definitions apply:**

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

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

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

**Composite distinct part.**

**(1) Definition. A composite distinct part is a distinct part consisting of two or more non-contiguous components that are not located within the same campus, as defined in §413.65(a)(2) of this chapter.**

**(2) Requirements. In addition to meeting the requirements of specified in the definition of "distinct part" of this section, a composite distinct part must meet all of the following requirements:**

**(i) A SNF or NF that is a composite of more than one location will be treated as a single distinct part of the institution of which it is a distinct part. As such, the composite distinct part will have only one provider agreement and only one provider number.**

**(ii) If two or more institutions (each with a distinct part SNF or NF) undergo a change of ownership, CMS must approve the existing SNFs or NFs as meeting the requirements before they are considered a composite distinct part of a single institution. In making such a determination, CMS considers whether its approval or disapproval of a composite distinct part promotes the effective and efficient use of public monies without sacrificing the quality of care. If there is a change of ownership of a composite distinct part SNF or NF, the assignment of the provider agreement to the new owner will apply to all of the approved locations that comprise the composite distinct part SNF or NF.**

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

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

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

**Distinct part**

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

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

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

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

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

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

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

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

**(iii) The SNF or NF must have a designated medical director who is responsible for implementing care policies and coordinating medical care, and who is directly accountable to the management of the institution of which it is a distinct part.**

**(iv) The SNF or NF is financially integrated with the institution of which it is a distinct part, as evidenced by the sharing of income and expenses with that institution, and the reporting of its costs on that institution's cost report.**

**(v) A single institution can have a maximum of only one distinct part SNF and one distinct part NF.**

**(vi) (A) An institution cannot designate a distinct part SNF or NF, but instead must submit a written request with documentation that demonstrates it meets the criteria set forth above to CMS to determine if it may be considered a distinct part.**

**(B) The effective date of approval of a distinct part is the date that CMS determines all requirements (including enrollment with the fiscal intermediary (FI)) are met for approval, and cannot be made retroactive.**

**(C) The institution must request approval from CMS for all proposed changes in the number of beds in the approved distinct part.**

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

**Facility defined. For purposes of this subpart, facility means a skilled nursing facility (SNF) that meets the requirements of section s1819(a), (b), (c), and (d) of the Act, or a nursing facility (NF) that meets the requirements of sections 1919(a), (b), (c), and (d) of the Act. "Facility" may include a distinct part of an institution (as**

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

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

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

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

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

**Mistreatment means inappropriate treatment or exploitation of a resident.**

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

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

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

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

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

***Representative of direct care employees. A representative of direct care employees is an employee of the facility, or a third party authorized by direct care employees at the facility to provide expertise and input on behalf of the employees for the purposes of informing a facility assessment.***

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

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

## F583

***(Rev. 225; Issued: 08-08-24; Effective: 08-08-24; Implementation: 08-08-24)***

**§483.10(h) Privacy and Confidentiality.**

**The resident has a right to personal privacy and confidentiality of his or her personal and medical records.**

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

**§483.10(h)(2) The facility must respect the residents right to personal privacy, including the right to privacy in his or her oral (that is, spoken), written, and electronic communications, including the right to send and promptly receive**

**unopened mail and other letters, packages and other materials delivered to the facility for the resident, including those delivered through a means other than a postal service.**

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

- **(i) The resident has the right to refuse the release of personal and medical records except as provided at §483.70(*h*)(2) or other applicable federal or state laws.**
- **(ii) The facility must allow representatives of the Office of the State Long-Term Care Ombudsman to examine a resident's medical, social, and administrative records in accordance with State law.**

**DEFINITIONS §483.10(h)**

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

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

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

**GUIDANCE §483.10(h)**

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

Residents in nursing homes have varying degrees of physical/psychosocial needs, intellectual disabilities, and/or cognitive impairments. A resident may be dependent on nursing home staff for some or all aspects of care, such as assistance with eating, ambulating, bathing, daily personal hygiene, dressing, and bathroom needs. Only authorized staff directly involved in providing care and services for the resident may be present when care is provided, unless the resident consents to other individuals being

present during the delivery of care. During the delivery of personal care and services, staff must remove residents from public view, pull privacy curtains or close doors, and provide clothing or draping to prevent exposure of body parts.

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

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

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

Personal resident information must be communicated in a way that protects the confidentiality of the information and the dignity of residents. This includes both verbal and written communications such as the presence of lists of residents with certain conditions such as incontinence and pressure ulcers at nursing stations in view or in hearing of residents and visitors. This does not include clinical information written in a resident's record.

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

All residents have the right to privacy in their communications, including justice involved residents. Additional guidance on mail, telephone, electronic communications and

visitation rights are addressed in §483.10(g)(6)-(9), F576 and §483.10(f)(4)(i)(A)-(G), F562. See §483.90(e)(1)(iv), F914, for full visual privacy around beds.

With the exception of the explicit requirement for privacy curtains in all initially certified facilities (see §483.90(e)(1)(v), F914), the facility is free to innovate to provide privacy for its residents. This may, but need not, be through the provision of a private room.

**PROCEDURES §483.10(h)**

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

## F604

***(Rev. 225; Issued: 08-08-24; Effective: 08-08-24; Implementation: 08-08-24)***

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

**§483.10(e)(1) The right to be free from any physical or chemical restraints imposed for purposes of discipline or convenience, and not required to treat the resident's medical symptoms, consistent with §483.12(a)(2).**

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

**§483.12(a) The facility must—**

**§483.12(a)(2) Ensure that the resident is free from physical or chemical restraints imposed for purposes of discipline or convenience and that are not required to treat the resident's medical symptoms. When the use of restraints is indicated, the facility must use the least restrictive alternative for the least amount of time and document ongoing re-evaluation of the need for restraints.**

## INTENT

The intent of this requirement is for each 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[1].

"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 assess
  the resident and determine how resident's needs will be met if
  the resident refuses/declines treatment.

- The length of time the restraint is anticipated to be used to treat the medical symptom, the identification of who may apply the restraint, where and how the

restraint is to be applied and used, the time and frequency the restraint should be released, and who may determine when the medical symptom has resolved in order to discontinue use of the restraint;
- The type of specific direct monitoring and supervision provided during the use of the restraint, including documentation of the monitoring;
- The identification of how the resident may request staff assistance and how needs will be met during use of the restraint, such as for re-positioning, hydration, meals, using the bathroom and hygiene;
- The resident's record includes ongoing re-evaluation for the need for a restraint and is effective in treating the medical symptom; and
- The development and implementation of interventions to prevent and address any risks related to the use of the restraint (See also the Long-Term Care Facility Resident Assessment Instrument User's Manual, Version 3.0, Chapter 3, Section P-Restraints for further guidance and 42 CFR §483.25(d) [F689] for concerns related to ensuring the resident receives adequate supervision to prevent accidents).

**NOTE**: Falls 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).

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

- The facility failed to identify the resident's medical symptom that warranted the use of a restraint. It was identified that a resident had repeated falls in his room usually after meals, when he attempted to transfer from his wheelchair to the bed. The clinical record documented that the resident repeatedly requested to be assisted to lie down after eating. Staff recorded that the belt restraint was being applied to prevent falls as he had fallen several times when attempting to stand up from the wheelchair after meals and lie down. Although the resident verbalized distress at being tied down in the wheelchair, staff stated they had informed the resident that they would put the resident in bed as soon as they finished taking care of the other residents in the dining room. It was documented that after staff left the room, the resident had attempted to stand up with the lap belt in place in the wheelchair, and as a result, the wheelchair tipped over and he sustained a fracture of his hand and had hit his head, resulting in hospitalization and treatment for multiple head and face lacerations and a subdural hematoma.

- The facility failed to identify bed rails as a physical restraint, failed to assess the resident for use of a bed rail, and failed to ensure that the bed rails did not pose a risk of injury from falls. A moderately cognitively impaired resident was admitted to the facility who required extensive assistance with bed mobility and

transfer, and was not ambulatory. The staff recorded on admission that the resident was at high risk for falls and as a result, placed full bed rails on all open sides of the bed. No assessment was conducted related to the use of bed rails, or the use of restraints. Documentation in the record revealed that the resident crawled to the foot of her bed while the full bed rails were in a raised position, attempted to stand and walk, and fell off the right side of the bed. The resident was hospitalized for surgical repair of a femoral neck fracture.

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

- The facility failed to assure that a restraint was an intervention to treat a medical symptom and was not being used for staff convenience. Facility staff had placed a resident in a bean bag chair from which he could not rise. Based on staff interview, the resident was ambulatory, but had fallen in the past when attempting to stand up. The facility staff did not recognize that the bean bag was a physical restraint; thus, the staff did not conduct any assessment to identify any medical symptoms that would necessitate a restraint. Staff stated that they placed the resident in the bean bag chair while caring for other residents. The resident reported being placed and left in the bean bag chair every day in the afternoon and was not able to stand to walk to his room or to activities. The resident said that he felt humiliated that he is not able to get out of the chair himself, when he wants to, especially since he enjoys talking with the other residents. The surveyor observed the resident struggling to get up, but was not able.

- The facility failed to assure that the use of a physical restraint was used to treat a resident's medical symptoms, and was not being used for staff convenience. A resident was admitted with a diagnosis of dementia, and had been hospitalized due to a head injury related to a fall at her home. The physician admission orders included an order for a lap belt to be used when the resident was up in the wheel chair; however, there was no identification of the medical symptom that necessitated the use of the lap belt. In a phone interview with the physician, he indicated that staff had requested the lap belt order due to the resident's falls. Based on observation, the resident sat in the day room in a wheel chair with the lap belt in place through the morning, from the breakfast service through the end of the noon meal. Staff did not provide repositioning, assistance with using the bathroom, or release of the lap belt for mobility. After lunch, the resident was transported to her room in the wheelchair with the lap belt in place; however, the lap belt was not removed and the resident remained in the same position through the afternoon without opportunities for repositioning, assistance with using the bathroom, or release of the lap belt for mobility. The resident was observed to be moving about restlessly, pulling at the lap belt, and calling out for help without staff response or intervention.

When staff prompted the resident to release the belt, the resident was not able. Observation of the resident's skin when put to bed after the PM shift arrived, revealed

reddened areas on the coccyx, urine soaked incontinence product with visible skin maceration. Staff interviewed stated that the lap belt was being used as a falls prevention intervention. They stated, and the record corroborated that there had been a decline in the resident's mobility, and continence since admission.

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

- The facility failed to assure that a physical restraint used for one resident was for the treatment of medical symptoms. Record review and observation revealed that the resident was alert and responded to her name, but was identified as mildly cognitively impaired and had fallen at home prior to her admission several weeks before. Observations revealed that a seat belt was used intermittently when the resident was in the wheelchair, but the resident had not attempted to rise, nor had attempted to remove the seatbelt. Staff stated that they thought the resident could release the seatbelt, although an assessment had not been completed regarding the use of the seatbelt. There was no documentation of an assessment for the use of the seat belt, whether the resident could release the seat belt or of identification of medical symptoms that would require the use of the seat belt while in the wheelchair. The resident's record reflected no decline in functional status.

- The facility failed to ensure that the use of a concave mattress was being used in the treatment of medical symptoms and not for staff convenience. A resident, who could independently transfer self from bed to wheelchair and to bathroom, was observed to have a concave mattress. During resident interview, the resident stated that it was hard to get out of bed. The resident's record indicated no history of falls or injuries. During interview, the nurse assigned to the resident verified that the concave mattress was used to prevent the resident from exiting the bed independently. The resident's record did not include any information in the assessment, physician's orders, or care plan related to the concave mattress.

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

The failure of the facility to assure residents are free from physical restraints not required to treat the resident's symptoms is more than minimal harm. Therefore, Severity Level 1 does not apply for this regulatory requirement.

[1] See CMS Minimum Data Set Resident Assessment Instrument Manual.

## F605

***(Rev. 225; Issued: 08-08-24; Effective: 08-08-24; Implementation: 08-08-24)***

**§483.10(e) Respect and Dignity.**

**The resident has a right to be treated with respect and dignity, including:**

**§483.10(e)(1) The right to be free from any physical or chemical restraints imposed for purposes of discipline or convenience, and not required to treat the resident's medical symptoms, consistent with §483.12(a)(2).**

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

**§483.12(a) The facility must—**

**§483.12(a)(2) Ensure that the resident is free from physical or chemical restraints imposed for purposes of discipline or convenience and that are not required to treat the resident's medical symptoms. When the use of restraints is indicated, the facility must use the least restrictive alternative for the least amount of time and document ongoing re-evaluation of the need for restraints.**

**INTENT**

The intent of this requirement is for each person to attain and maintain his/her highest practicable well-being in an environment that prohibits the use of chemical restraints:

- For discipline or convenience; and
- Not required to treat a resident's medical symptoms.

When a medication is indicated to treat a medical symptom, the facility must:
- Use the least restrictive alternative for the least amount of time;
- Provide ongoing re-evaluation of the need for the medication; and
- Not use the medication for discipline or convenience.

**NOTE**: The surveyor's review of medication use is not intended to constitute the practice of medicine. However, surveyors are expected to investigate the basis for decisions and interventions affecting residents.

**DEFINITIONS**
"**Chemical restraint**" is defined as any drug that is used for discipline or staff convenience and not required to treat medical symptoms.

"**Convenience**" is defined as the result of any action that has the effect of altering a resident's behavior such that the resident requires a lesser amount of effort or care, and is not in the resident's best interest.

"**Discipline**" is defined as any action taken by facility staff for the purpose of punishing or penalizing residents.

"**Indication for use**" is defined as the identified, documented clinical rationale for administering a medication that is based upon an assessment of the resident's condition and therapeutic goals

and is consistent with manufacturer's recommendations and/or clinical practice guidelines, clinical standards of practice, medication references, clinical studies or evidence-based review articles that are published in medical and/or pharmacy journals.

"**Medical symptom**" is defined as an indication or characteristic of a medical, physical or psychological condition.

**GUIDANCE**

The indication for use for any medication ordered for a resident must be identified and documented in the resident's record. (Also refer to F757 and/or F758.) When any medication restricts the resident's movement or cognition, or sedates or subdues the resident, and is not an accepted standard of practice for a resident's medical or psychiatric condition, the medication may be a chemical restraint. Even if use of the medication follows accepted standards of practice, it may be a chemical restraint if there was a less restrictive alternative treatment that could have been given that would meet the resident's needs and preferences or if the medical symptom justifying its use has subsided. The facility is accountable for the process to meet the minimum requirements of the regulation including appropriate assessment, care planning by the interdisciplinary team, and documentation of the medical symptoms and use of a less restrictive alternative for the least amount of time possible and provide ongoing re-evaluation.

**NOTE**: A medication may have been required to treat a medical symptom, and as a result, the medical symptom is no longer present. In some cases, the clinical goal of the continued use of the medication is to stabilize the symptoms of the disorder so that the resident can function at the highest level possible. In other words, the clinical goal is to have no symptoms of the disorder.

Although the symptom may no longer be present, the disease process is still present. For example, diseases may include:

- Chronic psychiatric illness such as schizophrenia or schizoaffective disorder, bipolar disorder, depression, or post-traumatic stress disorder;
- Neurological illness such as Huntington's disease or Tourette's syndrome; and
- Psychosis and psychotic episodes.

In such instances, if the medication is reduced or discontinued, the symptoms may return. Reducing or eliminating the use of the medication may be contraindicated and

must be individualized. If the medication is still being used, the clinical record must reflect the rationale for the continued administration of the medication. If no rationale is documented, this may meet the criteria for a chemical restraint, such as for staff convenience (See also F758 for concerns related to unnecessary use of a psychotropic medication and lack of gradual dose reduction).

**Determination of Medical Symptoms**

The clinical record must reflect whether the staff and practitioner have identified, to the extent possible, and addressed the underlying cause(s) of distressed behavior, either before or while treating a medical symptom. Potential underlying causes for expressions and/or indications of distress may include, but are not limited to:

- Delirium;
- Pain;
- The presence of an adverse consequence associated with the resident's current medication regimen; and
- Environmental factors, such as staffing levels, over stimulating noise or activities, under stimulating activities, lighting, hunger/thirst, alteration in the resident's customary location or daily routine, physical aggression leading to altercations, temperature of the environment, and crowding.

**NOTE**: If it is determined that the administration of a medication is being used to treat a medical symptom, the survey team should review to assure that the use of the medication is supported by adequate indication and rationale for use, and is used at the correct dose and duration, and with adequate monitoring. (See also F741, F757, and F758 for concerns related to non-pharmacological approaches of redirecting or addressing behavior)

**Determination of Indication for Medication Use**

The clinical record must reflect the following:

- Whether there is an adequate indication for use for the medication (e.g., a psychotropic medication is not administered unless the medication is used to treat a specific condition);
- Whether an excessive dose and/or duration of the medication was administered to the resident;
- Whether there is adequate monitoring for the effectiveness of the medication in treating the specific condition and for any adverse consequences resulting from the medication;
- Whether a resident who uses a psychotropic drug(s) is receiving gradual dose reduction and behavioral interventions, unless clinically contraindicated; and
- Whether a resident who receives a psychotropic drug(s) pursuant to a PRN (pro re nata, or as needed) order is not administered the medication unless the medication

is necessary to treat a diagnosed specific symptom, as documented in the clinical record.

If the practitioner orders a medication to be administered on a PRN time-limited basis for the provision of medical treatment to address an emergency medical condition (e.g., delirium), this would not be considered to be a chemical restraint. The dosage cannot exceed what is prescribed by the practitioner, and if the resident does not respond to the initial administration of the PRN medication, the practitioner must be contacted, regarding re-assessment of the resident's medical condition and evaluation of interventions. The administration of a PRN medication must be discontinued when the resident does not need the medication for treatment of the medical condition (also see §483.45(e) F758 for limitations on psychotropic and antipsychotic medication PRN orders). If staff continue to utilize a PRN medication that subdues or sedates a resident, and is not treating a medical condition, this would be considered to be a chemical restraint for staff convenience or discipline.

**Risks and Psychosocial Impacts Related to Use of Chemical Restraints**

A medication that is used for discipline or convenience and is not required to treat medical symptoms, may cause the resident to be:

- Subdued, sedated, or withdrawn;
- Asleep during hours that he/she would not ordinarily be asleep; or
- Limited in his/her functional capacity.

Additional effects resulting from sedating or subduing a resident may include, but are not limited to, the following:

- Loss of autonomy, dignity, self-respect and orientation;
- Confusion, cognitive decline, withdrawal, depression;
- Decreased activity levels, including social activities;
- Decline in skin integrity;
- Decline in continence level;
- Decline in physical functioning including an increased dependence in activities of daily living (e.g., ability to walk), impaired muscle strength and balance, decline in range of motion, and risk for development of contractures, increased risk of falls; and
- Weight loss if missing meals.

Facilities are responsible for knowing the effects medications have on their residents. If a medication has a sedating or subduing effect on a resident, and is not administered to treat a medical symptom, the medication is acting as a chemical restraint. The sedating/subduing effects to the resident may have been caused intentionally or unintentionally by staff, and would indicate an action of discipline or convenience. In the case of an unintentional chemical restraint, the facility did not intend to sedate or subdue a resident, but a medication is being administered that has that effect, and is not

the least restrictive alternative to treat the medical symptom. These effects may result in convenience for the staff, as the resident may require less effort than previously required. Even if a medication was initially administered for a medical symptom, the continued administration of a medication in the absence of a medical symptom, that sedates a resident or otherwise makes it easier to care for them, is a chemical restraint. Other examples of facility practices that indicate that a medication (ordered by a practitioner) is being used as a chemical restraint for staff convenience or discipline include, but are not limited to:

- Staff indicate that a medication is being administered based on the resident's representative's request to administer a medication to "calm down" the resident;
- Staff have recommended to the practitioner that a resident be administered a medication in order to prevent a resident from displaying behaviors such as wandering into other resident's rooms:
- Staff administer a medication to quiet the resident because the resident continually calls out, without attempting alternative interventions;
- Staff become frustrated with a resident who continually requests staff assistance (such as for toileting), or continually puts on the call light, and administer a medication to sedate or subdue the resident);
- Staff administer a medication that subdues or sedates a resident when insufficient staffing levels do not allow for the resident's needs to be met;
- Staff administer a medication to sedate or subdue the resident, and/or to restrict the resident to a seated or lying position, since the resident continually wanders into other resident's rooms or attempts to leave the unit; and
- Staff become upset with a resident who resists receiving a bath and pinches staff. The staff had not re-assessed the resident nor revised interventions regarding how to provide bathing care in order to meet the resident's needs. Instead, staff administer a medication that is used to subdue the resident prior to providing the bath, but the medication is not used to treat an identified medical symptom.

## INVESTIGATIVE PROTOCOL FOR CHEMICAL RESTRAINTS USE

Use this protocol to investigate whether the facility is using a medication as a chemical restraint when:

- An allegation of use of a chemical restraint is received; or
- The survey team determines noncompliance with F757 and/or F758, and the resident was or is receiving an unnecessary medication that restricts movement, or sedates or subdues the resident

**NOTE**: If the survey team identifies an unnecessary medication that is acting as a chemical restraint (sedating or subduing a resident), the noncompliance is cited at F605 – Chemical Restraints and not cited at F757 – Unnecessary Medications. Both tags shall not be cited for the same noncompliance.

## PROCEDURES

The survey team must first use the Interpretive Guidance (Refer to F757 and F758) and Critical Element Pathway for Unnecessary Medications, Psychotropic Medications, and Medication Regimen Review (Form CMS-20082) to determine whether the medication is used to treat a medical symptom.

Review the assessment, care plan, practitioner orders, and consulting pharmacist reviews to identify facility interventions and to guide observations to be made. Corroborate observations by interview and record review.

Gather information regarding the resident's mental, physical, functional, and psychosocial status and the medication-related therapeutic goals identified in the care plan as the basis for further review.

**Observation**

Record observations regarding any potential environmental causes of distress to the resident, such as staffing levels, over stimulating noise or activities, under stimulating activities, lighting, hunger/thirst, physical aggression leading to altercations, temperature of the environment, and crowding. In addition, observe for any alteration to the resident's customary location or daily routine.

Record any visible physical and psychosocial reaction to the potential use of a medication, such as:

- Drowsiness, somnolence, excessive sedation, and hallucinations;
- Neurologic consequences such as akathisia, neuroleptic malignant syndrome (NMS), parkinsonism, tardive dyskinesia; and/or
- Confusion, agitation, anxiety, nervousness;
- Social isolation, withdrawal, loss of self-esteem; and/or
- Lack of participation in individualized activities, according to the resident's care plan.

**Interviews**

Interview the resident, and/or resident representative, to the degree possible, to identify:

- Prior to administration of the medication:
    - Whether other interventions have been attempted; if so, what alternatives; and what the response was;
    - Whether staff provided information regarding why the medication was being used;
    - The risks and/or benefits of using the medication; and

  When and for how long the medication was going to be used.
- Who requested the medication to be used and why;
- Describe the effect of the medication on the resident's functioning, participation in individual and/or group activities, and how it makes them feel; and

- Describe any changes in the resident's ability to understand, sleeping patterns, or social involvement since receiving the medication.

Interview direct care staff and/or licensed personnel (e.g. nursing, social worker), as appropriate, on various shifts that provide care to the resident to determine:

- Why the medication is being administered and what effect (physical and/or psychosocial) it has on the resident;
- Depending on whether distressed behavior is expressed, how do staff respond and what individualized, person-centered interventions are attempted;
- Prior to administration of the medication, whether other interventions have been attempted; if so, what alternatives; and how the interventions met or failed to meet the resident's needs;
- How long the medication has been administered, and when it began;
- Prior to administration of the medication, what is determined to be the underlying cause(s) of the medical symptom that is being treated; how is the cause(s) treated;
- Who and how the facility monitors for adverse consequences related to the administration of the medication;
- How is it determined that the medical symptom is no longer present and who determines this;
- If the medication continues to be administered and the medical symptom is no longer present, what is the clinical rationale for continuing the use of the medication and where is this documented;
- How staff are assigned to monitor, care for, and be familiar with residents' behaviors (e.g., the number, location, and consistency of staff assigned across different shifts/units);
- Who supervises the overall delivery of care to the residents to assure care planned interventions are implemented and how supervision occurs (to assure that a chemical restraint is not used for staff convenience); and
- Whether staff have discussed concerns with the Director of Nurses and Administrator regarding the behavioral symptoms of specific residents and the monitoring of interventions, and whether staff have requested more resources or changes to resident assignments, and the response to the concerns.

Interview the practitioner regarding concerns identified during the investigation, including when the staff contacted him/her, what concerns they identified regarding the resident's behavior, the response provided, including whether other interventions were attempted prior to the use of a medication, what medical symptom is being treated with the medication, whether the medication is considered to be the least restrictive (in type, dose, and duration) that may be used to treat the symptom, and the plan for discontinuing and/or revising interventions.

Interview the pharmacist to identify when he/she conducted the last medication regimen review for the resident; if the medication was administered prior to the last review and it was not identified as a concern, whether he/she can provide information regarding the indication for use of the medication; if the medication was administered

prior to the last review and it was identified as a concern, , whether he/she notified the practitioner, Director of Nurses, and/or medical director and what was the response; and what is the facility's process for notifying the pharmacist when initiating a medication for a change in the resident's condition, such as when there are expressions or indications of distress, or other changes in a resident's psychosocial status.

Interview the social worker to determine any patterns of behaviors that may impact the resident's safety or care provided, whether he/she was aware of interventions attempted, how attempts met or did not meet the resident's needs, whether he/she was aware of what medications are administered to the resident, whether he/she has identified any changes in the resident's behavior or activity level after administration of the medication, and why he/she believes the medication is being administered.

Interview the Director of Nurses to identify his/her knowledge regarding the behavioral symptoms of specific residents and the monitoring of interventions. Also, interview the Director of Nurses and Administrator to identify whether staff have requested more resources or changes to resident assignments, and the response to the concerns.

**Record Review**

Review the assessment, care plan, practitioner orders, progress notes, and consulting pharmacist reviews. Determine whether there was a decline in the resident's functional and/or psychosocial status related to the medication that was administered. If so, the surveyor must determine whether the decline can be attributed to disease progression or administration of an unnecessary medication. Determine if documentation in the resident's record reflects:

Prior to administration of the medication, whether other interventions have been attempted; if so, what alternatives; and how the interventions met or failed to meet the resident's needs;

- Prior to administration of the medication, whether the facility identified, to the extent possible, and addressed the underlying cause(s) of the medical symptom;
- Indication for use for the medication(s), including the medical symptom(s) being treated;
- Whether the record reflects any adverse consequences after administration of the medication;
- Whether the record reflects whether there was a change in functioning and/or activity after administration of the medication;
- If a medication used to treat medical symptoms was appropriate at one time, determine if it was discontinued once it was no longer necessary, or if a clinical rationale to continue the medication is documented; and
- Whether the medication is administered on a PRN basis on particular days or shifts or when certain staff is caring for the resident and the symptoms for which the medication is prescribed are not documented.

**Facility Review**

It may be necessary to interview the medical director regarding medications that are not required to treat the resident's medical symptoms result in the resident being subdued, sedated, or withdrawn or limited in his/her functional capacity.

Determine whether the Quality Assessment & Assurance committee is aware of psychotropic medication used to address resident behavioral symptoms, whether there is sufficient, qualified staff trained to provide interventions for behavioral symptoms, and supervision of staff to assure that medications are only used to treat a medical symptom and do not have the effect of convenience or discipline.

## KEY ELEMENTS OF NONCOMPLIANCE

To cite deficient practice at F605, the surveyor's investigation will generally show that the facility has failed, in one or more areas, to do **any one** or more of the following:

- Assure that the resident is free from restraints imposed for discipline or staff convenience (convenience can be caused intentionally or unintentionally by staff);
- Identify medical symptoms that were being treated with the use of a chemical restraint;
- If a chemical restraint is in use, the facility:
  - Provides the least restrictive alternative for the least time possible, including and as appropriate, developing and implementing a plan for gradual dose reduction, in the absence of identified and documented clinical contraindications;
  - Monitors and evaluates the resident's response to the medication; and
  - Discontinues the use of the medication when the medical symptom is no longer being treated, unless reducing or eliminating the use of the medication may be clinically contraindicated.

## POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION

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

- 42 CFR §483.10, §483.10(a)(1)-(2), §483.10(b)(1)-(2), F550- Resident Rights and Dignity
- 42 CFR §483.10(c)(2)-(3), F553 - Right to Participate Planning Care
- 42 CFR §483.21(b)(1), F656- Develop/Implement Comprehensive Care Plan

- 42 CFR §483.35, §483.35(a), and §483.35(c)- F725 and F726 – Sufficient and Competent Staff
- 42 CFR §483.40(b)-(b)(1), F742- Treatment/Svc for Mental/Psychosocial Concerns
- 42 CFR §483.45(c), F756-Drug Regimen Review, Report Irregular, Act On
- 42 CFR §483.45(d), F757- Drug Regimen is Free From Unnecessary Drugs
- 42 CFR §483.45, F758- Psychotropic Medications
- 42 CFR §483.70(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).

**Examples of Severity Level 4 Noncompliance Immediate Jeopardy to Resident Health or Safety includes, but is not limited to:**

- The facility administered a medication to a resident for staff convenience without a medical symptom identified. The resident was admitted to a secured area of the facility two months prior to the survey. During observations the resident was observed lying in a reclining chair, sleeping and staff had difficulty arousing the resident for meals. The staff had to provide one to one assistance to assist the resident to eat. The resident was unable to hold the utensils, and was being fed a pureed meal. The resident required a two-person assist to transfer from bed to chair and required total assistance for activities of daily living. The resident's record revealed that on admission, the resident was independent in mobility and ambulation and did not require assistance to eat. Staff interviewed stated that they had difficulty monitoring the resident as they were taking care of other residents. They stated that there were no identified interventions or activities to address these behaviors. As a result, staff requested a medication from the physician for the wandering behavior. The physician was interviewed and stated that the medication was being administered for wandering, but that he was not aware that the resident was sedated and the resident's decline in walking and activities of daily living. There was no other evidence in the resident's record or from interviews with staff and the physician that indicate a medical reason for the decline and sedating effect.

- The facility failed to assure that a medication it administered to a resident was being used to treat a medical symptom and not for staff convenience. The resident was admitted for post-surgical rehabilitation of a fractured hip. During an interview, the resident's representative stated that prior to admission, the resident had been alert, was able to recognize her family members, was used to sitting with the family after the evening meal at home, and, although pleasantly confused, enjoyed a warm bath prior to bedtime and slept through the night. However, after

admission, there had been a significant change in the resident's status. The resident's record reflected that the resident, after admission, was immediately put to bed after the evening meal every day; subsequently, the resident began yelling out for help, wanted to get out of bed, and disrupted other residents' sleep. During an interview with the practitioner, staff had contacted him and requested an antipsychotic medication to keep the resident quiet during the night hours as she was disruptive and agitated. The practitioner ordered an antipsychotic medication twice a day, but did not provide documentation of a medical symptom being treated with the medication. Observations throughout the survey revealed the resident seated in a wheelchair, subdued or sleeping, sucking on her hand, mumbling to self, and not aware of surroundings or visitors. Staff interviewed corroborated that there had been a decline in the resident's condition since the administration of the medication. Due to the significant change in the resident's status related to the initiation and use of a chemical restraint, serious harm occurred to the resident.

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

- The facility administered a medication that was not being used to treat medical symptoms, the facility did not attempt any less restrictive interventions, and the medication was used for the convenience of staff. As a result of this noncompliance, the resident was sedated into the morning hours. The resident was unable to be aroused sufficiently to eat breakfast in the dining room where he normally eats meals, and now required assistance by staff to eat breakfast. The resident was observed to attend and participate in his other meals and activities for the rest of the day. The record did not indicate any falls or any decline in other activities of daily living. The resident, diagnosed with Alzheimer's disease, had displayed night time behaviors that frustrated other residents and nursing staff, such as wandering into other resident's rooms, and rummaging through drawers and closets. To address the resident's behavior, staff contacted the attending physician to discuss the issue and request a long-acting anti- anxiety medication. No other attempts of non-pharmacological interventions were identified or implemented prior to the use of the chemical restraint. Staff stated that they did not have the time to implement other interventions. The resident's record did not indicate a medical symptom being treated, nor a reduction of the medication when the resident's functional status declined.

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

- The facility failed to assure that an antianxiety medication was being administered to treat a medical symptom and not for the convenience of staff. Although the resident has not experienced falls or other adverse consequences in relation to the administration of the medication, the potential exists for more than minimal harm

with the continued use of the anti-anxiety medication in the absence of a medical symptom. Interviews and record review revealed that the facility was giving a resident anti-anxiety medication prior to the resident taking showers occasionally on weekends. Staff indicated that the resident had occasionally declined showers not because she was anxious, but because she found bed baths to be more relaxing than the shower environment. The staff interviewed stated that the nurse aides, who worked the daytime weekend shift, were upset about the resident refusing the shower as they did not have time to come back and shower the resident at another time not realizing that this was not the resident's preference. The weekend nurse contacted the physician for a medication to alleviate the resident's "anxiety to taking a shower." A nursing assistant who was assigned to provide the resident's care during the week, stated that sometimes the resident does not want to take a shower and on those occasions, she would give the resident a bed bath. The nursing assistant said the resident is not resistive or combative.

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

The failure of the facility to assure residents are free from chemical restraints is more than minimal harm. Therefore, Severity Level 1 does not apply for this regulatory requirement.

## F622

***(Rev. 225; Issued: 08-08-24; Effective: 08-08-24; Implementation: 08-08-24)***

**§483.15(c) Transfer and discharge-**

**§483.15(c)(1) Facility requirements-**

**(i) The facility must permit each resident to remain in the facility, and not transfer or discharge the resident from the facility unless—**

**(A) The transfer or discharge is necessary for the resident's welfare and the resident's needs cannot be met in the facility;**

**(B) The transfer or discharge is appropriate because the resident's health has improved sufficiently so the resident no longer needs the services provided by the facility;**

**(C) The safety of individuals in the facility is endangered due to the clinical or behavioral status of the resident;**

**(D) The health of individuals in the facility would otherwise be endangered;**

**(E) The resident has failed, after reasonable and appropriate notice, to pay for (or to have paid under Medicare or Medicaid) a stay at the facility. Nonpayment applies if the resident does not submit the necessary paperwork for third party payment or after the third party, including Medicare or Medicaid, denies the claim and the resident refuses to pay for his or her stay. For a resident who becomes eligible for Medicaid after admission to a facility, the facility may charge a resident only allowable charges under Medicaid; or**

**(F) The facility ceases to operate.**

**(ii) The facility may not transfer or discharge the resident while the appeal is pending, pursuant to § 431.230 of this chapter, when a resident exercises his or her right to appeal a transfer or discharge notice from the facility pursuant to § 431.220(a)(3) of this chapter, unless the failure to discharge or transfer would endanger the health or safety of the resident or other individuals in the facility. The facility must document the danger that failure to transfer or discharge would pose.**

**§483.15(c)(2) Documentation.**

**When the facility transfers or discharges a resident under any of the circumstances specified in paragraphs (c)(1)(i)(A) through (F) of this section, the facility must ensure that the transfer or discharge is documented in the resident's medical record and appropriate information is communicated to the receiving health care institution or provider.**

**(i) Documentation in the resident's medical record must include:**

**(A) The basis for the transfer per paragraph (c)(1)(i) of this section.**

**(B) In the case of paragraph (c)(1)(i)(A) of this section, the specific resident need(s) that cannot be met, facility attempts to meet the resident needs, and the service available at the receiving facility to meet the need(s).**

**(ii) The documentation required by paragraph (c)(2)(i) of this section must be made by—**

**(A) The resident's physician when transfer or discharge is necessary under paragraph (c) (1) (A) or (B) of this section; and**

**(B) A physician when transfer or discharge is necessary under paragraph (c)(1)(i)(C) or (D) of this section.**

**(iii) Information provided to the receiving provider must include a minimum of the following:**

**(A) Contact information of the practitioner responsible for the care of the resident.**

**(B) Resident representative information including contact information**

**(C) Advance Directive information**

**(D) All special instructions or precautions for ongoing care, as appropriate.**

**(E) Comprehensive care plan goals;**

**(F) All other necessary information, including a copy of the resident's discharge summary, consistent with §483.21(c)(2) as applicable, and any other documentation, as applicable, to ensure a safe and effective transition of care.**

## INTENT

To specify the limited conditions under which a skilled nursing facility or nursing facility may initiate transfer or discharge of a resident, the documentation that must be included in the medical record, and who is responsible for making the documentation. Additionally, these requirements specify the information that must be conveyed to the receiving provider for residents being transferred or discharged to another healthcare setting.

## DEFINITIONS

**"Facility-initiated transfer or discharge":** A transfer or discharge which the resident objects to, or did not originate through a resident's verbal or written request, and/or is not in alignment with the resident's stated goals for care and preferences.

**"Resident-initiated transfer or discharge":** Means the resident or, if appropriate, the resident representative has provided verbal or written notice of intent to leave the facility (leaving the facility does not include the general expression of a desire to return home or the elopement of residents with cognitive impairment).

**"Transfer and Discharge":** Includes movement of a resident to a bed outside of the certified facility whether that bed is in the same physical plant or not. Transfer and discharge does not refer to movement of a resident to a bed within the same certified facility. (See §483.5). Specifically, transfer refers to the movement of a resident from a bed in one certified facility to a bed in another certified facility when the resident expects to return to the original facility. Discharge refers to the movement of a resident from a bed in one certified facility to a bed in another certified facility or other location in the community, when return to the original facility is not expected.

## GUIDANCE

**NOTE**: The provisions at §483.15(c)(1) and (c)(2)(i)-(ii) only apply to transfers or discharges that are initiated by the facility (facility-initiated discharges), not by the resident (resident-initiated discharges). Section §483.15(c)(2)(iii) applies to both facility- and resident-initiated transfers (for information required at discharge, refer to F661, Discharge Summary).

Surveyors must determine whether a transfer or discharge is resident- or facility-initiated. The determination that a transfer or discharge is facility-initiated does not equate to noncompliance if the requirements in this regulatory section are met.

Resident-initiated transfers or discharges occur when the resident or, if appropriate, his/her representative has given written or verbal notice of their intent to leave the facility. A resident's expression of a general desire or goal to return to home or to the community or the elopement of a resident who is cognitively-impaired should not be taken as a notice of intent to leave the facility.

For resident-initiated discharges, the medical record should contain documentation or evidence of the resident's or resident representative's verbal or written notice of intent to leave the facility, a discharge care plan, and documented discussions with the resident or, if appropriate, his/her representative, containing details of discharge planning and arrangements for post-discharge care (See F660, Discharge Planning Process, and F661, Discharge Summary). Additionally, the comprehensive care plan should contain the resident's goals for admission and desired outcomes, which should be in alignment with the discharge if it is resident-initiated.

**NOTE:** Situations in which residents sign out of the facility, or leave Against Medical Advice (AMA) should be thoroughly investigated to determine if the discharge is facility- or resident-initiated. If evidence reveals that a resident or resident representative was forced, pressured, or intimidated into leaving AMA, the discharge would be considered a facility-initiated discharge, requiring further investigation to determine compliance with the requirements at 483.15(c), including the requirement to provide a notice at F623. See additional guidance on AMA discharges at F660 and guidance on Abuse, Neglect and Exploitation at F600.

If a surveyor has concerns about whether a resident-initiated transfer or discharge was actually a facility-initiated transfer or discharge, the surveyor should investigate further through interviews and record review.

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, it is considered a facility-initiated discharge and the requirements at §§483.15(c)(1) and (c)(2)(i)-(ii) apply to ensure the discharge is not involuntary. These situations may require further investigation to ensure that discrimination based on payment source has not occurred in accordance with §483.10(a)(2) (F550). Additionally, in cases where the resident does not appear to object to the discharge, or has not appealed it, the discharge could still be a facility-initiated discharge and be thoroughly investigated to determine if resident-, or facility-initiated.

These regulations limit the circumstances under which a facility can initiate a transfer or discharge, thus protecting nursing home residents from facility-initiated transfers and discharges which violate federal regulations.

In the following limited circumstances, facilities may initiate transfers or discharges**:**

1. The discharge or transfer is necessary for the resident's welfare and the facility cannot meet the resident's needs.
2. The resident's health has improved sufficiently so that the resident no longer needs the care and/or services of the facility.
3. The resident's clinical or behavioral status (or condition) endangers the safety of individuals in the facility.
4. The resident's clinical or behavioral status (or condition) otherwise endangers the

health of individuals in the facility.

5. The resident has failed, after reasonable and appropriate notice to pay, or have paid under Medicare or Medicaid, for his or her stay at the facility.
6. The facility ceases to operate.

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 above is met. For example, if a resident whose stay is being paid for under Medicaid is discharged from the facility, but he or she wants to stay in the facility and still meets a state's requirements for a nursing home level of care, this would be a facility-initiated discharge.

Surveyors must ensure that for discharges related to circumstances 1, 3, or 4 above, the facility has fully evaluated the resident, and does not base the discharge on the resident's status at the time of transfer to the acute care facility. See additional guidance at F626, §483.15(e)(1), Permitting Residents to Return. Facility-initiated transfers and discharges must meet the transfer and discharge requirements at §§483.15(c)(1) - (5) by having a valid basis for the transfer or discharge. There may be rare situations, such as when a serious crime (e.g., attempted murder or rape) has occurred, that a facility initiates a discharge immediately, with no expectation of the resident's return.

**NOTE**: In reviewing complaints for facility-initiated discharges that do not honor a resident's right to return following a hospitalization or therapeutic leave, surveyors would review both transfer and discharge requirements because the situation begins as a transfer and then changes to a discharge when the facility decides it will not permit the resident to return.

If transfer is due to a significant change in the resident's condition, but not an emergency requiring an immediate transfer, then prior to any action, the facility must conduct and document the appropriate assessment to determine if revisions to the care plan would allow the facility to meet the resident's needs. (See §483.20(b)(2)(ii), F637, for information concerning assessment upon significant change.)

A resident's declination of treatment does not constitute grounds for discharge, unless the facility is unable to meet the needs of the resident or protect the health and safety of others. The facility must be able to demonstrate that the resident or, if applicable, resident representative, received information regarding the risks of refusal of treatment, (§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 (§483.15(c)(2)(i)(B) and see also §§483.20 Resident Assessment and 483.35 Nursing Services).

**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.

**Emergency Transfers to Acute Care**

When residents are sent emergently to an acute care setting, these scenarios are considered facility-initiated 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 (§483.15(e)(1), F626). In a situation where the facility initiates discharge while the resident is in the hospital following emergency transfer, the facility must have evidence that the resident's status 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 any facility-initiated 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)).

**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.

**§483.15(c)(2) Required Documentation**

To demonstrate that any of the circumstances permissible for a facility to initiate a transfer or discharge as specified in 1 – 6 above have occurred, the medical record must show documentation of the basis for transfer or discharge.

For circumstances 1 and 2 listed above for facility-initiated transfer or discharge, the **resident's physician** must document information about the basis for the transfer or discharge. Additionally, for circumstance 1 above (the inability to meet the resident's needs) the documentation made by the **resident's physician must** include:

- The specific resident needs the facility could not meet;
- The facility efforts to meet those needs; and
- The specific services the receiving facility will provide to meet the needs of the resident which cannot be met at the current facility.

In circumstances 3 and 4 above, documentation regarding the reason for the transfer or discharge must be provided by a physician, not necessarily the attending physician.

**NOTE**: Documentation of the transfer or discharge may be completed by a non-physician practitioner (NPP) in accordance with State law.

**Information Conveyed to Receiving Provider**

The regulations at §483.15(c)(2)(iii) address information that must be conveyed to the receiving provider when a resident is transferred or discharged. The specific information which must be conveyed depends upon whether the resident is transferred (expected to return),or is discharged (not expected to return). If the resident is being transferred, and return is expected, the following information must be conveyed to the receiving provider:

- Contact information of the practitioner who was responsible for the care of the resident;
- Resident representative information, including contact information;
- Advance directive information;
- 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(***i***) 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, F661, 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.

## 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 transfer or discharge requirements.

### Summary of Investigative Procedure

Briefly review the most recent comprehensive assessment, comprehensive care plan, progress notes, and orders to identify the basis for the transfer or discharge; during this review, identify the extent to which the facility has developed and implemented interventions to avoid transferring or discharging the resident, in accordance with the resident's needs, goals for care and professional standards of practice. This information will guide observations and interviews to be made in order to corroborate concerns identified. **NOTE**: Always observe for visual cues of psychosocial distress and harm (see Guidance on Severity and Scope Levels and Psychosocial Outcome Severity Guide).

### Deficiency Categorization

In addition to actual or potential physical harm, always consider whether psychosocial harm has occurred when determining severity level (See 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.

### Examples of Severity Level 4 Non-compliance: Immediate Jeopardy to Resident

**Health or Safety include, but are not limited to:**

- Facility initiated a discharge on the basis that the resident's health had improved, 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. The resident developed sepsis from inadequate wound management, and remains hospitalized post-amputation of the infected limb.

- A facility initiated a discharge based on the facility's inability to meet a 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 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 challenging behaviors. The resident was discharged to the street and found by a passerby in the street, rolled up in a tarp, and in a health condition requiring immediate medical attention.

**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 initiated a resident's discharge 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 pain 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.

**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.

**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.**

## F623

***(Rev. 225; Issued: 08-08-24; Effective: 08-08-24; Implementation: 08-08-24)***

**§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(*k*).**

**DEFINITIONS**

**"Facility-initiated transfer or discharge":** A transfer or discharge which the resident objects to, did not originate through a resident's verbal or written request, and/or is not in alignment with the resident's stated goals for care and preferences.

**"Resident-initiated transfer or discharge":** Means the resident or, if appropriate, the resident representative has provided verbal or written notice of intent to leave the facility (leaving the facility does not include the general expression of a desire to return home or the elopement of residents with cognitive impairment).

**"Transfer and Discharge":** Includes movement of a resident to a bed outside of the

certified facility whether that bed is in the same physical plant or not. Transfer and discharge does not refer to movement of a resident to a bed within the same certified facility. (See §483.5) Specifically, transfer refers to the movement of a resident from a bed in one certified facility to a bed in another certified facility when the resident expects to return to the original facility. Discharge refers to the movement of a resident from a bed in one certified facility to a bed in another certified facility or other location in the community, when return to the original facility is not expected.

**GUIDANCE**

The requirements at §§483.15(c)(3)-(6) only apply to facility-initiated transfers and discharges, not resident-initiated transfers and discharges. This guidance will address the requirement to send a notice in situations where the facility initiates a transfer or discharge, including discharges that occur while the resident remains in the hospital after emergency transfer.

Facility-initiated transfers and discharges generally occur when the facility determines it should not, or cannot provide needed care or services to a resident in accordance with F622, Transfer and Discharge Requirements. Whether or not a resident agrees with the facility's decision, the requirements at §483.15(c)(3)-(6) apply whenever a facility initiates the transfer or discharge.

A resident-initiated transfer or discharge is one in which the resident has provided written or verbal notice of their intent to leave the facility, which is documented in the resident's record. A resident's expression of a general desire to return home or to the community or elopement of a resident who is cognitively impaired should not be taken as a notice of intent to leave. When a resident initiates his or her transfer or discharge, the medical record should contain documentation or evidence of the resident's or resident representative's verbal or written notice of intent to leave the facility, a discharge care plan, and documented discussions with the resident or if appropriate his/her representative, containing details of discharge planning, and arrangements for post- discharge care (See F660, Discharge Planning Process). Additionally, the comprehensive care plan should contain the resident's goals for admission and desired outcomes, which should be in alignment with the discharge if it is resident initiated.

Therapeutic leave is a type of resident-initiated transfer (See F625 for additional guidance on therapeutic leave). However, if the facility makes a determination to not allow the resident to return, the transfer becomes a facility-initiated discharge.

**NOTE**: Situations in which residents sign out of the facility or leave Against Medical Advice (AMA) should be thoroughly investigated to determine if the discharge is facility- or resident-initiated. If evidence reveals that a resident or resident representative was forced, pressured, or intimidated into leaving AMA, the discharge would be considered a facility-initiated discharge, requiring further investigation to determine compliance with the requirements at 483.15(c), including the requirement to provide a notice at F623. See additional guidance on AMA discharges at F660 and

guidance on Abuse, Neglect and Exploitation at F600.

**Notice of Transfer or Discharge and Ombudsman Notification**

For facility-initiated transfers or discharges of 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.

**Facility-Initiated Transfers and Discharges**

In situations where the facility has decided to discharge the resident while the resident is still hospitalized, the facility must send a notice of discharge to the resident and resident representative 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 as described below.

For any other types of facility-initiated discharges, the facility must provide notice of discharge to the resident and resident representative along with a copy of the notice to the Office of the State LTC Ombudsman at least 30 days prior to the discharge or as soon as possible. The copy of the notice to the ombudsman must be sent at the same time notice is provided to the resident and resident representative.

**Emergency Transfers**--When a resident is temporarily transferred on an emergency basis to an acute care facility, this type of transfer is considered to be a facility-initiated transfer and a notice of transfer must be provided to the resident and resident representative as soon as practicable 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).

**Resident-Initiated Transfers and Discharges**

A resident-initiated transfer or discharge means the resident or, if appropriate, the

resident representative has provided verbal or written notice of intent to leave the facility. The medical record must contain documentation or evidence of the resident's or resident representative's verbal or written notice of intent to leave the facility. While a resident's expression of a general desire or goal to return home or to the community or the elopement of a resident who is cognitively impaired should be taken into consideration for the purposes of discharge planning and community placement, it should not be taken as notice of intent to leave the facility and does not constitute a resident- initiated transfer or discharge. For resident-initiated transfers or discharges, sending a copy of the notice to the ombudsman is not required because the notice requirement does not apply to resident-initiated transfers or discharges.

Surveyors must determine whether a transfer or discharge is resident or facility-initiated. The medical record should contain documentation or evidence of the resident's or resident representative's verbal or written notice of intent to leave the facility, a discharge care plan, and documented discussions with the resident or, if appropriate, his/her representative, containing details of discharge planning and arrangements for post-discharge care (See F660, Discharge Planning Process, and F661, Discharge Summary). Additionally, the comprehensive care plan should contain the resident's goals for admission and desired outcomes, which should be in alignment with the discharge if it is resident-initiated. If a surveyor has concerns about whether a resident- initiated transfer or discharge was actually a facility-initiated transfer or discharge, the surveyor should investigate further through interviews and record review.

**Contents of the Notice**

The facility's notice must include 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.

**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.

**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.

**Notice in Advance of Facility Closure:**

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

## F656

***(Rev. 225; Issued: 08-08-24; Effective: 08-08-24; Implementation: 08-08-24)***

**§483.21(b) Comprehensive Care Plans**

**§483.21(b)(1) The facility must develop and implement a comprehensive person-centered care plan for each resident, consistent with the resident rights set forth at §483.10(c)(2) and §483.10(c)(3), that includes measurable objectives and timeframes to meet a resident's medical, nursing, and mental and psychosocial needs that are identified in the comprehensive assessment. The comprehensive care plan must describe the following —**

- **(i) The services that are to be furnished to attain or maintain the resident's highest practicable physical, mental, and psychosocial well-being as required under §483.24, §483.25 or §483.40; and**
- **(ii) Any services that would otherwise be required under §483.24, §483.25 or §483.40 but are not provided due to the resident's exercise of rights under §483.10, including the right to refuse treatment under §483.10(c)(6).**
- **(iii) Any specialized services or specialized rehabilitative services the nursing facility will provide as a result of PASARR recommendations. If a facility disagrees with the findings of the PASARR, it must indicate its rationale in the resident's medical record.**
- **(iv)In consultation with the resident and the resident's representative(s)—**
  - **(A) The resident's goals for admission and desired outcomes.**
  - **(B) The resident's preference and potential for future discharge. Facilities must document whether the resident's desire to return to the community was assessed and any referrals to local contact agencies and/or other appropriate entities, for this purpose.**
  - **(C) Discharge plans in the comprehensive care plan, as appropriate, in accordance with the requirements set forth in paragraph (c) of this section.**

**§483.21(b)(3) The services provided or arranged by the facility, as outlined by the comprehensive care plan, must—**

- **(iii) Be culturally-competent and trauma–informed.**

**INTENT**

Each resident will have a person-centered comprehensive care plan developed and implemented to meet his or her preferences and goals, and address the resident's medical, physical, mental and psychosocial needs.

**DEFINITIONS**

**"Culture"** is the conceptual system that structures the way people view the world—it is the particular set of beliefs, norms, and values that influence ideas about the nature of relationships, the way people live their lives, and the way people organize their world. Adopted from Substance Abuse and Mental Health Services Administration. Improving Cultural Competence.
Treatment Improvement Protocol (TIP) Series No. 59. HHS Publication No. (SMA) 14-4849.
https://store.samhsa.gov/system/files/sma14-4849.pdf.

**"Cultural Competency"** is a developmental process in which individuals or institutions achieve increasing levels of awareness, knowledge, and skills along a cultural competence continuum. Cultural competence involves valuing diversity, conducting self-assessments, avoiding stereotypes, managing the dynamics of difference, acquiring and institutionalizing cultural knowledge, and adapting to diversity and cultural contexts in communities.
US Department of Health and Human Services publication: A Blueprint for Advancing and Sustaining CLAS Policy and Practice at:
https://www.thinkculturalhealth.hhs.gov/clas/blueprint.

**"Resident's Goal"** refers to the resident's desired outcomes and preferences for admission, which guide decision-making during care planning.

**"Interventions"** are actions, treatments, procedures, or activities designed to meet an objective.

**"Measurable"** is the ability to be evaluated or quantified.

**"Objective"** is a statement describing the results to be achieved to meet the resident's goals.

**"Person-centered care"** means to focus on the resident as the locus of control and support the resident in making their own choices and having control over their daily lives.

**"Trauma-informed care"** is an approach to delivering care that involves understanding, recognizing and responding to the effects of all types of trauma. A trauma-informed approach to care delivery recognizes the widespread impact, and signs and symptoms of trauma in residents, and incorporates knowledge about trauma into care plans, policies, procedures and practices to avoid re-traumatization. Adapted from: SAMHSA's Concept of Trauma and Guidance for a Trauma-Informed Approach,
https://store.samhsa.gov/system/files/sma14-4884.pdf.

**GUIDANCE**

Through the care planning process, facility staff must work with the resident and his/her representative, if applicable, to understand and meet the resident's preferences, choices

and goals during their stay at the facility. The facility must establish, document and implement the care and services to be provided to each resident to assist in attaining or maintaining his or her highest practicable quality of life. Care planning drives the type of care and services that a resident receives. If care planning is not complete, or is inadequate, the consequences may negatively impact the resident's quality of life, as well as the quality of care and services received.

Facilities are required to develop care plans that describe the resident's medical, nursing, physical, mental and psychosocial needs and preferences and how the facility will assist in meeting these needs and preferences. Care plans must include person-specific, measurable objectives and timeframes in order to evaluate the resident's progress toward his/her goal(s).

Care plans must be person-centered and reflect the resident's goals for admission and desired outcomes. Person-centered care means the facility focuses on the resident as the center of control, and supports each resident in making his or her own choices. Person-centered care includes making an effort to understand what each resident is communicating, verbally and nonverbally, identifying what is important to each resident with regard to daily routines and preferred activities, and having an understanding of the resident's life before coming to reside in the nursing home.

Residents' goals set the expectations for the care and services he or she wishes to receive. For example, a resident admitted for rehabilitation may have the following goal – "Receive the necessary care and services so that I may return to independent living." Another resident may have a goal of receiving the necessary care and services to meet needs they cannot independently achieve, while maintaining as much independence as possible. And yet another resident or his or her representative, if applicable, may have a goal of receiving the necessary care and services to keep the resident comfortable and pain-free at the end of their life. Each of these examples would be supported by measurable objectives, interventions and timeframes designed to meet each specific resident goal.

Measurable objectives describe the steps toward achieving the resident's goals, and can be measured, quantified, and/or verified. For example, "Mrs. Jones, who underwent hip replacement, will report adequate pain control (as evidenced by pain at 1-3, on a scale of 1-10) throughout her SNF stay." Facility staff will use this objective to monitor the resident's progress.

The comprehensive care plan must reflect interventions to enable each resident to meet his/her objectives. Interventions are the specific care and services that will be implemented. Interventions for the example above, related to pain, may include, but are not limited to:

- Evaluate pain level using pain scale (0-10) 45 minutes after administering pain medication;
- Administer pain medication 45-60 minutes prior to physical therapy.

When developing the comprehensive care plan, facility staff must, at a minimum, use the Minimum Data Set (MDS) to assess the resident's clinical condition, cognitive and functional status, and use of services.

If a Care Area Assessment (CAA) is triggered, the facility must further assess the resident to determine whether the resident is at risk of developing, or currently has a weakness or need associated with that CAA, and how the risk, weakness or need affects the resident. Documentation regarding these assessments and the facility's rationale for deciding whether or not to proceed with care planning for each area triggered must be recorded in the medical record.

There may be times when a resident risk, weakness or need is identified within the context of the MDS assessment, but may not cause a CAA to trigger. The facility is responsible for addressing these areas and must document the assessment of these risks, weaknesses or needs in the medical record and determine whether or not to develop a care plan and interventions to address the area. If the decision to proceed to care planning is made, the interdisciplinary team (IDT), in conjunction with the resident and/or resident's representative, if applicable (§483.21(b)(2)(ii)), must develop and implement the comprehensive care plan and describe how the facility will address the resident's goals, preferences, strengths, weaknesses, and needs.

**NOTE**: Although Federal requirements dictate the completion of RAI assessments according to certain time frames, standards of good clinical practice dictate that the clinical assessment process is more fluid and should be ongoing. The lack of ongoing clinical assessment and identification of changes in condition to meet the resident's needs between required RAI assessments should be addressed at §483.35 Nursing Services, F726 (competency and skills to identify and address a change in condition), and the relevant outcome tag, such as §483.12 Abuse, §483.24 Quality of Life, §483.25 Quality of Care, and/or §483.40 Behavioral Health.

In some cases, a resident may wish to refuse certain services or treatments that professional staff believes may be indicated to assist the resident in reaching his or her highest practicable level of well-being or to keep the resident safe. In situations where a resident's choice to decline care or treatment (e.g., due to preferences, maintain autonomy, etc.) poses a risk to the resident's health or safety, the comprehensive care plan must identify the care or service being declined, the risk the declination poses to the resident, and efforts by the interdisciplinary team to educate the resident and the representative, as appropriate. The facility's attempts to find alternative means to address the identified risk/need should be documented in the care plan. See guidelines at §483.10(c)(6) (F578) for additional guidance concerning the resident's decision to refuse treatment. Additionally, a resident's decision-making ability may decline over time. The facility should determine how the resident's decisions may increase risks to health and safety, evaluate the resident's decision making capacity, and involve the interdisciplinary team and the resident's representative, if applicable, in the care planning process.

In addition to addressing preferences and needs assessed by the MDS, the comprehensive care plan must coordinate with and address any specialized services or specialized rehabilitation services the facility will provide or arrange as a result of PASARR recommendations. If the IDT disagrees with the findings of the PASARR, it must indicate its rationale in the resident's medical record. The rationale should include an explanation of why the resident's current assessed needs are inconsistent with the PASARR recommendations and how the resident would benefit from alternative interventions. The facility should also document a resident's the resident's preference for a different approach to achieve goals or refusal of recommended services.

Residents' preferences and goals may change throughout their stay, so facilities should have ongoing discussions with the resident and resident representative, if applicable, so that changes can be reflected in the comprehensive care plan.

The comprehensive care plan must address a resident's preference for future discharge, as early as upon admission, to ensure that each resident is given every opportunity to attain his/her highest quality of life. This encourages facilities to operate in a person-centered fashion that addresses resident choice and preferences.

**Culturally Competent Care**

Cultural competency, (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. it means being respectful and responsive to the health beliefs, practices and cultural and linguistic needs of diverse population groups, such as racial, ethnic, religious or social groups (https://www.samhsa.gov/capt/applying-strategic-prevention/cultural-competence). The interventions in the resident's care plan must reflect the individual resident's needs and preferences and align with the resident's cultural identity.

**Trauma-Informed Care**

Given the widespread nature and highly individualized experience of trauma, the utilization of trauma-informed approaches is an essential part of person-centered care. Facilities must recognize the effects of past trauma on residents and collaborate with the resident, family and friends of the resident to identify and implement individualized interventions. Interventions for trauma survivors should recognize the interrelation between trauma and symptoms of trauma such as substance abuse, eating disorders, aggression, depression, anxiety, and withdrawal or isolation from others.

Surveyors should refer to the following when investigating concerns related to culturally-competent, trauma-informed care:

- F656: For concerns related to development or implementation of culturally competent and/or trauma-informed care plan interventions;

- F699: For concerns related to outcomes or potential outcomes to the resident related to culturally-competent and/or trauma-informed care;
- F726: For concerns related to the knowledge, competencies, or skill sets of nursing staff to provide care or services that are culturally competent and trauma-informed.
- F742: For concerns related to treatment and services for resident with history of trauma and/or history of post-traumatic stress disorder (PTSD)

**INVESTIGATIVE PROCEDURES**

Use the Critical Element (CE) Pathway associated with the issue under investigation, or if there is no specific CE Pathway, use the General Critical Element Pathway, along with the above interpretive guidelines when determining if the facility meets the requirements for, or investigating concerns related to the facility's requirement to develop and implement a Comprehensive Care Plan. If systemic concerns are identified with Comprehensive Care Plans, use the probes below to assist in your investigation

**PROBES**

- Does the care plan address the goals, preferences, needs and strengths of the resident, including those identified in the comprehensive resident assessment, to assist the resident to attain or maintain his or her highest practicable well-being and prevent avoidable decline?
- Are objectives and interventions person-centered, measurable, and do they include time frames to achieve the desired outcomes?
- Is there evidence of resident and, if applicable resident representative participation (or attempts made by the facility to encourage participation) in developing person-centered, measurable objectives and interventions?
- Does the care plan describe specialized services and interventions to address PASARR recommendations, as appropriate?
- Does the care plan describe interventions that reflect the resident's cultural preferences, values and practices?
- For residents with a history of trauma, does the care plan describe corresponding interventions for care that are in accordance with professional standards of practice and accounting for residents' experiences and preferences in order to eliminate or mitigate triggers that may cause re-traumatization of the resident? (See §483.25(m))
- Is there evidence that care plan interventions were implemented consistently across all shifts?
- Is there a process in place to ensure direct care staff are aware of and educated about the care plan interventions?
- Determine whether the facility has provided adequate information to the resident and, if applicable resident representative so that he/she was able to make informed choices regarding treatment and services.
- Evaluate whether the care plan reflects the facility's efforts to find alternative means to address care of the resident if he or she has refused treatment.

## POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION

- F658: for concerns regarding the delivery of care within professional standards of practice.

If the surveyor identifies concerns about the resident's care plan being individualized and person-centered, the surveyor should also review requirements at:

- Resident Rights, §483.10
- Resident assessment, §483.20
- Activities, §483.24(c)
- Nursing services, §483.35
- Food and nutrition services, §483.60
- Facility assessment, §483.71
- Cultural competence and trauma-informed care, §483.25(m)
- Treatment/Services for mental/psychosocial concerns §483.40(b)(1)

## KEY ELEMENTS OF NON-COMPLIANCE

To cite deficient practice at F656, the surveyor's investigation will generally show that the facility failed to do one or more of the following:

- Develop and implement a care plan that:
    - Is comprehensive and individualized;
    - Is consistent with the resident's goals and right to be informed and participate in his/her treatment;
    - Meets each of the medical, nursing, mental and psychosocial needs identified on the resident's comprehensive assessment;
    - Includes measurable objectives, interventions and timeframes for how staff will meet the resident's needs.

- Develop and implement a care plan that describes all of the following:
    - Resident goals and desired outcomes;
    - The care/services that will be furnished so that the resident can attain or maintain his/her highest practicable physical, mental and psychosocial well-being;
    - The specialized services to be provided as a result of the PASARR evaluation and/or the comprehensive assessment;
    - The resident's discharge plan and any referrals to the local contact agency;
    - Refusals of care and action taken by facility staff to educate the resident and resident representative, if applicable, regarding alternatives and consequences;
    - Care and services which are culturally competent and trauma-informed.

## DEFICIENCY CATEGORIZATION

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

- A resident has a known history of inappropriate sexual behaviors and aggression, but the comprehensive care plan did not address the resident's inappropriate sexual behaviors or aggression which placed the resident and other residents in the facility at risk for serious physical and/or psychosocial injury, harm, impairment, or death.

- The facility failed to implement care plan interventions to monitor a resident with a known history of elopement attempts, which resulted in the resident leaving the building unsupervised, putting the resident at risk for serious injury or death.

- The facility failed to identify a resident's cultural dietary restrictions related to eating pork. After eating her dinner, upon realization that she had eaten pork, the resident began crying inconsolably and screaming that this was explicitly forbidden in her culture and faith of Islam. The resident remained tearful and inconsolable for several days, and would not eat the food provided by the facility, which resulted in weight loss and serious psychosocial harm.

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

- The CAA Summary for a resident indicates the need for a care plan to be developed to address nutritional risks in a resident who had poor nutritional intake. A care plan was not developed, or the care plan interventions did not address the problems/risks identified. The lack of interventions caused the resident to experience weight loss.

- Lack of care plan interventions to address a resident's anxiety, depression, and hallucinations resulted in psychosocial harm to the resident

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

- During the comprehensive assessment, a resident indicated a desire to participate in particular activities, but the comprehensive care plan did not address the resident's preferences for activities, which resulted in the resident complaining of being bored, and sometimes feeling sad about not participating in activities he/she expressed interest in attending.
- An inaccurate or incomplete care plan resulted in facility staff providing one staff to assist the resident, when the resident required the assistance of two staff, which had the potential to cause more than minimal harm.

**An example of Level 1, no actual harm with potential for no more than a minor negative impact on the resident, includes, but is not limited to:**

For one or more care plans, the staff did not include a measurable objective, which resulted in no more than a minor negative impact on the involved residents.

## F684

***(Rev. 225; Issued: 08-08-24; Effective: 08-08-24; Implementation: 08-08-24)***

**§ 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 F758 psychotropic medications and F757 unnecessary medications.);
- Nutrition and Hydration- The resident may experience a decline in appetite or have difficulty eating or swallowing. Care plan interventions, regarding nutrition/hydration, must be based upon the resident's assessment, disease processes, and resident choices/directives and include amount, type, texture and frequency for food and fluids. Dietary restrictions and/or weight measurements may be revised/discontinued based upon resident/representative and attending practitioner decisions, and must be included in the medical record. If the resident's condition has declined to the point where he/she may no longer swallow food or fluids, the determination of whether to use artificial

nutrition/hydration, based upon resident choices/directives, is made by the resident/ representative and the attending practitioner, and consistent with applicable State law and regulation. (For concerns related to nutrition, refer to F692, for concerns related to nutrition/hydration, and for concerns related to feeding tubes, refer to F693.); and/or

- Activities/Psychosocial Needs - Care plan interventions for activities must be based on the resident's assessment and include the resident's choices, personal beliefs, interests, ethnic/cultural practices and spiritual values, as appropriate. In addition, the resident's assessment may identify psychosocial needs, such as fear, loneliness, anxiety, or depression. Interventions to address the needs must be included in the plan of care. (For concerns related to the provision of activities, refer to F679. For concerns regarding medically related social services, refer to F745.)

For concerns related to developing and implementing the care plan, refer to F656, Comprehensive Care Plans; and for revision of care plans refer to F657, Comprehensive Care Plan Revision.

**Resident Care Policies**

The facility in collaboration with the medical director must develop and implement resident care policies that are consistent with current professional standards of practice for not only pain management and symptom control, but for assessing residents' physical, intellectual, emotional, social, and spiritual needs as appropriate. In addition, if the facility has a written agreement with a Medicare-certified hospice, the policies must identify the ongoing collaboration and communication processes established by the nursing home and the hospice. (Refer to F841 - §483.70(*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), F622.

If there is a conflict between the hospice and the resident's attending physician/practitioner regarding the care plan, there must be communication between the hospice and the nursing home regarding the issue. This communication should be timely and include the hospice medical director and the nursing home medical director as well as other pertinent hospice and facility staff, as needed.

The care of the resident receiving hospice services must reflect ongoing communication and collaboration between the nursing home and the hospice staff. It is essential that a communication process be established between the nursing home and the hospice to be used 24-hours a day and that it include how the communication will be documented to reflect concerns and responses. (Refer to F849 - which requires that the written agreement specify the process for hospice and nursing home communication of necessary information regarding the resident's care.)

**Review of Facility Practices/Written Agreement for Hospice Services**
Any concerns identified by the survey team related to end of life and/or care provided by a hospice should trigger a review of the facility's policies and procedures on end of life

and hospice care and/or related policies (e.g., advance directives). In addition, the survey team should request a copy of the written agreement between the nursing home and the hospice. If there is a failure to develop and or implement portions of the written agreement with a hospice, refer to F849 - Hospice Services.

**NOTE**: 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).

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**

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

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

- The facility failed to promptly identify and intervene for an acute change in a resident's condition related to congestive heart failure (CHF), resulting in the family calling 911 to transport the resident to the hospital. The resident was admitted to the hospital with respiratory distress, pulmonary edema, and complications of CHF.(Also cross-referenced and cited at F580, Notification of Changes.)
- As a result of the facility's continuous or repeated failure to implement comfort measures in accordance with the care plan, the resident experienced serious harm related to uncontrolled vomiting and nausea.

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

- The facility failed to provide care for a resident with a stasis ulcer as identified on the resident's care plan and physician's orders, resulting in worsening of the stasis ulcer, as evidenced by a large area of the skin surrounding the ulcer being reddened, swollen and, according to the nurse, warm to touch. There was exudate and slough on the wound bed, and according to measurements, the wound had increased in size.
- The facility failed to implement a resident's hospice/nursing home coordinated care plan that specified the resident not being transferred to the hospital for treatment. The facility transferred the resident to the hospital for treatment related to a urinary tract infection even though the resident and the coordinated care plan indicated the resident did not wish to be hospitalized and preferred treatment at the facility. The facility did not contact the hospice prior to initiating the transfer to the hospital. The resident experienced increased pain during the transfer to the hospital and continued to express emotional distress (tearful/crying) over the transfer.
- The resident had requested and the care plan included a symptom management plan with the use of medication to reduce the resident's symptoms but not to the point that the resident was symptom free so that the resident could be alert and able to participate in visits with family/friends. However, the facility failed to administer the medications as indicated in the plan of care. The resident experienced lethargy and somnolence and was unable to converse/relate to family/friends during visits.

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

Failure to follow physician orders to obtain daily weights for a resident with a diagnosis of congestive heart failure, as evidenced by no documented daily weights on three

consecutive weekends. Although this noncompliance resulted in no actual harm to the resident, it has a potential for more than minimal harm if the practice is not corrected.

The resident receiving the hospice benefit was on a pain management program utilizing opioids. The resident was experiencing episodic minimal discomfort related to the facility's failure to consistently implement the bowel management plan as identified in the coordinated care plan.

**Severity Level 1 Noncompliance: No Actual Harm, with Potential for Minimal Harm**

Failure to provide appropriate care and services to meet the resident's physical, mental and/or psychosocial needs places the resident at risk for more than minimal harm. Therefore, Severity Level 1 does not apply for this regulatory requirement.

## F689

***(Rev. 225; Issued: 08-08-24; Effective: 08-08-24; Implementation: 08-08-24)***

**§483.25(d) Accidents.**

**The facility must ensure that –**
**§483.25(d)(1) The resident environment remains as free of accident hazards as is possible; and**

**§483.25(d)(2) Each resident receives adequate supervision and assistance devices to prevent accidents.**

**INTENT: 483.25(d)**

The intent of this requirement is to ensure the facility provides an environment that is free from accident hazards over which the facility has control and provides supervision and assistive devices to each resident to prevent avoidable accidents. This includes:

- Identifying hazard(s) and risk(s);
- Evaluating and analyzing hazard(s) and risk(s);
- Implementing interventions to reduce hazard(s) and risk(s); and
- Monitoring for effectiveness and modifying interventions when necessary.

**DEFINITIONS 483.25(d)**

Definitions are provided to clarify terms related to providing supervision and other interventions to prevent accidents.

**"Accident"** refers to any unexpected or unintentional incident, which results or may result in injury or illness to a resident. This does not include other types of harm, such as adverse outcomes that are a direct consequence of treatment or care that is provided in

accordance with current professional standards of practice (e.g., drug side effects or reaction).

**"Avoidable Accident"** means that an accident occurred because the facility failed to:

- Identify environmental hazards and/or assess individual resident risk of an accident, including the need for supervision and/or assistive devices; and/or
- Evaluate and analyze the hazards and risks and eliminate them, if possible, or, if not possible, identify and implement measures to reduce the hazards/risks as much as possible; and/or
- Implement interventions, including adequate supervision and assistive devices, consistent with a resident's needs, goals, care plan and current professional standards of practice in order to eliminate the risk, if possible, and, if not, reduce the risk of an accident; and/or
- Monitor the effectiveness of the interventions and modify the care plan as necessary, in accordance with current professional standards of practice.

**"Unavoidable Accident"** means that an accident occurred despite sufficient and comprehensive facility systems designed and implemented to:

- Identify environmental hazards and individual resident risk of an accident, including the need for supervision; and
- Evaluate and analyze the hazards and risks and eliminate them, if possible and, if not possible, reduce them as much as possible;
- Implement interventions, including adequate supervision, consistent with the resident's needs, goals, plan of care, and current professional standards of practice in order to eliminate the risk, if possible, and, if not, reduce the risk of an accident; and
- Monitor the effectiveness of the interventions and modify the interventions as necessary, in accordance with current professional standards of practice.

**"Assistance Device"** or **"Assistive Device"** refers to any item (e.g., fixtures such as handrails, grab bars, and mechanical devices/equipment such as stand-alone or overhead transfer lifts, canes, wheelchairs, and walkers, etc.) that is used by, or in the care of a resident to promote, supplement, or enhance the resident's function and/or safety.

**NOTE**: The currently accepted nomenclature refers to "assistive devices." Although the term "assistance devices" is used in the regulation, the Guidance provided in this document will refer to "assistive devices." These terms mean the same thing, and may be used interchangeably.

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

**"Fall"** refers to unintentionally coming to rest on the ground, floor, or other lower level, but not as a result of an overwhelming external force (e.g., resident pushes another resident). An episode where a resident lost his/her balance and would have fallen, if not for another person or if he or she had not caught him/herself, is considered a fall. A fall without injury is still a fall. Unless there is evidence suggesting otherwise, when a resident is found on the floor, a fall is considered to have occurred (refer to Resident Assessment Instrument User's Manual. Version 3.0, Chapter 3, page J-27).

**"Hazards"** refer to elements of the resident environment that have the potential to cause injury or illness.

- "Hazards over which the facility has control" are those hazards in the resident environment where reasonable efforts by the facility could influence the risk for resulting injury or illness.
- "Free of accident hazards as is possible" refers to being free of accident hazards over which the facility has control.

"**Position change alarms**" are alerting devices intended to monitor a resident's movement. The devices emit an audible signal when the resident moves in a certain way. Types of position change alarms include chair and bed sensor pads, bedside alarmed mats, alarms clipped to a resident's clothing, seatbelt alarms, and infrared beam motion detectors.[2] Position change alarms do not include alarms intended to monitor for unsafe wandering such as door or elevator alarms.

**"Risk"** refers to any external factor, facility characteristic (e.g., staffing or physical environment) or characteristic of an individual resident that influences the likelihood of an accident.

**"Supervision/Adequate Supervision"** refers to an intervention and means of mitigating the risk of an accident. Facilities are obligated to provide adequate supervision to prevent accidents. Adequate supervision is determined by assessing the appropriate level and number of staff required, the competency and training of the staff, and the frequency of supervision needed. This determination is based on the individual resident's assessed needs and identified hazards in the resident environment. Adequate supervision may vary from resident to resident and from time to time for the same resident.

**GUIDANCE OVERVIEW** §483.25(d)
Numerous and varied accident hazards exist in everyday life. Not all accidents are avoidable. The frailty of some residents increases their vulnerability to hazards in the resident environment and can result in life-threatening injuries. It is important that all facility staff understand the facility's responsibility, as well as their own, to ensure the safest environment possible for residents.

The facility is responsible for providing care to residents in a manner that helps promote quality of life. This includes respecting residents' rights to privacy, dignity and self-

determination, and their right to make choices about significant aspects of their life in the facility.

An effective way for the facility to avoid accidents is to develop a culture of safety and commit to implementing systems that address resident risk and environmental hazards to minimize the likelihood of accidents. A facility with a commitment to safety:

- Acknowledges the high-risk nature of its population and setting;
- Develops effective communication, including a reporting system that does not place blame on the staff member for reporting resident risks and environmental hazards;
- Engages all staff, residents and families in training on safety, and promotes ongoing discussions about safety with input from staff at all levels of the organization, as well as residents and families;
- Encourages the use of data to identify potential hazards, risks, and solutions related to specific safety issues that arise;
- Directs resources to address safety concerns; and
- Demonstrates a commitment to safety at all levels of the organization.

## A SYSTEMS APPROACH

Processes in a facility's interdisciplinary systematic approach may include:

- Identification of hazards, including inadequate supervision, and a resident's risks of potentially avoidable accidents in the resident environment;
- Evaluation and analysis of hazards and risks;
- Implementation of individualized, resident-centered interventions, including adequate supervision and assistive devices, to reduce individual risks related to hazards in the environment; and
- Monitoring for effectiveness and modification of interventions when necessary.

A key element of a systematic approach is the consistent application of a process to address identified hazards and/or risks. Risks may pertain to individual residents, groups of residents, or the entire facility. Hazards may include, but are not limited to, aspects of the physical plant, equipment, and devices that are defective or are not used properly (per manufacturer's specifications), are disabled/removed, or are not individually adapted or fitted to the resident's needs. An effective system not only proactively identifies environmental hazards and the resident's risk for an avoidable accident, but also evaluates the resident's need for supervision.

Identifying and addressing risks, including the potential for accidents, includes consideration of the environment, the resident's risk factors, and the need for supervision, care, and assistive devices. This will allow the facility to communicate information about observed hazards, identify resident-specific information, develop and implement an individualized care plan based on the Resident Assessment Instrument (RAI) to address each resident's needs and goals, and to monitor the results of the planned interventions.

The care plan should strive to balance the resident's wishes with the potential impact on the safety of the resident and other residents.

A systematic approach enables the facility to evaluate safety throughout its environment and among all staff, and make appropriate adjustments in training and competency testing as required. Each resident and their family members or representatives should be aware of the risks and potential hazards related to falls and of various devices used to reduce fall risk. Furthermore, a systematic approach enables leadership and direct care staff to work together to revise policies and procedures, based on feedback from workers who are most familiar with the residents and care processes. Effective facility systems address how to:

- communicate the observations of hazards,
- record resident specific information, and
- monitor data related to care processes that potentially lead to accidents.

**Identification of Hazards and Risks**

Identification of hazards and risks is the process through which the facility becomes aware of potential hazards in the resident environment and the risk of a resident having an avoidable accident. All staff (e.g., professional, administrative, maintenance, etc.) are to be involved in observing and identifying potential hazards in the environment, while taking into consideration the unique characteristics and abilities of each resident. The facility should make a reasonable effort to identify the hazards and risk factors for each resident. Various sources provide information about hazards and risks in the resident environment. These sources may include, but are not limited to, Quality Assessment and Assurance (QAA) activities, environmental rounds, MDS/CAAs data, medical history and physical exam, facility assessment as required in F838, and individual observation. This information is to be documented and communicated across all disciplines.

**Evaluation and Analysis**

Evaluation and analysis is the process of examining data to identify specific hazards and risks and to develop targeted interventions to reduce the potential for accidents. Interdisciplinary involvement is a critical component of this process. Analysis may include, for example, considering the severity of hazards, the immediacy of risk, and trends such as time of day, location, etc.

Both the facility-centered and resident-directed approaches include evaluating hazards and accident risk data which includes prior accidents/incidents, analysis to identify the root causes of each hazard and accident risk, and identifying or developing interventions based on the severity of the hazards and immediacy of risk. Evaluations also look at trends such as time of day, location, etc.

**Implementation of Interventions**

Implementation refers to using specific interventions to try to reduce a resident's risks from hazards in the environment. The process includes: Communicating the interventions to all relevant staff, assigning responsibility, providing training as needed, documenting interventions (e.g., plans of action developed through the QAA committee or care plans for the individual resident), and ensuring that the interventions are put into action.

Interventions are based on the results of the evaluation and analysis of information about hazards and risks and are consistent with professional standards, including evidence-based practice. Development of interim safety measures may be necessary if interventions cannot immediately be implemented fully.

Facility-based interventions may include, but are not limited to, educating staff, repairing the device/equipment, and developing or revising policies and procedures. Resident-directed approaches may include implementing specific interventions as part of the plan of care, supervising staff and residents, etc. Facility records document the implementation of these interventions.

**Monitoring and Modification**

Monitoring is the process of evaluating the effectiveness of care plan interventions. Modification is the process of adjusting interventions as needed to make them more effective in addressing hazards and risks.

Monitoring and modification processes include:

- Ensuring that interventions are implemented correctly and consistently;
- Evaluating the effectiveness of interventions;
- Modifying or replacing interventions as needed and
- Evaluating the effectiveness of new interventions.

An example of facility-specific modification is additional training of staff when equipment has been upgraded, while a resident-specific modification is revising the care plan to reflect the resident's current condition and risk factors that may have changed since the previous assessment.

For example, a facility implements a position change alarm for a newly admitted resident with a history of falls. After completing a comprehensive assessment of the resident, facility staff identify the resident's routines and patterns, remove the alarm, and implement more individualized interventions that address the actual cause of why a resident may be changing position (e.g. has been in one position too long or is trying to reach for a personal item) which could lead to a fall.

**Supervision**

Supervision is an intervention and a means of mitigating accident risk. Facilities are obligated to provide adequate supervision to prevent accidents. Adequacy of supervision is defined by type and frequency, based on the individual resident's assessed needs, and identified hazards in the resident environment. Adequate supervision may vary from resident to resident and from time to time for the same resident. Devices such as position change alarms may help to monitor a resident's movement temporarily, but do not eliminate the need for adequate supervision.

The resident environment may contain temporary hazards (e.g., construction, painting, housekeeping activities, etc.) that warrant additional supervision or alternative measures such as barriers to prevent access to affected areas of the resident environment.

Adequate supervision to prevent accidents is enhanced when the facility:

- Accurately assesses a resident and/or the resident environment to determine whether supervision to avoid an accident is necessary; and/or
- Determines that supervision of the resident was necessary and provides supervision based on the individual resident's assessed needs and the risks identified in the environment.

**Resident Smoking**

Some facilities permit residents to smoke tobacco products. In these facilities, assessment of the resident's capabilities and deficits determines whether or not supervision is required. If the facility identifies that the resident needs assistance and supervision for smoking, the facility includes this information in the resident's care plan, and reviews and revises the plan periodically as needed.

The facility may designate certain areas for resident smoking. The facility must ensure precautions are taken for the resident's individual safety, as well as the safety of others in the facility. Such precautions may include smoking only in designated areas, supervising residents whose assessment and care plans indicate a need for assisted and supervised smoking, and limiting the accessibility of matches and lighters by residents who need supervision when smoking for safety reasons. Smoking by residents when oxygen is in use is prohibited, and any smoking by others near flammable substances is also problematic. Additional measures may include informing all visitors of smoking policies and hazards.

Guidance concerning resident smoking regulations can be found in NFPA 101, 2012 edition, the Life Safety Code at 19.7.4, Smoking, including requirements for signage, prohibiting smoking by residents classified as not responsible, and disposal of smoking materials.

**Electronic cigarettes** – While electronic cigarettes (e-cigs), or vapor pens, are not considered smoking devices, and their heating element does not pose the same dangers of ignition as regular cigarettes, they are not without risk. A review of literature by the

Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), and Federal Emergency Management Agency (FEMA) shows that as electronic cigarette use has increased, risks associated with their use have also increased. Risks and concerns include:

- Potential health effects for the smoker, such as respiratory illness or lung injury which may present with symptoms of breathing difficulty, shortness of breath, chest pain, mild to moderate gastrointestinal illness, fever or fatigue;
- Second-hand aerosol exposure;
- Nicotine overdose by ingestion or contact with the skin; and
- Explosion or fire caused by the battery.

Because these devices are not without risk and have accidents associated with them, facilities have a responsibility to oversee their use and provide supervision to maintain an accident-free environment.

In August 2016, the World Health Organization recommended that electronic cigarettes be banned indoors or where smoking is prohibited because of the second-hand exposure to potentially toxic chemicals, and many local and state jurisdictions have begun enacting laws that prohibit electronic cigarette use everywhere that smoking is banned. Facilities that decide, in accordance with State and local laws, to allow e-cigarette use, should develop and implement policies for safe use of e-cigarettes, along with policies for traditional cigarettes. Policies should include where e-cigarettes can be used and how to handle the devices, batteries and refill cartridges. The FDA has published recommendations for safe handling at the following link: https://www.fda.gov/tobaccoproducts/labeling/productsingredientscomponents/ucm539362.htm#blue.

Residents who wish to use e-cigarettes should be assessed for their ability to safely handle the device. Concerns related to resident safety with use of e-cigarettes should be investigated using the guidance at 42 CFR 483.25(d), F689, Accidents and Supervision. Surveyors should also consider how facilities balance resident safety with a resident's right to use these devices while also considering the rights of residents who do not want to be exposed to second-hand aerosol. For concerns related to resident choice to use e-cigarettes in facilities where the devices are permitted and for residents who do not wish to be exposed to second-hand aerosol, surveyors should use guidance at 42 CFR 483.10(c)(3) Right to Participate in Planning Care, F553 and 483.10(f), F561, Self-Determination. For concerns about a facility's policies for e-cigarettes, use F926, 483.90(i)(5), Smoking Policies.

**Resident-to-Resident Altercations**

**NOTE:** A resident to resident altercation should be reviewed as a potential situation of abuse which should be investigated under the guidance for 42 CFR §483.12, (F600). The surveyor should not automatically assume that abuse did not occur for a resident identified as having a cognitive impairment or mental

disorder, as it does not preclude the resident from deliberate (willful) or non-accidental actions. "Willful" as defined at §483.5 and as used in the definition of "abuse," "means the individual must have acted deliberately, not that the individual must have intended to inflict injury or harm." Even though a resident may have a cognitive impairment, he/she could still commit a willful act. If during the investigation of an allegation of abuse, it is determined that the action was not willful, the surveyor must investigate whether the facility is in compliance with the requirement to maintain an environment as free of accident hazards as possible, and that each resident receives adequate supervision using guidance at this tag, F689, Accidents.

It is important that a facility take reasonable precautions, including providing adequate supervision, when the risk of resident-to-resident altercation is identified, or should have been identified. Certain situations or conditions may increase the potential for such altercations, including, but not limited to:

- A history of aggressive behaviors including striking out, verbal outbursts, or negative interactions with other resident(s); and/or
- Behavior that may disrupt or annoy others such as constant verbalization (e.g., crying, yelling, calling out for help), making negative remarks, restlessness, repetitive behaviors, taking items that do not belong to them, going into other residents' rooms, drawers, or closets, and undressing in inappropriate areas. Although these behaviors may not be aggressive in nature, they may precipitate a negative response from others, resulting in verbal, physical, and/or emotional harm.

The facility is responsible for identifying residents who have a history of disruptive or intrusive interactions, or who exhibit other behaviors that make them more likely to be involved in an altercation. The facility should identify the factors (e.g., pain, specific triggers in the environment, etc.) that increase the risks associated with individual residents, including those that could trigger an altercation. The interdisciplinary team reviews the assessment along with the resident and/or his/her representative, in order to address the underlying reasons for the behavioral manifestations and to identify interventions to try to prevent altercations.

The interventions listed below include supervision and other actions that could address potential or actual negative interactions:

- Evaluating staffing levels to ensure adequate supervision (if it is adequate, it is meeting the resident's needs) (refer to F725, §483.35(a)(1)(2), to evaluate staffing levels for any nursing services not related to behavioral health care or dementia care and F741, §483.40, for any staff caring for residents with dementia, mental and psychosocial disorder, substance use disorder, or a history of trauma and/or post-traumatic stress disorder);

- Evaluating staffing assignments to ensure consistent staff who are more familiar with the resident and who thus may be able to identify changes in a resident's condition and behavior;
- Providing safe supervised areas for unrestricted movement;
- Eliminating or reducing underlying causes of distressed behavior such as boredom and pain;
- Monitoring environmental influences such as temperatures, lighting, and noise levels; and
- Ongoing staff training, competencies and supervision, including how to approach a resident who may be agitated, combative, verbally or physically aggressive, or anxious, and how and when to obtain assistance in managing a resident with behavior symptoms (refer to F726, §483.35(a)(3)(4)(c), to evaluate staff competency for any nursing services not related to behavioral health care or dementia care and F741, §483.40, for any staff caring for residents with dementia, mental and psychosocial disorder, substance use disorder, or a history of trauma and/or post-traumatic stress disorder).

## RISKS AND ENVIRONMENTAL HAZARDS

This section discusses common, but not all, potential risks and hazards found in the resident environment.

**NOTE:** The information included in the following sections is based on current professional standards of practice or "best practice" models as described in the literature.

The physical plant, devices, and equipment described in this section may not be hazards by themselves but can become hazardous when a vulnerable resident interacts with them. Some temporary hazards in the resident environment can affect most residents who have access to them (e.g., construction, painting, and housekeeping activities). Other situations may be hazardous only for certain individuals (e.g., accessible smoking materials).

In order to be considered hazardous, an element of the resident environment must be accessible to a vulnerable resident. Resident vulnerability is based on risk factors including the individual resident's functional status, medical condition, cognitive abilities, mood, and health treatments (e.g., medications). Resident vulnerability to hazards may change over time. Ongoing assessment helps identify when elements in the environment pose hazards to a particular resident.

Certain sharp items, such as scissors, kitchen utensils, knitting needles, or other items, may be appropriate for many residents but hazardous for others with cognitive impairments. Handrails, assistive devices, and any surface that a resident may come in contact with may cause injury, if the surface is not in good condition, free from sharp edges or other hazards or not installed properly.

Improper actions or omissions by staff can create hazards in the physical plant (e.g., building and grounds), environment, and/or with devices and equipment. Examples of such hazards might include fire doors that have been propped open, disabled locks or latches, nonfunctioning alarms, buckled or badly torn carpets, cords on floors, irregular walking surfaces, improper storage and access to toxic chemicals, exposure to unsafe heating unit surfaces, and unsafe water temperatures. Other potential hazards may include furniture that is not appropriate for a resident (e.g., chairs or beds that are not the proper height or width for the resident to transfer to and from safely or unstable as to present a fall hazard) and lighting that is either inadequate or so intense as to create glare. Devices for resident care, such as pumps, ventilators, and assistive devices, may be hazardous when they are defective, disabled, or improperly used (i.e., used in a manner that is not per manufacturer's recommendations or current professional standards of practice).

**Resident Vulnerabilities**

The responsibility to respect a resident's choices is balanced by considering the resident's right to direct the care they receive with the potential impact of these choices on their well-being, other residents, and on the facility's obligation to protect residents from harm. The facility has a responsibility to educate a resident, family, and staff regarding significant risks related to a resident's choices. When a resident's choice poses some risk, staff should work with the resident to understand reasons for the choice, and discuss options for the facility to honor the choice. For example, a resident may express a desire to use a cane instead of a walker or wheelchair in order to maintain dignity and self-esteem. This preference should be discussed to review potential positive and negative consequences of possible courses of action (including potential negative consequences that may result from preventing the choice) and to find ways to develop a care plan in which staff honor the choice while mitigating risks. For resources on care planning to mitigate risk, see A Process for Care Planning Resident Choice at https://www.pioneernetwork.net/wp-content/uploads/2016/10/Process-for-Care-Planning-for-Resident-Choice-.pdf .

Verbal consent or signed consent/waiver forms do not eliminate a facility's responsibility to protect a resident from an avoidable accident, nor does it relieve the provider of its responsibility to assure the health, safety, and welfare of its residents. While Federal regulations affirm the resident's right to participate in care planning and to refuse treatment, the regulations do not create the right for a resident or representative to demand the facility use specific medical interventions or treatments that the facility deems inappropriate. The regulations hold the facility ultimately accountable for the resident's care and safety.

Falls and unsafe wandering/elopement are of particular concern. The following section reviews these issues along with some common potential hazards.

**Falls** - The MDS defines a fall as unintentionally coming to rest on the ground, floor, or other lower level but not as a result of an overwhelming external force (e.g., resident

pushes another resident). An episode where a resident lost his/her balance and would have fallen, if not for another person or if he or she had not caught him/herself, is considered a fall. A fall without injury is still a fall. Unless there is evidence suggesting otherwise, when a resident is found on the floor, a fall is considered to have occurred.

**NOTE**: Challenging a resident's balance and training him/her to recover from loss of balance is an intentional therapeutic intervention. The losses of balance that occur during supervised therapeutic interventions are not considered a fall.

Some factors that may result in resident falls include, but are not limited to:

- Environmental hazards, such as wet floors, poor lighting, incorrect bed height and/or width, or improperly fitted or maintained wheelchairs;
- Unsafe or absent footwear and loose or improperly worn clothing;
- Underlying chronic medical conditions, such as arthritis, heart failure, anemia and neurological disorders;
- Acute change in condition such as fever, infection, delirium;
- Medication side effects;
- Orthostatic hypotension;
- Lower extremity weakness;
- Balance disorders;
- Poor grip strength;
- Functional impairments (difficulty rising from a chair, getting on or off toilet, etc.);
- Gait disorders;
- Cognitive impairment;
- Visual deficits;
- Pain; and
- Incontinence.

Older persons have both a high incidence of falls and a high susceptibility to injury.[3] Serious potential consequences of falls include physical injuries, pain, increased risk of death, impaired function, fear of falling, and self-imposed limitations on activities leading to social isolation.[4] Evaluation of all of the causal factors leading to a resident fall assists the facility in developing and implementing relevant, consistent, and individualized interventions to prevent future occurrences. Proper actions following a fall include:

- Ascertaining if there were injuries, and providing treatment as necessary;
- Determining what may have caused or contributed to the fall, including ascertaining what the resident was trying to do before he or she fell;
- Addressing the risk factors for the fall such as the resident's medical conditions(s), facility environment issues, or staffing issues; and
- Revising the resident's plan of care and/or facility practices, as needed, to reduce the likelihood of another fall.

**NOTE:** A fall by a resident does not necessarily indicate a deficient practice because not every fall can be avoided.

**Position Change Alarms:**

Facilities often implement position change alarms as a fall prevention strategy or in response to a resident fall. The alarms are designed to alert staff that the resident has changed position, increasing the risk for falling. However, the efficacy of alarms to prevent falls has not been proven and a study of hospitalized patients concluded these devices may only alert staff that a fall has already occurred. The same study also noted false alarms are a common problem leading to "alarm fatigue," where staff no longer respond to the sound of an alarm.[5] A study on bed-exit alarms concluded the alarms are not a substitute for staff assisting residents and bed-exit alarms may not always function reliably for residents who weigh less than 100 pounds or who are restless.[6] Individual facility efforts to reduce use of alarms have shown falls actually decrease when alarms are eliminated, and replaced with other interventions such as purposeful checks to proactively address resident needs, adjusting staff to cover times of day when most falls occur, assessing resident routines, and making individualized environmental or care changes that suit each resident. [7] For example, brighter lighting might help a resident with macular degeneration ambulate more easily in his or her room but would cause glare and make walking more difficult for a resident with cataracts.[8]

Facilities must implement comprehensive, resident-centered fall prevention plans for each resident at risk for falls or with a history of falls. While position change alarms are not prohibited from being included as part of a plan, they should not be the primary or sole intervention to prevent falls. If facility staff choose to implement alarms, they should document their use aimed at assisting the staff to assess patterns and routines of the resident. Use of these devices, like any care planning intervention, must be based on assessment of the resident and monitored for efficacy on an on-going basis. Position change alarms have been used to monitor a resident's movement in chairs or beds, etc. However, there must be sufficient staff and supervision to meet the resident's needs and staff must be vigilant in order to respond to alarms in a timely manner. Alarms do not replace necessary supervision. Facilities must take steps to identify issues that place the resident at risk for falls and implement approaches to address those risks in a manner that enables the resident to achieve or maintain his or her highest practicable physical, mental, and psychosocial well-being.

**Wandering and Elopement** - Wandering is random or repetitive locomotion. This movement may be goal-directed (e.g., the person appears to be searching for something such as an exit) or may be non-goal-directed or aimless. Non-goal-directed wandering requires a response in a manner that addresses both safety issues and an evaluation to identify root causes to the degree possible. Moving about the facility aimlessly may indicate that the resident is frustrated, anxious, bored, hungry, or depressed. Goal-directed wandering may fulfill a resident's need for exercise or provide sensory stimulation. This goal directed wandering should also require staff supervision and a facility response to address safety issues.

Wandering may become unsafe when a resident becomes overly tired or enters an area that is physically hazardous or that contains potential safety hazards (e.g., chemicals, tools, and equipment, etc.). Entering into another resident's room may lead to an altercation or contact with hazardous items. Unsafe wandering can be associated with an increased risk for falls and injuries.

While wander, door, or building alarms can help to monitor a resident's activities, staff must be vigilant in order to respond to them in a timely manner. Alarms do not replace necessary supervision, and require scheduled maintenance and testing to ensure proper functioning.

A situation in which a resident leaves the premises or a safe area without the facility's knowledge and supervision, if necessary, would be considered an elopement. This situation represents a risk to the resident's health and safety and places the resident at risk of heat or cold exposure, dehydration and/or other medical complications, drowning, or being struck by a motor vehicle.

Facility policies that clearly define the mechanisms and procedures for assessing or identifying, monitoring and managing residents at risk for elopement can help to minimize the risk of a resident leaving a safe area without the facility's awareness and/or appropriate supervision. In addition, the resident at risk should have interventions in their comprehensive plan of care to address the potential for elopement. Furthermore, a facility's disaster and emergency preparedness plan should include a plan to locate a missing resident.

**Safety for Residents with Substance Use Disorder (SUD)**

Residents with a history of substance use disorder may be at increased risk for leaving the facility without notification and/or for illegal or prescription drug overdose if the resident continues using substances while residing in the nursing home. Residents with a history of substance use disorder should be assessed for these risks and care plan interventions should be implemented to ensure the safety of all residents.

For example, residents with substance use disorder may leave the facility to satisfy an addiction to alcohol, prescription drugs, or illegal substances. Care planning interventions should address this risk by providing appropriate diversions for residents and encouraging residents to seek out facility staff to discuss their plan of care, including discharge planning, rather than leaving to seek out substances which could endanger the resident's health and/or safety. The facility should advise residents of the risks of leaving the facility to seek out substances and/or early, unplanned discharge, and provide appropriate referrals and discharge instructions whenever possible.

Facilities are responsible for identifying and assessing a resident's risk for leaving the facility without notification to staff and developing interventions to address this risk. A situation in which a resident with decision-making capacity leaves the facility

intentionally would generally not be considered an elopement **unless the facility is unaware of the resident's departure and/or whereabouts**. A resident who leaves the facility prior to his or her planned discharge, but with facility knowledge of the departure and despite facility efforts to explain the risks of leaving, would be leaving against medical advice (AMA). Documentation in the medical record should show that facility staff attempted to provide other options to the resident and informed the resident of potential risks of leaving AMA. Documentation should also identify the time the facility became aware of the resident leaving the facility.

NOTE: This guidance is not intended to restrict a resident's ability to leave and return to the facility in accordance with the resident's medical orders, care plan, facility policy and §§483.10(c)(6), (f)(3), and (f)(8).

Additionally, residents with SUD may try to continue using substances during their stay in the nursing home. Facility staff should assess the resident for the risk for substance use in the facility and have knowledge of signs and symptoms of possible substance use such as: frequent leaves of absence with or without facility knowledge, odors, new needle marks, and changes in resident behavior such as unexplained drowsiness, slurred speech, lack of coordination, and mood changes, particularly after interaction with visitors or absences from the facility. Efforts to prevent substance use may include providing substance use treatment services, such as behavioral health services, medication-assisted treatment (MAT), alcoholic/narcotics anonymous meetings, working with the resident and the family, if appropriate, to address goals related to their stay in the nursing home, and increased monitoring and supervision.

When investigating overdose occurrences, surveyors should evaluate whether the facility assessed and identified that the resident who experienced an overdose had a history of substance use and was at risk for using substances which could lead to an overdose while in the facility. If there is a history of SUD, the resident's comprehensive care plan should contain interventions, if appropriate, to prevent substance use in the facility as well as interventions for when substance use is suspected or identified. Facility staff should implement care plan interventions which should include increased monitoring and supervision of the resident, increased supervision of visitors, and notification of the resident's physician or non-physician practitioner. For example, a resident displays changes in behavior or unexplained lethargy after his or her visitors leave or other residents report observing the use of substances. When substance use is suspected, (in the facility or upon return from an absence from the facility) which could lead to overdose, facility staff should implement the care plan interventions.

Facilities and surveyors should be aware that relapses of substance use can be common in individuals with SUD, and may result in a drug overdose. Facilities that accept residents with SUD are typically doing so to treat a medical-related issue, and are not expected to fully cure individuals with SUD of their underlying addictive behaviors while in the facility. However, facility staff should be prepared to address emergencies related to substance use by providing increased monitoring, maintaining and having knowledge of administering opioid reversal agents like naloxone, initiating CPR as appropriate, and

contacting emergency medical services as soon as possible. The United States Surgeon General has recommended that naloxone be kept on hand where there is a risk for an opioid overdose. Information on safe naloxone administration may be found on this document developed by the Substance Abuse and Mental Health Administration (SAMHSA), https://store.samhsa.gov/system/files/sma18-4742.pdf.

NOTE: Surveyors should be aware that the occurrence of an overdose does not automatically mean that noncompliance exists. As noted above, drug overdoses can be expected with individuals with SUD and facilities are not expected to fully cure these residents of their underlying disease or SUD. For example, a resident with a known history of SUD and drug seeking behaviors when offsite, returns from an absence from the facility. Evidence shows the facility took steps to increase its monitoring of the resident, and despite this effort, the resident overdosed between checks or immediately upon return before increased monitoring had begun. Additionally, the facility attempted CPR and administered naloxone. This example demonstrates a negative outcome, however, noncompliance with this requirement does not exist. Conversely, if the same resident returns from an absence but the facility did not take steps to increase monitoring, noncompliance with the requirements at §483.25(d) may exist due to failure to identify the resident's risk for overdose and implement interventions.

**Physical Plant Hazards**

**NOTE:** Refer to guidance at 483.7*1* (F838) for facility responsibilities regarding the facility's physical environment.

Supervision and/or containment of hazards are needed to protect residents from harm caused by environmental hazards. Examples of such hazards can range from common chemical cleaning materials to those caused by adverse water temperatures or improper use of electrical devices.

Chemicals and Toxins - Various materials in the resident environment can pose a potential hazard to residents. Hazardous materials can be found in the form of solids, liquids, gases, mists, dusts, fumes, and vapors. The routes of exposure for toxic materials may include inhalation, absorption, or ingestion.

For a material to pose a safety hazard to a resident, it must be toxic, caustic, or allergenic; accessible and available in a sufficient amount to cause harm. Toxic materials that may be present in the resident environment are unlikely to pose a hazard unless residents have access or are exposed to them. Some materials that would be considered harmless when used as designed could pose a hazard to a resident who accidentally ingests or makes contact with them.

Examples of materials that may pose a hazard to a resident include (but are not limited to):

- Chemicals used by the facility staff in the course of their duties (e.g., housekeeping chemicals, cleaning and sanitizing agents) and chemicals or other

materials brought into the resident environment by staff, other residents, or visitors;
- Drugs and therapeutic agents;
- Plants and other "natural" materials found in the resident environment or in the outdoor environment (e.g., poison ivy).

One source of information concerning the hazards of a material that a facility may obtain is the Safety Data Sheet (SDS).[9] The Occupational Safety and Health Administration (OSHA) requires employers to have a SDS available for all hazardous materials that staff use while performing their duties.[10] SDSs are available on-line for numerous chemicals and non-toxic materials, and should be reviewed carefully to determine if the material is toxic and poses a hazard. Poison control centers are another source of information for potential hazards, including non-chemical hazards such as plants.

**NOTE:** Toxicological profiles for a limited number of hazardous materials are accessible on the Agency for Toxic Substances & Disease Registry Web site at http://www.atsdr.cdc.gov/.

**Water Temperature** - Water may reach hazardous temperatures in hand sinks, showers, tubs, and any other source or location where hot water is accessible to a resident. Burns related to hot water/liquids may also be due to spills and/or immersion. Many residents in long-term care facilities have conditions that may put them at increased risk for burns caused by scalding. These conditions include: decreased skin thickness, decreased skin sensitivity, peripheral neuropathy, decreased agility (reduced reaction time), decreased cognition or dementia, decreased mobility, and decreased ability to communicate.[11]

The degree of injury depends on factors including the water temperature, the amount of skin exposed, and the duration of exposure. Some States have regulations regarding allowable maximum water temperature. Table 1 illustrates damage to skin in relation to the temperature of the water and the length of time of exposure.[12]

Table 1. Time and Temperature Relationship to Serious Burns

| Water Temperature | | Time Required for a 3rd Degree Burn to Occur |
|---|---|---|
| 155°F | 68°C | 1 sec |
| 148°F | 64°C | 2 sec |
| 140°F | 60°C | 5 sec |
| 133°F | 56°C | 15 sec |
| 127°F | 52°C | 1 min |
| 124°F | 51°C | 3 min |
| 120°F | 48°C | 5 min |
| 100°F | 37°C | Safe Temperatures for Bathing (see Note) |

**NOTE:** Burns can occur even at water temperatures below those identified in the table, depending on an individual's condition and the length of exposure.

Based upon the time of the exposure and the temperature of the water, the severity of the harm to the skin is identified by the degree of burn, as follows.[13]

- First-degree burns involve the top layer of skin (e.g., minor sunburn). These may present as red and painful to touch, and the skin will show mild swelling.

- Second-degree burns involve the first two layers of skin. These may present as deep reddening of the skin, pain, blisters, glossy appearance from leaking fluid, and possible loss of some skin.

- Third-degree burns penetrate the entire thickness of the skin and permanently destroy tissue. These present as loss of skin layers, often painless (pain may be caused by patches of first- and second-degree burns surrounding third-degree burns), and dry, leathery skin. Skin may appear charred or have patches that appear white, brown, or black.

**Electrical Safety** - Any electrical device, whether or not it needs to be plugged into an electric outlet, can become hazardous to the residents through improper use or improper maintenance. Electrical equipment such as electrical cords can become tripping hazards. Halogen lamps or heat lamps can cause burns or fires if not properly installed away from combustibles in the resident environment. The Life Safety Code prohibits the use of portable electrical space heaters in resident areas.

Extension cords should not be used to take the place of adequate wiring in a facility. If extension cords are used, the cords should be properly secured and not be placed overhead, under carpets or rugs, or anywhere that the cord can cause trips, falls, or overheat. Extension cords should be connected to only one device to prevent overloading of the circuit. The cord itself should be of a size and type for the expected electrical load and made of material that will not fray or cut easily. Electrical cords including extension cords should have proper grounding if required and should not have any grounding devices removed, or should not be used without the grounding devices.

Power strips may not be used as a substitute for adequate electrical outlets in a facility. Power strips may be used for a computer, monitor, and printer. Power strips are not designed to be used with medical devices in patient care areas. Precautions needed if power strips are used include: installing internal ground fault and over-current protection devices; preventing cords from becoming tripping hazards; and using power strips that are adequate for the number and types of devices used. Overload on any circuit can potentially cause overheating and fire. The use of ground fault circuit interruption (GFCIs) may be required in locations near water sources to prevent electrocution of staff or residents.[14]

The proper use of electric blankets and heating pads is essential to avoid thermal injuries. These items should not be tucked in or squeezed. Constriction can cause the internal wires to break. A resident should not go to sleep with an electric blanket or heating pad turned on. Manufacturer's instructions for use should be followed closely. Injuries and deaths have been related to burns and fires related to the use of heating pads. Most deaths are attributable to heating pads that generated fires, but most injuries are burns from prolonged use or inappropriate temperature setting. Prolonged use on one area of the body can cause a severe burn, even when the heating pad is at a low temperature setting.

**Lighting** - The risk of an accident increases when there is insufficient light or too much light, which often results in glare. Vision among older persons varies widely; therefore, no single level of illumination can ensure safety for all residents. The proper amount of light depends on the resident's visual needs and the task he/she is performing. An older person typically needs more light to see. However, a resident with cataracts or glaucoma may be overly sensitive to bright light, and excessive lighting could make it more difficult to see clearly and thereby increase his/her fall risk.[15] Creating transitional zones between light and dark spaces helps to improve sight recovery and enable safer mobility. Providing extra visual cues that clearly define needed items or spaces in areas with limited or variable light can help to enable safe performance of tasks (e.g., turning on a light). Providing supplemental light near beds for residents who are mobile may assist in safe mobility at night.[16]

**NOTE:** Refer to guidance under 42 CFR 483.10(i)(5), F584, Safe Environment regarding adequate and comfortable lighting.

**Assistive Devices/Equipment Hazards**

Assistive devices also can help to prevent accidents. Assistive devices and equipment can help residents move with increased independence, transfer with greater comfort, and feel physically more secure. However, there are risks associated with the use of such devices and equipment, particularly if or when they are not properly maintained and these risks need to be balanced with the benefits gained from their use. Training of staff, residents, family members and volunteers on the proper use of assistive devices/equipment is crucial to prevent accidents. It is also important to communicate clearly the approaches identified in the care plan to all staff, including temporary staff. It is important to train staff regarding resident assessment, safe transfer techniques, and the proper use of mechanical lifts including device weight limitations.

**NOTE:** The Safe Medical Devices Act of 1990 (SMDA) requires hospitals, nursing homes, and other user facilities to report deaths, serious illnesses, and injuries associated with the use of medical devices to manufacturers and the Food and Drug Administration.

Assistive Devices for Mobility - Mobility devices include all types of assistive devices, such as, but not limited to, canes, standard and rolling walkers, manual or non-powered

wheelchairs, and powered wheelchairs. Three primary factors that may be associated with an increased accident risk related to the use of assistive devices include:

1. Resident Condition. Lower extremity weakness, gait disturbances, decreased range of motion, and poor balance may affect some residents. These conditions combined with cognitive impairment can increase the accident risks of using mobility devices. Unsafe behavior, such as failure to lock wheelchair brakes and trying to stand or transfer from a wheelchair unsafely, can result in falls and related injuries;

2. Personal Fit and Device Condition. Devices can pose a hazard if not fitted and/or maintained properly.[17] Personal fit, or how well the assistive device meets the individual needs of the resident, may influence the likelihood of an avoidable accident; and

3. Staff Practices. Mobility devices that a resident cannot readily reach may create a hazardous situation. Unsafe transfer technique used by staff may result in an accident. Inadequate supervision by staff of a resident during the initial trial period of assistive device use or after a change in the resident's functional status can increase the risk of falls and/or injury. Additionally, staff needs to ensure assistive devises properly fit the resident and the resident has received proper training in the use of the assistive device.

Assistive Devices for Transfer - Mechanical assistive devices for transfer include, but are not limited to, portable and stationary total body lifts, sit-to-stand devices, and transfer or gait belts. The resident assessment helps to determine the resident's degree of mobility and physical impairment and the proper transfer method; for example, whether one or more caregivers or a mechanical device is needed for a safe transfer. Residents who become frightened during transfer in a mechanical lift may exhibit resistance movements that can result in avoidable accidents. Communicating with the resident and addressing the resident's fear may reduce the risk.

Factors that may influence a resident's risk of accident during transfer include staff availability, resident abilities, staff training and competency. The resident's ability to communicate and identify physical limitations or to aid in the transfer will help determine the need for an assistive device, such as a mechanical lift. The Occupational Safety and Health Administration (OSHA) provides information and guidelines on identifying problems and implementing solutions relating to handling residents during transfers.[18]

Devices Associated with Entrapment Risks - Devices can be therapeutic and beneficial; however, devices are not necessarily risk free so it is important to weigh the relative risks and benefits of using certain devices. For example, while physical restraints may be used to treat a resident's medical symptom, the devices may create a risk for entrapment. Physical restraints are defined as any manual method, physical or mechanical device/equipment or material that meets all of the following criteria:

- Is attached or adjacent to a resident's body;
- Cannot be removed easily by the resident; and
- Restricts the resident's freedom of movement or normal access to his/her body.

Serious injuries, as well as death, have been reported as a result of using physical restraints. Some physical restraints carry a risk of severe injury, strangulation, and asphyxiation. Restrained residents may be injured or die when they try to remove restraints, to ambulate while restrained, or due to an improperly fitted or used device. Evidence shows that physical restraints cause more harm than good and seriously infringe upon a person's autonomy as explained in this article in the Journal of Medical Ethics, "Use of physical restraint in nursing homes: clinical-ethical considerations."[19] The Food and Drug Administration (FDA) also provides guidance on bed rail safety and reducing entrapment:

- https://www.fda.gov/medical-devices/hospital-beds/guide-bed-safety-bed-rails-hospitals-nursing-homes-and-home-health-care-facts, A Guide to Bed Safety Bed Rails in Hospitals, Nursing Homes and Home Health Care: The Facts

- https://www.fda.gov/medical-devices/bed-rail-safety/recommendations-health-care-providers-about-bed-rails, Recommendations for Health Care Providers About Bed Rails

- https://www.fda.gov/regulatory-information/search-fda-guidance-documents/hospital-bed-system-dimensional-and-assessment-guidance-reduce-entrapment, Guidance for Industry and FDA Staff: Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment.

Regardless of the purpose for use, bed rails (also referred to as "side rails," "bed side rails," and "safety rails") and other bed accessories (e.g. transfer bar, bed enclosures), while assisting with transfer and positioning, can increase resident safety risk. Bed rails include rails of various sizes (e.g., full length rails, half rails, quarter rails) that may be positioned in various locations on the bed. Residents most at risk for entrapment are those who are frail or elderly or those who have conditions such as agitation, delirium, confusion, pain, uncontrolled body movement, hypoxia, fecal impaction, acute urinary retention, etc. that may cause them to move about the bed or try to exit from the bed. The failure to provide timely assistance with using the bathroom, inappropriate bed positioning, and other care-related activities can contribute to the risk of entrapment. The FDA provides detailed information about bed rails, including recommendations for health care providers.[20]

Entrapment may occur when a resident is caught between the mattress and bed rail or in the bed rail itself. Technical issues, such as the proper sizing of mattresses, fit and integrity of bed rails or other design elements (e.g., wide spaces between bars in the bed rails) can also affect the risk of resident entrapment.[21]

**NOTE:** §483.25(n) (F700) requires that facilities attempt appropriate alternatives before installing/ using bed rails, and if a bed or side rail is used, the facility must ensure correct installation, use, and maintenance of bed rails.

The use of a specialty air-filled mattress or a therapeutic air-filled bed may also present an entrapment risk that is different from rail entrapment with a regular mattress. The high compressibility of an air-filled mattress compared to a regular conventional mattress requires appropriate precautions when used for a resident at risk for entrapment. An air-filled mattress compresses on the side to which a person moves, thus raising the center of the mattress and lowering the side. This may make it easier for a resident to slide off the mattress or against the rail. Mattress compression widens the space between the mattress and rail. When a resident is between the mattress and rail, the mattress can re-expand and press the chest, neck, or head against the rail. While using air therapy to prevent and treat pressure ulcer/injuries, facilities should also take precautions to reduce the risk of entrapment. Precautions may include following manufacturer equipment alerts and increasing supervision.[22]

**NOTE:** §483.12 (F604), applies to the use of physical restraints. This guidance at §483.25(d), (F689) applies to assistive devices that create hazards (e.g., devices that are defective; not used properly or according to manufacturer's specifications; disabled or removed; not provided or do not meet the resident's needs (poor fit or not adapted); and/or used without adequate supervision when required). §483.25(n) (F700) applies to the installation of bed rails.

## KEY ELEMENTS OF NONCOMPLIANCE

To cite deficient practice at F689, the surveyor's investigation will generally show that the facility failed to do one or more of the following:

- Identify and eliminate all known and foreseeable accident hazards in the resident's environment, to the extent possible; or
- To the extent possible, reduce the risk of all known or foreseeable accident hazards that cannot be eliminated; or
- Provide appropriate and sufficient supervision to each resident to prevent an avoidable accident; or
- Provide assistance devices necessary to prevent an avoidable accident from occurring.

## INVESTIGATIVE SUMMARY

### Use

Use the Accidents Critical Element (CE) Pathway along with the above interpretive guidelines when determining if the facility meets the requirements to ensure that the resident's environment remains as free from accident hazards as possible and that each resident receives adequate supervision and assistance devices to prevent accidents.

**Summary of Accident and Supervision Investigative Procedure**

Observe the general environment of the facility to determine if the facility provides an environment that is free from accident hazards over which the facility has control and provides supervision and assistive devices to each resident to prevent avoidable accidents. During observation of the facility, the survey team should observe the environment for the presence of potential/actual hazards. For a resident with an identified concern, briefly review the assessment and plan of care to determine whether the facility identified resident risks and implemented interventions as necessary.

If the resident has been in the facility for less than 14 days (before completion of all the Resident Assessment Instrument (RAI) is required), review the baseline 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.

## 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).

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

- The facility failed to keep corrosive cleaning supplies out of the reach of ambulatory residents with dementia, resulting in one resident ingesting drain opener and sustaining esophageal damage.

- The facility failed to provide supervision to a unit which had ambulatory cognitively impaired residents. The facility failed to keep these residents from gaining access to the employee locker room. When the surveyor conducted her tour of the facility, she found a confused resident who was trapped in the employee locker room.

- The facility failed to keep a resident free from hazards and provide the necessary monitoring and supervision for a resident with known substance use disorder and history of using illicit substances when outside of the facility. Through an interview with a certified nurse aide (CNA), the surveyor discovered the resident left the facility for approximately five hours with facility knowledge of the absence. Upon return to the facility, the resident went to his room. Facility staff did not assess the resident's condition for several hours and then found the resident unresponsive. Medical records showed that the resident had sustained an overdose.

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

- The facility failed to apply a smoking apron to a resident while smoking, which was necessary and documented on the care plan. The resident sustained a 2nd degree burn after the cigarette fell onto his/her lap.

- The facility failed to use a two-person transfer, as determined necessary by the comprehensive care plan, during a transfer from the resident's bed to wheelchair, resulting in the resident falling to the floor, sustaining a laceration requiring sutures.

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

- The facility failed to remove clutter and building materials from a construction area, immediately adjacent to a walkway used by residents and their families, creating a hazard which poses a risk for more than minimal harm.

- A cognitively intact resident with known SUD but no other safety concerns was observed lingering by doors that were not monitored. After interviewing staff, the survey team identified that the facility did not have a consistent process for how residents notify the facility when they leave the facility, or have a process to identify when residents leave the facility if the resident does not notify facility staff.

**Severity Level 1 Noncompliance No Actual Harm with Potential for Minimal Harm**

The failure of the facility to provide a safe environment and adequate supervision places residents at risk for more than minimal harm. Therefore, Severity Level 1 does not apply for this regulatory requirement.

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://www.ncoa.org/professionals/health/center-for-healthy-aging/national-falls-prevention-resource-center
Centers for Disease Control and Prevention at
http://www.cdc.gov/homeandrecreationalsafety/falls/

World Health Organization Fall Prevention in Older Age at
https://www.who.int/publications/i/item/9789241563536
National Institute on Aging, Falls and Fall Prevention,
https://www.nia.nih.gov/health/topics/falls-and-falls-prevention
Wandering and Elopement Resources
National Council of Certified Dementia Practitioners at http://www.nccdp.or

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[8] Becker, C., Rapp, K. (2010) Fall Prevention in Nursing Homes. Clinics in Geriatric Medicine 26(4)693-704.

[9] *US Dept. of Health and Human Services,* Agency for Toxic Substances & Disease Registry, *Toxicological Profiles, http://www.atsdr.cdc.gov/toxprofiles/index.asp.*

[10] US Dept. of Labor, Occupational Safety and Health Standards, 29 CFR 1910.1200 (g)(1) and (2).

[11] Katcher, L.K. (1981). Scald Burns from Hot Tap Water. Journal of Am Med Assoc., 246(11), 1219-1222.

[12] Moritz, A.R., Henriques F.C. Jr. (1947). Studies of Thermal Injury: II. The Relative Importance of Time and Surface Temperatures in the Causation of Cutaneous Burns. Am J Pathology, 23, 695-720.

[13] US Dept. of Health and Human Services. Centers for Disease Control and Prevention. Emergency Preparedness & Response, *https://www.cdc.gov/masstrauma/factsheets/public/burns.pdf.*

[14] *Electrical Safety Foundation International Resource Library.*

[15] Tideiksaar, R. (1998). Falls in Older Persons: Prevention and Management (2nd Edition). Baltimore, MD: Health Profession Press.

[16] Warren, M. (2001), Occupational Therapy Practice Guidelines for Adults with Low Vision, The American Occupational Therapy Association, Inc.

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[18] US Department of Labor, , Occupational Safety & Health Administration. Guidelines for Nursing Homes (Revised March 2009), https://www.osha.gov/ergonomics/guidelines/nursinghome/final_nh_guidelines.html.

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# F695

*(Rev. 225; Issued: 08-08-24; Effective: 08-08-24; Implementation: 08-08-24)*

**§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 harm (see Appendix P, Guidance on Severity and Scope Levels and Psychosocial Outcome Severity Guide).

**NOTE**: If noncompliance with respiratory care provided by nursing services is related to staff competency issues, also consider F725, §483.35(a)(3), Nursing Services

**KEY ELEMENTS OF NONCOMPLIANCE §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)**

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

**Examples of Severity Level 4 Noncompliance: Immediate Jeopardy to Resident Health or Safety includes but is not limited to:**

- The facility 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.

## F711

***(Rev. 225; Issued: 08-08-24; Effective: 08-08-24; Implementation: 08-08-24)***

**§483.30(b) Physician Visits**
**The physician must—**

**§483.30(b)(1) Review the resident's total program of care, including medications and treatments, at each visit required by paragraph (c) of this section;**

**§483.30(b)(2) Write, sign, and date progress notes at each visit; and**

**§483.30(b)(3) Sign and date all orders with the exception of influenza and pneumococcal vaccines, which may be administered per physician-approved facility policy after an assessment for contraindications.**

**INTENT §483.30(b)**

The intent of this regulation is to have the physician take an active role in supervising the care of the residents. Physician visits should not be superficial visits, but must include an evaluation of the resident's condition and total program of care, including medications and treatments, and a decision about the continued appropriateness of the resident's current medical regimen.

**GUIDANCE §483.30(b)**

Except where the regulation specifies the task must be completed **personally** by the physician, the term "attending physician" or "physician" also includes a non-physician practitioner (NPP) involved in the management of the resident's care, to the extent permitted by State law.

Total program of care includes all care the facility provides residents to maintain or improve their highest practicable physical, mental and psychosocial well-being, as defined by the comprehensive assessment and plan of care. Care includes medical services and medication management, physical, occupational, and speech/language therapy, nursing care, nutritional interventions, social work and activity services that maintain or improve psychosocial functioning.

During required visits, the physician must document a review of the resident's total program of care, including the resident's current condition, progress and problems in maintaining or improving their physical, mental and psychosocial well-being and decisions about the continued appropriateness of the resident's current medical regimen.

The physician need not review the total plan of care at each visit, but must review the total plan of care at visits required by §483.30(c), F712.

Progress notes must be written, signed and dated at each physician visit, which may be done in a physical chart or electronic record, in keeping with facility practices.

During visits, the physician must also sign and date all orders, with the exception of influenza and pneumococcal vaccinations, which may be administered per physician-approved facility policy after an assessment for contraindications. This includes co-signing orders written by NPPs, qualified dietitians, other clinically qualified nutrition professionals and qualified therapists, as required by state law.

In cases where facilities have created the option for a resident's record to be maintained by computer, rather than hard copy, electronic signatures are acceptable. See Guidelines for §483.70(*h*)(1), F842, for information on facility safeguards concerning electronic signatures.

Physician orders may be transmitted by facsimile machine if the following conditions are met:

- The physician should have signed and retained the original order from which the facsimile was transmitted and be able to provide it upon request. Alternatively, the original may be sent to the facility at a later time and substituted for the facsimile.
- The facility should photocopy the faxed order, if the faxed order is subject to fading over time. The facsimile copy can be discarded after facility photocopies it.
- It is not necessary for a physician to re-sign the facsimile order when he/she visits the facility.

When rubber stamp signatures are authorized by the facility's management, the individual whose signature the stamp represents shall place in the administrative offices of the facility a signed statement to the effect that he/she is the only one who has the stamp and uses it. A list of computer codes, identification numbers and/or written signatures must be readily available and maintained under adequate safeguards. Adequate safeguards may include, but are not limited to, locked in a drawer; locked in a location that is accessible only by appropriate staff as defined by the facility; or available on a protected electronic site accessible by appropriate staff as defined by the facility.

**PROBES §483.30(b)**

- Are physician progress notes written, signed and dated during each physician visit?
- For visits required by §483.30(c), do physician progress notes reflect a review of the resident's total program of care and current condition, including medications and treatments?
- Do physician progress notes reflect the physician's decisions about the continued appropriateness of the resident's current medical regimen?

- Does the physician sign and date all physician orders, during visits, with the exception of influenza and pneumococcal vaccines as outlined above?
- If the physician has not met the requirements of physician visits, how has the facility worked with the physician or sought alternate physician participation to assure that the resident receives appropriate care and treatment?
- If facility management allows for the use of rubber stamp signatures, are adequate safeguards in place to ensure the security of the stamps?

**POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION**

If concerns regarding physician supervision of the resident's care are identified, investigate §483.30(a), F710.

For concerns related to admission orders, see §483.20(a), F635.

For concerns related to the frequency of physician visits, see §483.30(c), F712.

For concerns related to the medical director's follow-up on clinical issues or physician activities, see §483.70(*g*), F841.

**DEFICIENCY CATEGORIZATION §483.30(b)**
**Examples of Level 4, immediate jeopardy to resident health and safety, include, but are not limited to:**

- After a recent hospitalization, the facility failed to ensure the attending physician reviewed the hospital discharge summary or hospital progress notes. This lack of review of the resident's total program of care, including medications and treatments, resulted in the resident not receiving orders for new medications essential to the resident's medical treatment. As a result of the lack of essential medications, serious harm or death occurred or was likely to occur.

- Facility staff contacted the physician on multiple occasions regarding the resident's elevated blood sugar levels. During a visit, the physician did not review the resident's recorded blood sugar values, or talk to the nurse regarding the resident's status or order changes to the resident's treatment regimen. The facility's failure to intervene when the physician was onsite or to seek alternate intervention resulted in the resident experiencing diabetic ketoacidosis which required hospitalization for management.

**Example of level 3, actual harm that is not immediate jeopardy, includes, but is not limited to:**

- The facility failed to ensure the physician completed a medical evaluation of a resident's condition and review the appropriateness of the resident's medical regimen. Specifically, a resident who had executed a Living Will at a time when

he had capacity, indicated that it was his desire to refuse any treatment, other than comfort measures, in the event of an irreversible terminal illness from which there was no hope of recovery. Despite documentation from the pulmonologist that there was no expectation that the resident could survive without artificial means and contrary to the resident's wishes, the attending physician ordered, and the facility provided, aggressive, life-sustaining treatment including artificial ventilation and feeding. As a result, the resident received unwanted treatment in the facility.

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

- While the physician reviewed areas identified as high priority for the physician to address in the resident's program of care, the facility failed to ensure the physician reviewed the resident's total program of care or wrote, signed and dated progress notes with each visit.

- The facility failed to ensure physician progress notes that documented the physician's involvement in the assessment and care of residents were completed as required.

**Example of Level 1, no actual harm with potential for no more than a minor negative impact on the resident, includes, but is not limited to:**

- During a physician visit, the physician failed to sign and date new orders, however the orders were followed as intended and no adverse outcome was experienced by the resident.

## F715

***(Rev. 225; Issued: 08-08-24; Effective: 08-08-24; Implementation: 08-08-24)***

**§483.30(e)(2) A resident's attending physician may delegate the task of writing dietary orders, consistent with §483.60, to a qualified dietitian or other clinically qualified nutrition professional who—**

**(i) Is acting within the scope of practice as defined by State law; and**
**(ii) Is under the supervision of the physician.**

**§483.30(e)(3) A resident's attending physician may delegate the task of writing therapy orders, consistent with §483.65, to a qualified therapist who—**
**(i) Is acting within the scope of practice as defined by State law; and**
**(ii) Is under the supervision of the physician**

**INTENT §483.30(e)(2)-(3)**

To provide physicians with the flexibility to delegate to a qualified dietitian/other clinically qualified nutrition professional the task of writing dietary orders, and to delegate to a qualified therapist the task of writing therapy orders. This flexibility is beneficial to the physician and the resident, allowing the physician to determine how to best use his or her time and allowing the resident to have more frequent adjustments to nutritional needs and therapy as his or her condition or abilities change.

**DEFINITIONS §483.30(e)(2)-(3)**

**"Qualified dietitian"** – is defined in §483.60 as follows: §483.60(a)(1) A qualified dietitian or other clinically qualified nutrition professional either full-time, part-time, or on a consultant basis. A qualified dietitian or other clinically qualified nutrition professional is one who—

(i) Holds a bachelor's or higher degree granted by a regionally accredited college or university in the United States (or an equivalent foreign degree) with completion of the academic requirements of a program in nutrition or dietetics accredited by an appropriate national accreditation organization recognized for this purpose.
(ii) Has completed at least 900 hours of supervised dietetics practice under the supervision of a registered dietitian or nutrition professional.
(iii) Is licensed or certified as a dietitian or nutrition professional by the State in which the services are performed. In a State that does not provide for licensure or certification, the individual will be deemed to have met this requirement if he or she is recognized as a "registered dietitian" by the Commission on Dietetic Registration or its successor organization, or meets the requirements of paragraphs (a)(1)(i) and (ii) of this section.
(iv) For dietitians hired or contracted with prior to November 28, 2016, meets these requirements no later than 5 years after November 28, 2016 or as required by state law.

**"Qualified therapist"** – professional staff, licensed, certified or registered to provide specialized therapy/rehabilitative services in accordance with State laws. Includes: Physical, Occupational, and Respiratory therapists and Speech-Language Pathologists.

**GUIDANCE §483.30(e)(2)-(3)**

Physicians and NPPs may delegate the task of writing orders to qualified dietitians or clinically qualified nutrition professionals and qualified therapists if the State practice act allows the delegation of the task, and the State practice act for the qualified individual being delegated the task of writing orders permits such performance. Delegation of this task does not relieve the physician of the obligation to supervise the medical care of his/her residents. Physician responsibilities related to physician supervision of resident care are located in §483.30(a), F710, and physician obligations for conducting resident visits are located at §483.30(b), F711.

Dietary orders written by a qualified dietitian/clinically qualified nutritional professional, or therapy orders written by therapists, do not require physician co-signature, except as required by State law.

**PROBES 483.30(e)(2)-(3)**

- If the dietitian/other clinically qualified nutrition professional is writing dietary orders, or a qualified therapist is writing therapy orders, did the attending physician delegate this task?
- If State law allows dietitians or other clinically qualified nutrition professionals to write dietary orders, are they functioning within the scope of practice defined by State law?
- If State law allows therapists to write therapy orders, are they functioning within the scope of practice defined by State law?
- Do physicians cosign dietitian/other clinically qualified nutrition professional orders and/or therapists orders, if required by State law?
- Is there evidence of physician supervision of dietitians/other clinically qualified nutritional professionals and/or qualified therapists who write orders? Examples of supervision may include face-to-face encounters, clinical record reviews, telephone consults, e-mail, telehealth, and electronic health records.
- When facility policy and State law allows physicians to delegate the task of writing orders to qualified dietitians, other clinically qualified nutrition professionals and qualified therapists, how does the facility ensure the physician supervision of individuals performing these tasks?

**§483.35 Nursing Services**

**The facility must have sufficient nursing staff with the appropriate competencies and skills sets to provide nursing and related services to assure resident safety and attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident, as determined by resident assessments and individual plans of care and considering the number, acuity and diagnoses of the facility's resident population in accordance with the facility assessment required at §483.7*1*.**

Always, review nursing services requirements under §483.35 during a standard or extended survey, when a waiver of RN and/or licensed nurse (RN/LPN) staffing has been requested or granted, or if a complaint has been received regarding nursing services.

If the survey investigation reveals that there are not sufficient or competent staff refer to:

- F725 or 726, §483.35(a),(c) for any nursing services not related to behavioral health care or dementia care;
- F741, §483.40(a) for any staff caring for residents with dementia or a history of trauma and/or post-traumatic stress disorder;
- F801, §483.60(a) for Food and Nutrition staff;
- F826, §483.65(b), Specialized rehabilitative services;

- F839, §483.70(*e*), Administration for any other staff not referenced above.

**Potential Requirements for Additional Investigation**

If noncompliance with §483.35 has been identified, the surveyor may have identified concerns with related structure, process, and/or outcome requirements. If any additional concerns have been identified, the surveyor must investigate the identified concern. Do not cite any related or associated requirements before first investigating to determine compliance or noncompliance with the related or associated requirement. Examples include, but are not limited to, the following:

- Freedom from abuse, neglect, and exploitation, §483.12;
- Quality of Life, §483.24;
- Quality of Care, §483.25;
- Behavioral Health Services, §483.40;
- Administration §483.70, Staff Qualifications §483.70(*e*), or Use of Outside Resources §483.70(*f*);
- *§483.71 Facility Assessment*
- Quality Assurance and Performance Improvement §483.75;
- Training, §483.95.

## F725

***(Rev. 225; Issued: 08-08-24; Effective: 08-08-24; Implementation: 08-08-24)***

**§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 §483.7*1*.**

**§483.35(a) Sufficient Staff.**

**§483.35(a)(1) The facility must provide services by sufficient numbers of each of the following types of personnel on a 24-hour basis to provide nursing care to all residents in accordance with resident care plans:**

**(i) Except when waived under paragraph (e) of this section, licensed nurses; and**

**(ii) Other nursing personnel, including but not limited to nurse aides.**

**§483.35(a)(2) Except when waived under paragraph [(e)] of this section, the facility must designate a licensed nurse to serve as a charge nurse on each tour of duty.**

**INTENT §483.35(a)(1)-(2)**

To assure that there is sufficient qualified nursing staff available at all times to provide nursing and related services to meet the residents' needs safely and in a manner that promotes each resident's rights, physical, mental and psychosocial well-being.

**DEFINITIONS §483.35(a)(1)-(2)**

**"Nurse Aide,"** as defined in §483.5, is any individual providing nursing or nursing-related services to residents in a facility. This term may also include an individual who provides these services through an agency or under a contract with the facility, but is not a licensed health professional, a registered dietitian, or someone who volunteers to provide such services without pay. Nurse aides do not include those individuals who furnish services to residents only as paid feeding assistants as defined in §488.301.

**GUIDANCE §483.35(a)(1)-(2)**
**NOTE:** Cite this Tag only if there are deficiencies related to the **sufficiency** of nursing staff.

If the survey investigation reveals that there are not sufficient staff in areas other than Nursing Services, refer to:

- F741, §483.40(a) for any staff caring for residents with dementia or a history of trauma and/or post-traumatic stress disorder;
- F801, §483.60(a) for Food and Nutrition staff;
- F826, §483.65(b) for Specialized rehabilitative services; and
- F839, §483.70(*e*) for Administration for any other staff not referenced above.

**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.

Many factors must be considered when determining whether or not a facility has sufficient nursing staff to care for residents' needs, as identified through the facility assessment, resident assessments, and as described in their plan of care. A staffing deficiency under this requirement may or may not be directly related to an adverse outcome to a resident's care or services. It may also include the **potential** for physical or psychosocial harm.

As required under Administration at F838, §483.7*l* 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 should drive staffing decisions and inform the facility about what skills and competencies staff must possess in order to deliver the necessary care required by the residents being served.

**PROCEDURE: §483.35(a)(1)-(2)**

Although federal regulations do not define minimum nursing staff ratios, many States do. If a facility does not meet State regulations for staffing, do NOT cite that as a deficiency here, but refer to Administration, F836, §483.70(b). In addition, even if a facility meets the State's staffing regulations that is not, by itself, sufficient to demonstrate that the facility has sufficient staff to care for its residents. Compliance with State staffing standards is not necessarily determinative of compliance with Federal staffing standards that require a sufficient number of staff to meet all of the residents' basic and individualized care needs. A facility may meet a state's minimum staffing ratio requirement, and still need more staff to meet the needs of its residents. Additionally, the facility is required to provide licensed nursing staff 24 hours a day, 7 days a week.

Surveyors must determine through information obtained by observations, interviews and verified by record reviews, whether the facility employed sufficient staff to provide care and services in assisting residents to attain or maintain their highest practicable level of physical, mental, and psycho-social well-being. The facility is responsible for submitting staffing data through the CMS Payroll-Based Journal (PBJ) system (Refer to F851, §483.70(*p*)). This data can be obtained through the Certification and Survey Provider Enhanced Reports (CASPER) reporting system. This PBJ Staffing Data Report contains information about overall direct care staffing levels, including nurse staffing. Surveyors will utilize the P B J Staffing Data Report available through CASPER reporting system to identify concerns with staffing. The Long Term Care Survey Process (LTCSP) software application will alert the surveyors of specific dates that require further investigation related to staffing. Surveyors are expected to verify infraction dates indicated on the PBJ staffing data report. If concerns were identified on this report, as well as from other sources, refer to the critical element pathway of Sufficient and Competent Staffing, and the probes noted below.

**PROBES:**

- When interviewing staff, residents and others, are concerns raised with the amount of time staff are available to provide care and services, such that there is not sufficient time allowed to provide the necessary care and services to a resident? If so, verify these concerns through observations and record review if necessary.

- Does the facility assessment describe the type and level of staff required to meet each resident's needs as assessed under §483.7*1*. Does the type and level of the staff onsite reflect the expectations described in the facility assessment?

- Does the workload or assignments of the nursing staff allow them time to participate in team meetings, care planning meetings, attend training, spend time caring for residents and take time for breaks including meal breaks?

- Are the numbers of licensed staff sufficient such that those staff members have enough time to provide direct services to residents as well as to assist and monitor all of the aides they are responsible for supervising?

- Do residents and families report that nursing staff are responsive to residents' request for assistance, such as call bells typically answered promptly? Do they feel that they can have a conversation with a direct caregiver and not feel rushed?

- Are there any indications of delays in responsiveness for staff such as pungent odors, residents calling out, or residents wandering with inadequate supervision?

- Are there any indications of inappropriate use of devices or practices to manage residents' behaviors or activities that may suggest facility staff are using these devices or practices to compensate for lack of sufficient staff? Examples include high numbers and/or inappropriate use of position-change alarms, positioning residents in chairs that limit their movement, or residents who are subdued or sedated?

- Are residents who are unable to use call bells or otherwise communicate their needs checked frequently (e.g., each half hour) for safety, comfort, bathroom needs positioning, and offered fluids and other provisions of care? Have care problems associated with a specific unit, day or tour of duty been identified by the facility? For example, does documentation show that skin integrity issues are identified more on days following a long weekend? Does the facility have adequate staff to monitor residents at risk for wandering?

- Has the use of overtime hours increased? (If overtime hours have increased substantially, it can indicate that there is not sufficient staff or a back-up plan when staff call-out).
- When there are staff call-outs, did the facility fill those positions in a timely manner? Does the facility have licensed nursing staff 24 hours a day?

- If the surveyor is made aware of the absences of licensed nursing staff in a 24 hour period:

    - Interview direct care staff;
        - Are you ever made aware of the absence of licensed nursing staff during your shift?
        - When was the last time that licensed staff was not available during your shift?
        - How often does this occur?
        - How does this impact residents in the facility?
        - Are you aware of any residents that missed medications or treatments due to no available licensed nurse?

        - Who do you notify in the event of an emergency and there is no licensed nurses available?

    - Interview the Director of Nursing or Administrator;
        - When was the last time that licensed nursing staff were not available on a shift?
        - How often does the facility not have licensed nursing staff at all times?
        - What is the facility's policy when there is not a licensed nurse available in a 24 hour period?
        - How does the facility provide care to residents that require a licensed nurse if one is not available to work?
        - How does this impact residents in the facility?

Concerns such as falls, weight loss, dehydration, pressure ulcers, as well as the incidence of elopement and resident altercations can also offer insight into the sufficiency of the numbers of staff. Surveyors must investigate if these adverse outcomes are related to sufficient staffing.

**KEY ELEMENTS OF NONCOMPLIANCE**

To cite deficient practice at F725, the surveyor's investigation will generally show that the facility failed to do any one of the following:

- Ensure there are a sufficient number of skilled licensed nurses, nurse aides, and other nursing personnel to provide care and respond to each resident's 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; **or**
- Ensure a licensed nurse is designated to serve as a charge nurse on each tour of duty, except when waived.

**DEFICIENCY CATEGORIZATION**

Once the survey team has completed its investigation, analyzed the data, reviewed the regulatory requirements, and determined that noncompliance exists, the team must determine the severity of each deficiency, based on the harm or potential for harm to the resident.

**An example of Level 4, immediate jeopardy to resident health and safety includes, but is not limited to:**

- A resident with a Stage 4 pressure injury, did not receive skin assessments and treatments for two weeks due to the absence of the only trained wound nurse on the resident's scheduled skin assessment days. No accommodations were made for coverage in the absence of this wound nurse and no other nursing staff were trained to provide this care. The pressure injury became infected during this

timeframe and resulted in the resident being hospitalized requiring IV antibiotics for sepsis. Failure to provide sufficient staff with the necessary skill set to provide skin assessments and treatments created the likelihood for serious injury, harm, impairment or death for the resident.

- A resident had 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 survey team was made aware the facility had 4 days in the previous quarter of PBJ submission when there were no licensed nurses in the facility for all 24 hours of each day. After a thorough investigation, the team determined the absences of a licensed nurse in the facility created the likelihood for serious injury, harm, impairment or death for all residents.

**Examples of Level 3, actual harm (physical or psychosocial) that is not immediate jeopardy includes, but are not limited to:**

- A resident's room has a strong smell of urine. Upon further investigation, the surveyor discovers the resident is incontinent and has soiled undergarments. Upon interview, the resident stated he called for help about an hour ago and was told by staff that they were short-staffed today and would get to him as soon as they could. He also mentioned that this happens almost every day and he is embarrassed to ask staff for help to clean himself up, so he remains withdrawn in his room until a staff member can assist him. Refer to the Psychosocial Outcome Guide 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. After several minutes no help arrived so 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. There was no licensed nurse on duty to assess the resident for any injuries or provide medication for pain. 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 and required surgery to repair the re-fractured hip.

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

A resident's family complained that their loved one's personal hygiene was never completed in a timely manner due to lack of staff. When interviewed, staff stated that they typically assist this resident once the care is completed for all other residents in their assignment since it takes longer to provide care for him. This 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 cause anxiety. Refer to the Psychosocial Outcome Guide for additional direction.

**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. 225; Issued: 08-08-24; Effective: 08-08-24; Implementation: 08-08-24)***

**§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 §483.7*1*.**

**§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(c) Proficiency of nurse aides.**

**The facility must ensure that nurse aides are able to demonstrate competency in skills and techniques necessary to care for residents' needs, as identified through resident assessments, and described in the plan of care.**

**INTENT §483.35(a)(3)-(4),(c)**

To assure that all nursing staff possess the competencies and skill sets necessary to provide nursing and related services to meet the residents' needs safely and in a manner that promotes each resident's rights, physical, mental and psychosocial well-being.

**DEFINITIONS §483.35**

**"Competency"** is a measurable pattern of knowledge, skills, abilities, behaviors, and other characteristics that an individual needs to perform work roles or occupational functions successfully.

**GUIDANCE §483.35(a)(3)-(4),(c)**

Cite this Tag only if there are deficiencies related to the **competency** of nursing staff.

If the survey investigation reveals that there are concerns with the competency of staff in areas other than Nursing Services refer to;

- F741, §483.40(a) for any staff caring for residents with dementia or a history of trauma and/or post-traumatic stress disorder;
- F801, §483.60(a) for Food and Nutrition staff;
- F826, §483.65(b), Specialized rehabilitative services;
- F839, §483.70(*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, §483.7*1*, 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 (§483.7*1*), facilities are required to address the staff competencies that are necessary to provide the level and types of care needed for the resident population considering the types of diseases, conditions, physical and cognitive disabilities, overall acuity, and other pertinent facts that are present within that population. Furthermore, per §483.95, facilities must determine the amount and types of training based on the facility assessment. We also note that the curriculum of a nurse aide training program must include training on recognizing abnormal changes in body functioning and the importance of reporting such changes to a supervisor (§483.152(b)(2)(iv)).Therefore, facility staff are expected to know how to identify residents' changes in conditions, and what to do once one is identified.

Facilities may adopt certain tools to aid staff with these competencies, as these tools have proven to be effective. For example, the Agency for Healthcare Research and Quality (AHRQ) has training modules for detecting and communicating resident changes in condition https://www.ahrq.gov/professionals/systems/long-term-care/resources/facilities/ptsafety/ltcmodule1.html. Also, Interventions to Reduce Acute Care Transfers (INTERACT) is a program with several resources aimed at improving staff competencies in this area https://interact2.net/tools_v4.html. Staff may inform surveyors of the tools they use to help show evidence of the required competencies. However, merely stating or referencing the tools is not enough on its own to verify compliance. Staff must also demonstrate that they possess the competency to use the tools in a manner that accomplishes their purpose, of aiding to effectively identify and address resident changes in condition.

**Cultural Competencies**

Cultural competencies help staff communicate effectively with residents and their families and help provide care that is appropriate to the culture and the individual. The term cultural competence (also known as cultural responsiveness, cultural awareness, and cultural sensitivity) refers to a person's ability to interact effectively with persons of cultures different from his/her own. With regard to health care, cultural competence is a set of behaviors and attitudes held by clinicians that allows them to communicate effectively with individuals of various cultural backgrounds and to plan for and provide care that is appropriate to the culture and to the individual.

The following resources are intended for informational purposes only:

- The National Center for Cultural Competency https://nccc.georgetown.edu/index.html
- The National Standards for Culturally and Linguistically appropriate Services in Health and Health Care (developed by the Office of Minority Health in HHS) https://www.thinkculturalhealth.hhs.gov/pdfs/EnhancedCLASStandardsBlueprint.pdf

**NOTE:** References to non-CMS sources do not constitute or imply endorsement of these organizations or their programs by CMS or the U.S. Department of Health and Human Services and were current as of the date of this publication.

**Demonstration of Competency**

Competency may not be demonstrated simply by documenting that staff attended a training, listened to a lecture, or watched a video. A staff's ability to use and integrate the knowledge and skills that were the subject of the training, lecture or video must be assessed and evaluated by staff already determined to be competent in these skill areas.

Examples for evaluating competencies may include but are not limited to:

- Lecture with return demonstration for physical activities;
- A pre- and post-test for documentation issues;
- Demonstrated ability to use tools, devices, or equipment that were the subject of training and used to care for residents;
- Reviewing adverse events that occurred as an indication of gaps in competency; or
- Demonstrated ability to perform activities that is in the scope of practice an individual is licensed or certified to perform.

Nursing leadership with input from the Medical Director should delineate the competencies required for all nursing staff to deliver, individualize, and provide safe care for the facility's residents. There should also be a process to evaluate staff skill levels, and to develop individualized competency-based training, that ensure resident safety and quality of care and service being delivered. A competency-based program might include the following elements:

a. Evaluates current staff training programming to ensure nursing competencies (e.g. skills fairs, training topics, return demonstration).
b. Identifies gaps in education that is contributing to poor outcomes (e.g. potentially preventable re-hospitalization) and recommends educational programing to address these gaps.
c. Outlines what education is needed based on the resident population (e.g. geriatric assessment, mental health needs) with delineation of licensed nursing staff verses non-licensed nursing and other staff member of the facility.
d. Delineates what specific training is needed based on the facility assessment (e.g. ventilator, IV's, trachs).
e. Details the tracking system or mechanism in place to ensure that the competency-based staffing model is assessing, planning, implementing, and evaluating effectiveness of training.
f. Ensures that competency-based training is not limited to online computer based but should also test for critical thinking skills as well as the ability to manage care in complex environments with multiple interruptions.

**PROCEDURES AND PROBES §483.35(a)(3)-(4),(c)**

For specific survey procedures see the Sufficient and Competent Staffing Critical Element Pathway.

Surveyors must determine through information obtained by observations, interviews and verified by record reviews, whether the facility employs competent nursing staff to provide care and services in assisting residents to attain or maintain their highest practicable level of physical, mental, functional and psychosocial well-being.

- How are staff competencies and skill sets evaluated upon their initial hire and routinely thereafter and when new technologies/equipment are put into use?

- Does the facility assessment describe the type of competencies required to meet each resident's needs as required under §483.71. 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 §483.35(a)(3)-(4),(c)**

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

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

## F727

*(Rev. 225; Issued: 08-08-24; Effective: 08-08-24; Implementation: 08-08-24)*

**§483.35(b) Registered nurse**

**§483.35(b)(1) Except when waived under paragraph (e) or (f) of this section, the facility must use the services of a registered nurse for at least 8 consecutive hours a day, 7 days a week.**

**§483.35(b)(2) Except when waived under paragraph (e) or (f) of this section, the facility must designate a registered nurse to serve as the director of nursing on a full time basis.**

**§483.35(b)(3) The director of nursing may serve as a charge nurse only when the facility has an average daily occupancy of 60 or fewer residents.**

**DEFINITIONS §483.35(b)**
**"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.

**PROCEDURE AND GUIDANCE §483.35(b)**

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, 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, §483.7*1*, 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. 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 facility must designate a registered nurse (RN) to serve as the DON on a full-time basis. The facility can only be waived from this requirement if it has obtained a waiver under subsections §483.35(e) or (f). 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.

The facility is responsible for submitting staffing data through the PBJ (Refer to F851, §483.70 (*p*). This data is available through PBJ reports that can be obtained through the Certification and Survey Provider Enhanced Reports (CASPER) reporting system. These reports, titled PBJ Staffing Data Report will be utilized by surveyors and contains information about overall direct care staffing levels as well as licensed nurse staffing, and if an RN was onsite for 8 hours a day, 7 days a week. If concerns were identified on this report, as well as from other sources, refer to the Critical Element pathway Sufficient and Competent Staffing, and the probes noted below.

Probes:

- Review the facility's posted daily staffing data.
- Does the facility have an RN on duty at least 8 consecutive hours a day, 7 days a week?
- Does the facility have an RN to serve as the DON on a full time basis?
- Does the facility ensure that the DON serves as a charge nurse only when the facility has an average daily occupancy of 60 or fewer residents?
- If there is no RN coverage for at least 8 consecutive hours each day, (e.g., as indicated by the PBJ Staffing Report), interview:
    - front line staff (i.e., nurse aides, LPNs/LVNs)
        - Is there an RN providing services to the residents for at least 8 consecutive hours in the day?
        - Are you ever made aware when there is no RN available in the facility?
        - Are you ever aware of a resident who needed care or services only performed by an RN (i.e., intravenous medications, assessment) and did not receive it?
    - Director of Nursing or Administrator;
        - How often are there days with no RN onsite?
        - What does the facility do when there is not an RN available to work the required 8 consecutive hours each day?
        - How does the facility provide care to residents that require an RN if one is not available to work?

Deficiency Categorization:

**Example of Severity Level 4 Noncompliance: Immediate Jeopardy to Resident Health or Safety includes but is not 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 investigation 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.

**Example of Severity Level 3 Noncompliance: Actual Harm that is not Immediate Jeopardy includes, 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.

**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:**

- 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 surveyor verified an RN was routinely on duty for only 7 consecutive hours a day last quarter. No actual harm to residents was identified. However, there was a potential for more than minimal harm due to the facility's failure to have an RN on duty for at least 8 consecutive hours a day, 7 days a week in order to ensure that all the residents' clinical needs were met either directly by the RN or indirectly by the LPNs or CNAs for whom the RN was responsible for overseeing resident care.

- 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.

## F740

***(Rev. 225; Issued: 08-08-24; Effective: 08-08-24; Implementation: 08-08-24)***

**§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 §483.7*1* (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 F622, §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. 225; Issued: 08-08-24; Effective: 08-08-24; Implementation: 08-08-24)***

**§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 §483.7*1*. 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 §483.7*1*, 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 §483.7*1*. 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) (F758), Psychotropic Drugs for additional guidance.

**INVESTIGATIVE PROTOCOL §483.40(a), (a)(1) & (a)(2)**
**Determination of Sufficient Staffing**

One factor used to determine sufficiency of staff (including both quantity and competency of staff) is the facility's ability to provide needed care for residents as determined by resident assessments and individual care plans. A staffing deficiency must be supported by examples of care deficits caused by insufficient quantity or competency of staff. The surveyor's investigation will include whether inadequate quantity or competency of staff prevented residents from reaching the highest practicable level of well-being.

A deficiency of insufficient staffing is determined through observations, interviews, and/or record reviews. Information gathered through these sources will help the surveyor in determining non-compliance. Concerns such as expressions or indications of distress by residents or family members, residents living with mental, psychosocial, and/or 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 §483.7*1* (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.

## F745

***(Rev. 225; Issued: 08-08-24; Effective: 08-08-24; Implementation: 08-08-24)***

**§483.40(d) The facility must provide medically-related social services to attain or maintain the highest practicable physical, mental and psychosocial well-being of each resident.**

**INTENT §483.40(d)**

To assure that sufficient and appropriate social services are provided to meet the resident's needs.

**DEFINITIONS §483.40(d)**

Definitions are provided to clarify terminology related to behavioral health services and the attainment or maintenance of a resident's highest practicable well-being.

**"Medically-related social services"** means services provided by the facility's staff to assist residents in attaining or maintaining their mental and psychosocial health.

**GUIDANCE §483.40(d)**

All facilities are required to provide medically-related social services for each resident. Facilities must identify the need for medically-related social services and ensure that these services are provided. It is not required that a qualified social worker necessarily provide all of these services, except as required by State law.

If there are concerns about requirements involving qualified social workers, refer to §483.70(*o*) (F850), Social worker.

Examples of medically-related social services include, but are not limited to the following:

- Advocating for residents and assisting them in the assertion of their rights within the facility in accordance with §483.10, Resident Rights, §483.12, Freedom from Abuse, Neglect, and Exploitation, §483.15, Transitions of Care, §483.20, Resident Assessments (PASARR), and §483.21, Comprehensive Person-Centered Care Planning;
- Assisting residents in voicing and obtaining resolution to grievances about treatment, living conditions, visitation rights, and accommodation of needs;
- Assisting or arranging for a resident's communication of needs through the resident's primary method of communication or in a language that the resident understands;
- Making arrangements for obtaining items, such as clothing and personal items;
- Assisting with informing and educating residents, their family, and/or representative(s) about health care options and ramifications;
- Making referrals and obtaining needed services from outside entities (e.g., talking books, absentee ballots, community wheelchair transportation);
- Assisting residents with financial and legal matters (e.g., applying for pensions, referrals to lawyers, referrals to funeral homes for preplanning arrangements);
- Transitions of care services (e.g., assisting the resident with identifying community placement options and completion of the application process, arranging intake for home care services for residents returning home, assisting with transfer arrangements to other facilities);

- Providing or arranging for needed mental and psychosocial counseling services;
- Identifying and seeking ways to support residents' individual needs through the assessment and care planning process;
- Encouraging staff to maintain or enhance each resident's dignity in recognition of each resident's individuality;
- Assisting residents with advance care planning, including but not limited to completion of advance directives (For additional information pertaining to advance directives, refer to §483.10(g)(12) (F578)), Advance Directives);
- Identifying and promoting individualized, non-pharmacological approaches to care that meet the mental and psychosocial needs of each resident; and
- Meeting the needs of residents who are grieving from losses and coping with stressful events.

Situations in which the facility should provide social services or obtain needed services from outside entities include, but are not limited to the following:

- Lack of an effective family or community support system or legal representative;
- Expressions or indications of distress that affect the resident's mental and psychosocial well-being, resulting from depression, chronic diseases (e.g., Alzheimer's disease and other dementia related diseases, schizophrenia, multiple sclerosis), difficulty with personal interaction and socialization skills, and resident to resident altercations;
- Abuse of any kind (e.g., alcohol or other drugs, physical, psychological, sexual, neglect, exploitation);
- Difficulty coping with change or loss (e.g., change in living arrangement, change in condition or functional ability, loss of meaningful employment or activities, loss of a loved one); and
- Need for emotional support.

**NOTE:** When needed services are not covered by Medicaid, nursing facilities are still required to attempt to obtain these services on behalf of the resident (e.g., arranging transportation services).

## F755

***(Rev. 225; Issued: 08-08-24; Effective: 08-08-24; Implementation: 08-08-24)***

**§483.45 Pharmacy Services**

**The facility must provide routine and emergency drugs and biologicals to its residents, or obtain them under an agreement described in §483.70(f). The facility may permit unlicensed personnel to administer drugs if State law permits, but only under the general supervision of a licensed nurse.**

**§483.45(a) Procedures. A facility must provide pharmaceutical services (including procedures that assure the accurate acquiring, receiving, dispensing, and administering of all drugs and biologicals) to meet the needs of each resident.**

**§483.45(b) Service Consultation. The facility must employ or obtain the services of a licensed pharmacist who--**

**§483.45(b)(1) Provides consultation on all aspects of the provision of pharmacy services in the facility;**

**§483.45(b)(2) Establishes a system of records of receipt and disposition of all controlled drugs in sufficient detail to enable an accurate reconciliation; and**

**§483.45(b)(3) Determines that drug records are in order and that an account of all controlled drugs is maintained and periodically reconciled.**

**INTENT §483.45(a) and (b)(1), (2), and (3)**

The intent of this requirement is that:

- In order to meet the needs of each resident, the facility accurately and safely provides or obtains pharmaceutical services, including the provision of routine and emergency medications and biologicals, and the services of a licensed pharmacist;
- The facility utilizes only persons authorized by state or local, regulation, or other guidance to administer medications during the course of employment by a facility;
- The licensed pharmacist collaborates with facility leadership and staff to coordinate pharmaceutical services within the facility, guide development and evaluation of pharmaceutical services procedures, and help the facility identify, evaluate, and resolve pharmaceutical concerns which affect resident care, medical care or quality of life such as the:
  - Provision of consultative services by a licensed pharmacist as necessary; and
  - Coordination of the pharmaceutical services if multiple pharmaceutical service providers are utilized (e.g., pharmacy, infusion, hospice, prescription drug plans [PDP]).
- The facility, in coordination with the licensed pharmacist, provides for:
  - A system of medication records that enables periodic accurate reconciliation and accounting for all controlled medications;
  - Prompt identification of loss or potential diversion of controlled medications; and
  - Determination of the extent of loss or potential diversion of controlled medications.

**NOTE:** Although the regulatory language refers to "drugs," the guidance in this document generally will refer to "medications," except in those situations where the term "drug" has become part of an established pharmaceutical term (e.g., adverse drug event, adverse drug reaction or consequence).

For purposes of this guidance, references to "the pharmacist" mean the licensed pharmacist, whether employed directly by the facility or through arrangement.

**DEFINITIONS §483.45**

Definitions are provided to clarify terminology related to pharmaceutical services and the management of each resident's medication regimen for effectiveness and safety.

**"Acquiring medication"** is the process by which a facility requests and obtains a medication.

**"Biologicals"** are made from a variety of natural sources—human, animal, or microorganisms. Biologicals are used to treat, prevent, or diagnose diseases and medical conditions. They may include a wide range of products such as vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins.

**"Controlled Medications"** are substances that have an accepted medical use (medications which fall under US Drug Enforcement Agency (DEA) Schedules II—V), have a potential for abuse, ranging from low to high, and may also lead to physical or psychological dependence.

**"Dispensing"** is a process that includes the interpretation of a prescription; selection, measurement, and packaging or repackaging of the product (as necessary); and labeling of the medication or device pursuant to a prescription/order.

**"Disposition"** is the process of returning and/or destroying unused medications.

**"Diversion of medications"** is the transfer of a controlled substance or other medication from a lawful to an unlawful channel of distribution or use, as adapted from the Uniform Controlled Substances Act.

**"Pharmaceutical Services"** refers to:

- The process (including documentation, as applicable) of receiving and interpreting prescriber's orders; acquiring, receiving, storing, controlling, reconciling, compounding (e.g., intravenous antibiotics), dispensing, packaging, labeling, distributing, administering, monitoring responses to, using and/or disposing of all medications, biologicals, chemicals (e.g., povidone iodine, hydrogen peroxide);
- The provision of medication-related information to health care professionals and residents;
- The process of identifying, evaluating and addressing medication-related issues including the prevention and reporting of medication errors; and
- The provision, monitoring and/or the use of medication-related devices.

**"Pharmacy assistant or technician"** refers to the ancillary personnel who work under the supervision and delegation of the pharmacist, consistent with state requirements.

**"Receiving medication"**—for the purpose of this guidance—is the process that a facility uses to ensure that medications, accepted from the facility's pharmacy or an outside source (e.g., vending pharmacy delivery agent, Veterans Administration, family member), are accurate (e.g., doses, amount).

**"Reconciliation"**—for the purpose of this guidance—refers to a system of recordkeeping that ensures an accurate inventory of medications by accounting for controlled medications that have been received, dispensed, administered, and/or, including the process of disposition.

**Guidance §483.45**

The provision of pharmaceutical services is an integral part of the care provided to nursing home residents. The management of complex medication regimens is challenging and requires diverse pharmaceutical services and formal mechanisms to safely handle and control medications, to maintain accurate and timely medication records, and to minimize medication-related adverse consequences or events. The overall goal of the pharmaceutical services system within a facility is to ensure the safe and effective use of medications.

Preventable medication-related adverse consequences and events are a serious concern in nursing homes. The U.S. Department of Health and Human Services (HHS) Office of the Inspector General issued a report in February 2014, Adverse Events in Skilled Nursing Facilities: National Incidence among Medicare Beneficiaries (OEI-06-11-00370). The OIG found that one in three SNF residents experienced an adverse event or temporary harm event. Thirty-seven percent of these adverse events were related to medications and 66% of all medication-related events were preventable. Medication-related adverse events included excessive bleeding due to anticoagulant use without adequate monitoring and acute hypoglycemia. Consequences of medication-related adverse events included a prolonged SNF stay, hospitalization, life sustaining interventions, permanent harm, and death.

Factors that increase the risk of adverse consequences associated with medication use in the nursing home setting include complex medication regimens, numbers and types of medication used, physiological changes accompanying the aging process, as well as multiple comorbidities.

The consultative services of a pharmacist can promote safe and effective medication use. A pharmacist, in collaboration with facility staff, establishes, evaluates and coordinates all aspects of pharmaceutical services provided to all residents within a facility by all providers (e.g., pharmacy, prescription drug plan, prescribers). A pharmacist can also help in the development of medication-related documentation procedures, such as identification of abbreviations approved for use in the facility and can help guide the

selection and use of medications in accordance with the authorized prescriber's orders, applicable state and federal requirements, manufacturers' specifications, characteristics of the resident population, and individual resident conditions.

Providing pharmaceutical consultation is an ongoing, interactive process with prospective, concurrent, and retrospective components. To accomplish some of these consultative responsibilities, pharmacists can use various methods and resources, such as technology, additional personnel (e.g., dispensing pharmacists, pharmacy technicians), and related policies and procedures.

Numerous recognized resources address different aspects of pharmaceutical services and medication utilization, such as:

- US Department of Health and Human Services (DHHS), Food and Drug Administration (FDA) Find Information about a Drug, Information on FDA-approved drugs released for sale on the market;
- The American Society of Health System Pharmacists (ASHP) http://www.ashp.org;
- The National Institutes of Health U.S. National Library of Medicine Medline Plus, https://medlineplus.gov/druginformation.html.
- AMDA - The Society for Post-Acute and Long-Term Care Medicine (American Medical Directors Association) https://paltc.org/;
- The National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP), https://www.nccmerp.org/;
- American Society for Parenteral and Enteral Nutrition (ASPEN), https://www.nutritioncare.org/.

**NOTE:** References to non-CMS sources do not constitute or imply endorsement of these organizations or their programs by CMS or the U.S. Department of Health and Human Services and were current as of the date of this publication.

## A. PROVISION OF ROUTINE AND/OR EMERGENCY MEDICATIONS

The regulation at 42 CFR 483.45 requires that the facility provide or obtain routine and emergency medications and biologicals in order to meet the needs of each resident. Facility procedures and applicable state laws may allow the facility to maintain a limited supply of medications in the facility for use during emergency or after-hours situations. Whether prescribed on a routine, emergency, or as needed basis, medications should be administered in a timely manner. Delayed acquisition of a medication may impede timely administration and adversely affect a resident's condition. Factors that may help determine timeliness and guide acquisition procedures include:

- Availability of medications to enable continuity of care for an anticipated admission or transfer of a resident from acute care or other institutional settings;

- Condition of the resident including the severity or instability of his/her condition, a significant change in condition, discomfort, risk factors, current signs and symptoms, and the potential impact of any delay in acquiring the medications;
- Category of medication, such as antibiotics or analgesics;
- Availability of medications in emergency supply, if applicable; and
- Ordered start time/date for a medication.

Procedures should identify how staff, who are responsible for medication administration:

- Ensure each resident has a sufficient supply of his or her prescribed medications (for example, a resident who is on pain management has an adequate supply of medication available to meet his or her needs). At a minimum, the system is expected to include a process for the timely ordering and reordering of a medication;
- Monitor the delivery and receipt of medications when they are ordered; and
- Determine the appropriate action, e.g., contact the prescriber or pharmacist, when a resident's medication(s) is not available for administration.

**NOTE:** Facility staff may encounter situations in which a medication is not available in the resident's supply or the facility's emergency medication supply and then decide to "borrow" medications from another resident's supply. This practice of borrowing medications from other residents' supplies is not consistent with professional standards and contributes to medication errors. Concerns about whether the facility has a system in place to ensure each resident has a sufficient supply of medications for timely administration should be cited under this tag Pharmacy Services (F755). However, if staff borrow any medication from another resident's supply due to failure to order the medication and/or not following the facility's system for reordering medications, refer to §483.21(b)(3), F658, Services Provided Meet Professional Standards. Instances of "borrowing," as described in this paragraph, would not be considered to be drug diversion.

**Foreign Acquired Medications**

It has been reported that some residents and/or facilities may be obtaining medications from foreign sources. Medications obtained from foreign sources may present safety issues since they have been manufactured or held outside of the jurisdiction of the United States (U.S.) regulatory system. These medications may not be safe and effective for their intended uses. The Federal Food, Drug, and Cosmetic Act (FFDCA) strictly limits the types of drugs that may be imported into the U.S. Medications imported into the U.S. may violate the FFDCA if they are unapproved by the FDA, labeled incorrectly, or dispensed without a valid prescription. The facility should, in collaboration with the pharmacist, assure that medications are provided or obtained from approved sources and do not violate the FFDCA.

If it is determined that the facility is providing/obtaining foreign medications that are not FDA approved for use by the residents, the State Agency must make referrals to

appropriate agencies, such as the FDA; depending on the medication classification, the Drug Enforcement Administration; State Board of Nursing; State Board of Pharmacy; and the State Licensure Board for Nursing Home Administrators.

## B. PHARMACEUTICAL SERVICES PROCEDURES

The pharmacist, in collaboration with the facility and medical director, helps develop and evaluate the implementation of pharmaceutical services procedures that address the needs of the residents, are consistent with state and federal requirements, and reflect current standards of practice. These procedures address, but are not limited to, acquiring; receiving; dispensing; administering; disposing; labeling and storage of medications; and personnel authorized to access or administer medications.

### Acquisition of Medications

Examples of procedures addressing acquisition of medications include:

- Availability of an emergency supply of medications, if allowed by state law, including the types or categories of medications; amounts, dosages/strengths to be provided; location of the supply; personnel authorized to access the supply; record keeping; monitoring for expiration dates; and the steps for replacing the supply when medications are used;
- When, how to, and who may contact the pharmacy regarding acquisition of medications and the steps to follow for contacting the pharmacy for an original routine medication order, emergency medication order, and refills;
- The availability of medications when needed, that is, the medication is either in the facility (in the emergency supply) or obtained from a pharmacy that can be reached 24 hours a day, seven days a week;
- The receipt, labeling, storage, and administration of medications dispensed by the prescriber, if allowed by state requirements;
- Verification or clarification of an order to facilitate accurate acquisition of a medication when necessary (e.g., clarification when the resident has allergies to, or there are contraindications to the medication being prescribed);
- Procedure when delivery of a medication will be delayed or the medication is not or will not be available; and
- Transportation of medications from the dispensing pharmacy or vendor to the facility consistent with manufacturer's specifications, state and federal requirements, and standards of professional practice to prevent contamination, degradation, and diversion of medications.

### Receiving Medication(s)

Examples of procedures addressing receipt of medications include:

- How the receipt of medications from dispensing pharmacies (and family members or others, where permitted by state requirements) will occur and how it will be reconciled with the prescriber's order and the requisition for the medication;
- How staff will be identified and authorized in accordance with applicable laws and requirements to receive the medications and how access to the medications will be controlled until the medications are delivered to the secured storage area; and
- Which staff will be responsible for assuring that medications are incorporated into the resident's specific allocation/storage area.

**Dispensing Medication(s)**

Examples of procedures to assure compatible and safe medication delivery, to minimize medication administration errors, and to address the facility's expectations of the in-house pharmacy and/or outside dispensing pharmacies include:

- Delivery and receipt;
- Labeling; and
- The types of medication packaging (e.g., unit dose, multi-dose vial, blister cards).

**Administering Medications**
Examples of procedures addressing administration of medications include:

- Providing continuity of staff to ensure that medications are administered without unnecessary interruptions;
- Reporting medication administration errors, including how and to whom to report;
- Authorizing personnel, consistent with state requirements, to administer the medications, including medications needing intravenous administration (see Authorized Personnel section within this document);
- Assuring that the correct medication is administered in the correct dose, in accordance with manufacturer's specifications and with standards of practice, to the correct person via the correct route in the correct dosage form and at the correct time;
- Defining the schedules for administering medications to:

    - Maximize the effectiveness (optimal therapeutic effect) of the medication (for example, antibiotics, antihypertensives, insulin, pain medications, proton pump inhibitors, metered dose inhalers, and medications via enteral feeding tubes);
    - Prevent potential significant medication interactions such as medication-medication or medication-food interactions; and
    - Honor resident choices and activities, as much as possible, consistent with the person-centered comprehensive care plan;

- Defining general guidelines for specific monitoring related to medications, when ordered or indicated, including specific item(s) to monitor (e.g., blood pressure,

pulse, blood sugar, weight), frequency (e.g., weekly, daily), timing (e.g., before or after administering the medication), and parameters for notifying the prescriber;
- Defining pertinent techniques and precautions that meet current standards of practice for administering medications through alternate routes such as eye, ear, buccal, injection, intravenous, atomizer/aerosol/ inhalation therapy, or enteral tubes. For example, for enteral feeding tubes, define procedures including but not limited to:

    - Types of medications that may be safely administered via enteral feeding tube;
    - Appropriate dosage forms;
    - Techniques to monitor and verify that the feeding tube is in the right location (e.g., stomach or small intestine, depending on the tube) before administering medications; and
    - Preparing drugs for enteral administration, administering drugs separately, diluting drugs as appropriate, and flushing the feeding tube before, between, and after drug administration, including the amount of water to be used for the flushing and administration of medications (and obtaining physician/practitioners order to address a resident with fluid restrictions).

**NOTE:** Enteral feeding tube practice recommendations may be found in ASPEN Safe Practices for Enteral Nutrition Therapy, https://aspenjournals.onlinelibrary.wiley.com/doi/full/10.1177/0148607116673053. References to non-CMS sources do not constitute or imply endorsement of these organizations or their programs by CMS or the U.S. Department of Health and Human Services and were current as of the date of this publication.

- Documenting the administration of medications, including:

    - The administration of routine medication(s), and, if not administered, an explanation of why not;
    - The administration of "as-needed" (PRN) medications including the justification and response;
    - The route, if other than oral (intended route may be preprinted on Medication Administration Record (MAR); and
    - Location of administration sites such as transdermal patches and injections;

- Providing accessible current information about medications (e.g., medication information references) and medication-related devices and equipment (e.g., user's manual) for all staff involved with the medication administration process;
- Clarifying any order that is incomplete, illegible, or presents any other concerns, prior to administering the medication; and
- Reconciling medication orders including telephone orders, monthly or other periodic recapitulations, and MAR, including who may transcribe prescriber's orders and enter the orders onto the MAR.

**Disposition of Medications**

Examples of procedures addressing the disposition of medications include:

- Timely identification and removal (from current medication supply) of medications for disposition;
- Identification of storage method for medications awaiting final disposition;
- Control and accountability of medications awaiting final disposition consistent with standards of practice;
- Documentation of actual disposition of medications to include: resident name, medication name, strength, prescription number (as applicable), quantity, date of disposition, and involved facility staff, consultant(s) or other applicable individuals; and
- Method of disposition (including controlled medications) should prevent diversion and/or accidental exposure and is consistent with applicable state and federal requirements, local ordinances, and standards of practice;

**Authorized Personnel**

The facility may permit unlicensed personnel to administer medications if state law permits, but only under the general supervision of a licensed nurse.

The facility assures that all persons administering medications are authorized according to state and federal requirements, oriented to the facility's medication-related procedures, and have access to current information regarding medications being used by the residents, including side effects of medications, contraindications, doses, etc.

Examples of procedures addressing authorized personnel include:

- How the facility assures ongoing competency of all staff (including temporary, agency, or on-call staff) authorized to administer medications and biologicals;
- Training regarding the operation, limitations, monitoring, and precautions associated with medication administration devices or other equipment, if used, such as:

    - IV pumps or other IV delivery systems including calculating dosage, infusion rates, and compatibility of medications to be added to the IV or enteral feeding pump;
    - Blood glucose meters, including calibration and cleaning between individual residents; and
    - Using, maintaining, cleaning, and disposing of the various types of devices for administration including nebulizers, inhalers, syringes, medication cups, spoons, and pill crushers;

- Identifying pharmacy personnel in addition to the pharmacist (e.g., pharmacy technicians, pharmacist assistants) who are authorized under state and federal requirements to access medications and biologicals.

## C. SERVICES OF A LICENSED PHARMACIST

The facility is responsible for employing or contracting for the services of a pharmacist to provide consultation on all aspects of pharmaceutical services. The facility may provide for this service through any of several methods (in accordance with state requirements) such as direct employment or contractual agreement with a pharmacist. Whatever the arrangement or method employed, the facility and the pharmacist identify how they will collaborate for effective consultation regarding pharmaceutical services. The pharmacist reviews and evaluates the pharmaceutical services by helping the facility identify, evaluate, and address medication issues that may affect resident care, medical care, and quality of life.

The pharmacist is responsible for helping the facility obtain and maintain timely and appropriate pharmaceutical services that support residents' healthcare needs, goals, and quality of life that are consistent with current standards of practice, and that meet state and federal requirements. This should include, but is not limited to, collaborating with the facility and medical director to:

- Develop, implement, evaluate, and revise (as necessary) the procedures for the provision of all aspects of pharmaceutical services, including procedures to support resident quality of life such as those that support safe, individualized medication administration programs;
- Coordinate pharmaceutical services if and when multiple pharmaceutical service providers are utilized (e.g., pharmacy, infusion, hospice, prescription drug plans [PDP])
- Develop intravenous (IV) therapy procedures if used within the facility (consistent with state requirements) which may include: determining competency of staff and facility-based IV admixture procedures that address sterile compounding, dosage calculations, IV pump use, and flushing procedures;

- Determine (in accordance with or as permitted by state law) the contents of the emergency supply of medications and monitor the use, replacement, and disposition of the supply;
- Develop mechanisms for communicating, addressing, and resolving issues related to pharmaceutical services;
- Strive to assure that medications are requested, received, and administered in a timely manner as ordered by the authorized prescriber (in accordance with state requirements), including physicians, advanced practice nurses, pharmacists, and physician assistants;
- Provide feedback about performance and practices related to medication administration and medication errors.

In addition, the pharmacist may collaborate with the facility and medical director on other aspects of pharmaceutical services including, but not limited to:

- Developing procedures and guidance regarding when to contact a prescriber about a medication issue and/or adverse effects, including what information to gather before contacting the prescriber;
- Developing the process for receiving, transcribing, and recapitulating medication orders;
- Recommending the type(s) of medication delivery system(s) to standardize packaging, such as bottles, bubble packs, tear strips, in an effort to minimize medication errors;
- Developing and implementing procedures regarding automated medication delivery devices or cabinets, if automated devices or cabinets are used, including: the types or categories of medications, amounts stored, location of supply, personnel authorized to access the supply, record keeping, monitoring for expiration dates, method to ensure accurate removal of medications and the steps for replacing the supply when dosages are used, and monitoring the availability of medications within the system;
- Interacting with the quality assessment and assurance committee to develop procedures and evaluate pharmaceutical services including delivery and storage systems within the various locations of the facility in order to prevent, to the degree possible, loss or tampering with the medication supplies, and to define and monitor corrective actions for problems related to pharmaceutical services and medications, including medication errors;
- Recommending current resources to help staff identify medications and information on contraindications, side effects and/or adverse effects, dosage levels, and other pertinent information; and
- Identifying facility educational and informational needs about medications and providing information from sources such as nationally recognized organizations to the facility staff, practitioners, residents, and families.

**NOTE:** This does not imply that the pharmacist must personally present educational programs.

## D. CONTROLLED MEDICATIONS

Regulations require that the facility have a system to account for controlled medications' receipt and disposition in sufficient detail to enable an accurate reconciliation, and that the facility conduct a periodic reconciliation. This system should include, but is not limited to:

- Record of receipt of all controlled medications with sufficient detail to allow reconciliation (e.g., specifying the name and strength of the medication, the quantity and date received, and the resident's name). However, in some delivery systems (e.g., single unit package medication delivery system or automated dispensing systems utilizing single-unit packages of medications that are not

dispensed pursuant to a specific order), the resident's name may not be applicable;

**NOTE**: If permitted by, and in accordance with, state requirements, the facility may store some controlled medications in an emergency medication supply. The facility's policies and procedures must address the reconciliation of this supply, see 42 C.F.R. § 483.45(b)(2) and (3).

- Records of personnel access, usage, and disposition of all controlled medications with sufficient detail to allow reconciliation (e.g., the MAR, proof-of-use sheets, or declining inventory sheets), including destruction, wastage, return to the pharmacy/manufacturer, or disposal in accordance with applicable State requirements;

- Periodic reconciliation of records of receipt, disposition, usage, and inventory for all controlled medications (as defined by facility procedures or when loss is identified). The reconciliation identifies loss or potential diversion of controlled medications so as to minimize the time between the actual loss or potential diversion and the time of detection and follow-up to determine the extent of loss. Because diversion can occur at any time, periodic reconciliation should accommodate actual facility experience, such that if there is any evidence or even suspicion that diversion may be occurring, then that may dictate conducting the periodic reconciliation as frequently as daily. State or other federal requirements may specify the frequency of reconciliation.

    - If discrepancies are identified during the reconciliation, the pharmacist and the facility develop and implement recommendations for resolving them, and make referrals to law enforcement agencies as appropriate.
    - Data from injectable, scheduled drug tracking should be regularly reviewed and discrepancies or unusual access patterns are investigated including whether residents should be screened for exposure to blood borne pathogens. See §483.80 Infection Control, F880.
    - Liquid controlled medications are often dispensed in multi-dose containers which indicate approximate volume. The containers may also be opaque to protect the medication from light. It should be noted that absolute accuracy in tracking volume and use of liquid controlled medications may not be possible. The actual volume in these containers may be slightly over or under the manufacturer's stated volume depending on the shape and material of the container and the formulation of the medication such as thick liquid suspensions. The opaque container, measurement markings, manufacturer fill volume variation, and method for recording usage all make detection of diversion for liquid controlled medications more difficult. The general standard of practice for documenting usage of liquid controlled medications is to record the starting volume from the label, record each dose administered, subtract the dose administered from the previously recorded volume, and record the remaining amount. Any observed discrepancy between the

recorded amount and what appears to be remaining in the container should be reported according to facility policy. Manufacturer's instructions may list the estimated volume variance (e.g., 30 mL plus or minus 2.5 mL). For liquid controlled medications, signs of diversion may include: an observable discrepancy between the written balances of remaining medication compared to the remaining amount in the bottle upon visual inspection; changes in the viscosity or color of the medication; reports of spills; and, as with other controlled medications, statements from a resident that the medication is not working.

- Disposal methods for controlled medications must involve a secure and safe method to prevent diversion and/or accidental exposure.
- Fentanyl transdermal patches present a unique situation given the multiple boxed warnings, and the substantial amount of fentanyl remaining in the patch after removal, creating a potential for abuse, misuse, diversion, or accidental exposure. Due to the life threatening risks associated with exposure to or ingestion of the patch, the Food and Drug Administration (FDA) and manufacturer instructions recommend consumers dispose of used fentanyl patches by folding the patch in half with the sticky sides together and flushing the patch down the sink or toilet, https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=e15a7e9b-8025-49dd-9a6d-bafcccf1959f&type=display. . The Environmental Protection Agency bans flushing of pharmaceuticals if they are considered hazardous waste pharmaceuticals; fentanyl patches are not in this category, https://www.epa.gov/hw/defining-hazardous-waste-listed-characteristic-and-mixed-radiological-wastes#PandU. However, this method of disposal may not always be appropriate in nursing homes, particularly in areas where state or local laws restrict flushing of pharmaceuticals. Therefore, nursing homes may use drug disposal products or systems for fentanyl patches and other controlled medications as long as the facility can show that the product or system minimizes accidental exposure or diversion. Disposal in common areas or resident room trashcans or sharps containers are methods that would not prevent accidental exposure or diversion. Concerns related to fentanyl patch disposal which could lead to accidental exposure should be investigated at F689.

**NOTE:** The pharmacist is not required by these regulations to perform the reconciliation of medications, but rather to evaluate and determine that the facility maintains an accurate account of all controlled medications and completes the reconciliation according to its procedures, consistent with State and federal requirements.

**PROCEDURES §483.45**

Use the Medication Administration Observation and the Medication Storage and Labelling Critical Element Pathway, as appropriate, along with the above interpretive guidelines when determining if the facility meets the requirements for, or investigating concerns related to, the provision of Pharmacy Services.

## KEY ELEMENTS OF NONCOMPLIANCE

To cite deficient practice at F755, the surveyor's investigation will generally show that the facility failed to:

- Provide medications and/or biologicals, as ordered by the prescriber, to meet the needs of each resident; or
- Ensure that only appropriate personnel administer medications, consistent with applicable state law and regulations; or
- Provide pharmaceutical services to meet each resident's needs which includes: acquiring, receiving, dispensing, accurately administering, or disposing of medications; or
- Provide or arrange for a licensed pharmacist who consults on all aspects of pharmaceutical services; or
- Establish systems to accurately reconcile controlled medications using acceptable standards of practice; or
- Have safeguards and systems in place to control, account for, and periodically reconcile controlled medications in order to prevent loss, diversion, or accidental exposure.

## DEFICIENCY CATEGORIZATION

In addition to actual or potential physical harm, always consider whether psychosocial harm has occurred when determining severity level. 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.

**Examples of noncompliance that demonstrate severity at Level 4 may include, but are not limited to**:

- The facility, in collaboration with the pharmacist, failed to establish effective procedures to meet the needs of the residents, such as:

    - Assuring that pain medications were available to meet the needs of the resident-- The facility failed to obtain the routine regularly scheduled pain medicine for a resident who was to receive it every six hours. The investigation confirmed that the resident had been without pain medication for 2 days, the equivalent of 8 missed doses. This failure resulted in the resident complaining of excruciating, unrelieved pain (e.g., a pain score of 9 on a 10-point scale). The pain was all-consuming and overwhelming, leading to sleep loss, and a loss in interest and ability to perform activities of daily living.
    - Assuring that devices used to administer medications (such as IV pumps) were working properly, leading to an adverse consequence at the immediate jeopardy level, in which a resident received an incorrect dose of IV medication.

- Provisions to assure that staff were trained or competent to use new medication-related devices (e.g., intravenous pump). This resulted in a resident receiving an inappropriate dose of medication requiring subsequent hospitalization.

**Examples of Level 3, Actual harm (physical or psychosocial) that are not immediate jeopardy, may include, but are not limited to:**

- The facility and the pharmacist failed to assure that procedures were developed and implemented so that all medication orders were processed consistently and accurately through the stages of ordering, receiving, and administering medications (including transfer orders, admission orders, telephone orders, order renewals, and the MAR). For example, an ordering error led to an incorrect dose of a medication being administered and the resident experienced spontaneous bruising and frequent nosebleeds requiring medical intervention that was able to be performed in the nursing home.

- The facility failed to implement a system to consistently and accurately reconcile controlled medications. As a result, when staff attempted to administer pain medication to a resident, staff found no available medications despite documentation which showed the medications were available. The resident experienced mild to moderate pain that prevented the resident from attending physical therapy.

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

- As a result of failure of licensed staff to supervise medication administration by authorized unlicensed personnel, two residents received their oral antibiotics late on one day, however the residents did not experience any harm.

- The facility failed to obtain or provide the services of a pharmacist or to collaborate with the pharmacist to assure that effective policies and procedures were established and implemented including, for example:

  - A resident did not receive medication for heartburn for two or more days and had difficulty sleeping during that time due to nocturnal heartburn. The level of discomfort did not interfere with the resident's participating in activities or performing activities of daily living.
  - As a result of failure to identify medications that should not be crushed for administration, a resident received a newly ordered medication that was crushed, contrary to the manufacturer's specifications. While the resident did not experience any harm, the potential for harm to the resident was present.

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

Severity Level 1 does not apply for this regulatory requirement because the failure of the facility to provide routine and emergency drugs and biologicals to its residents creates the potential for more than minimal harm. This provision, along with pharmaceutical procedures and services are essential aspects of both process and outcome requirements.

**Potential Tags for Additional Investigation**

Examples of some of the related requirements that should be considered when concerns have been identified include the following:

- 42 CFR §483.12, F602, Right to be Free from Misappropriation/Exploitation
  - Determine if the facility diverted a resident's medication, including, but not limited to, controlled substances for staff use or personal gain. If it is determined that a resident's medications were diverted, the State Agency must make referrals to appropriate agencies, such as local law enforcement; Drug Enforcement Administration; State Board of Nursing; State Board of Pharmacy; the state Medicaid Fraud Control Unit, and possibly the State licensure board for Nursing Home Administrators.

- 42 CFR §483.35, F725, Sufficient Staff and F726, Competent Staff
  - Determine if the facility had competent staff in sufficient numbers available to provide medications on a 24-hour basis to meet the needs of the residents, based upon the comprehensive assessment and care plan.

- 42 CFR §483.45(g) and (h), F761, Labeling and Storage of Drugs and Biologicals
  - Determine if the facility properly labeled and stored all drugs and biological in accordance with currently accepted professional principles.

- 42 CFR §483.70(*g*), F841, Medical Director
  - Determine whether the medical director, in collaboration with the facility and the pharmacist, and based on current standards of practice, helped the facility develop procedures for the safe and accurate provision of medications to meet the needs of the residents.

- 42 CFR §483.70(*h*), F842, Medical Records
  - Determine whether the facility has maintained clinical records, including medication administration, in accordance with accepted professional standards and practices that are complete, accurately documented, and readily accessible.
- 42 CFR §483.75(g), F867, Quality Assessment and Assurance
  - If concerns regarding pharmaceutical services have been identified, determine whether the quality assessment and assurance committee has identified and responded to those concerns, as appropriate, and has developed, implemented, and monitored appropriate plans of action to correct identified quality deficiencies.

## F756

*(Rev. 225; Issued: 08-08-24; Effective: 08-08-24; Implementation: 08-08-24)*

**§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

**NOTE:** References to non-CMS sources or sites on the Internet are provided as a service and do not constitute or imply endorsement of these organizations or their programs by CMS or the U.S. Department of Health and Human Services. CMS is not responsible for the content of pages found at these sites. URL addresses were current as of the date of this publication.

**Identification of Irregularities**

An objective of the MRR is to try to minimize or prevent adverse consequences by identifying irregularities including, for example: syndromes potentially related to medication therapy, emerging or existing adverse medication consequences (e.g., drug reactions or medication errors). The resident's record may contain information regarding

possible and/or actual medication irregularities. Possible sources to obtain this information include: the medication administration records (MAR); prescribers' orders; progress, nursing and consultants' notes; the Resident Assessment Instrument (RAI); laboratory and diagnostic test results, and other sources of information about documented expressions or indications of distress and/or changes in condition. The pharmacist may also obtain information from the Quality Measures/Quality Indicator reports, the attending physician, facility staff, and (as appropriate) from interviewing, assessing, and/or observing the resident.

The pharmacist's review considers factors such as:

- Whether the physician and staff have documented objective findings, diagnoses, symptom(s), and/or resident goals and preferences to support indications for use;
- Whether the physician and staff have identified and acted upon, or should be notified about, the resident's allergies and/or potential side effects and significant medication interactions;
- Whether the medication dose, frequency, route of administration, and duration are consistent with the resident's condition, manufacturer's recommendations, and applicable standards of practice;
- Whether the physician and staff have documented progress towards, decline from, or maintenance of the resident's goal(s) for the medication therapy;
- Whether the physician and staff have documented any attempts for gradual dose reduction (GDR) or added any non-pharmacological approaches, in an effort to reduce or discontinue a drug;
- Whether the physician and staff have obtained and acted upon laboratory results, diagnostic studies, or other measurements (such as bowel function, intake and output) as applicable;
- Whether medication errors exist or circumstances exist that make them likely to occur; and
- Whether the physician and staff have noted and acted upon possible medication-related causes of recent or persistent changes in the resident's condition such as worsening of an existing problem or the emergence of new signs or symptoms. Some examples of changes potentially related to medication use that could occur include:

    - Anorexia and/or unplanned weight loss, or weight gain;
    - Expressions or indications of distress, or other changes in a resident's psychosocial status;
    - Bowel function changes including constipation, ileus, impaction;
    - Confusion, cognitive decline, worsening of dementia (including delirium);
    - Dehydration, fluid/electrolyte imbalance;
    - Excessive sedation, insomnia, or sleep disturbance;
    - Falls, dizziness, or evidence of impaired coordination;
    - Headaches, muscle pain, generalized aching or pain;
    - Rash, pruritus;
    - Spontaneous or unexplained bleeding, bruising; and

- Urinary retention or incontinence.

Upon conducting the MRR, the pharmacist may identify and report irregularities in one or more of the following categories:

- The use of a medication without identifiable evidence of adequate indications for use, such as, the use of a medication to treat a clinical condition without identifiable evidence that safer alternatives or more clinically appropriate medications have been considered;
- The use of homeopathic or herbal options (e.g., St. John's Wort) that may interfere with the effectiveness of clinically appropriate medications;
- The use of an appropriate medication that is not helping attain the intended treatment or resident's goals because of timing of administration, dosing intervals, sufficiency of dose, techniques of administration, or other reasons;
- The use of a medication in an excessive dose (including duplicate therapy) or for excessive duration, thereby placing the resident at greater risk for adverse consequences or causing existing adverse consequences;
- The presence of an adverse consequence associated with the resident's current medication regimen;
- The use of a medication without evidence of adequate monitoring; i.e., either inadequate monitoring of the response to a medication or an inadequate response to the findings;
- Presence of medication errors or the risk for such errors;
- Presence of a clinical condition that might warrant initiation of medication therapy; and

**NOTE:** The presence of a diagnosis or symptom does not necessarily warrant medication, but often depends on the consideration of many factors simultaneously.

- A medication interaction associated with the current medication regimen.

**NOTE:** Concomitant use of certain medication combinations is not necessarily inappropriate. Often, several medications with documented interactions can be given together safely. However, concomitant use of certain medications warrants careful consideration of potential alternatives, possible need to modify doses, and diligent monitoring.

Websites for organizations such as AMDA - The Society for Post-Acute and Long-Term Care Medicine (American Medical Directors Association) have made information available regarding problematic medication interactions in the long-term care population:

- https://www.amda.com/tools/clinical/m3/topten.cfm; and
- https://www.crediblemeds.org/healthcare-providers/drug-drug-interaction, Woosley, RL and Romero, KA, www.Crediblemeds.org, QTdrugs List, [Accessed March6, 2017], AZCERT, Inc. 1822 Innovation Park Dr., Oro Valley, AZ 85755.

**NOTE**: References to non-CMS sources do not constitute or imply endorsement of these organizations or their programs by CMS or the U.S. Department of Health and Human Services and were current as of the date of this publication.

**Location and Notification of Medication Regimen Review Findings**

The pharmacist is expected to document either that no irregularity was identified or the nature of any identified irregularities. The pharmacist is responsible for reporting any identified irregularities to the attending physician, the facility's medical director, and director of nursing. The timeliness of notification of irregularities depends on factors including the potential for or presence of serious adverse consequences; for example, immediate notification is indicated in cases of bleeding in a resident who is receiving anticoagulants or in cases of possible allergic reactions to antibiotic therapy. The pharmacist must document any identified irregularities in a separate, written report. The report may be in paper or electronic form. If no irregularities were identified during the review, the pharmacist includes a signed and dated statement to that effect.

The pharmacist does not need to document a continuing irregularity in the report each month if the attending physician has documented a valid clinical rationale for rejecting the pharmacist's recommendation unless warranted by a change in the resident's condition or other circumstances.

The pharmacist's findings are considered part of each resident's medical record and as such are available to the resident/representative upon request. If documentation of the findings is not in the active record, it is maintained within the facility and is readily available for review. Establishing a consistent location for the pharmacist's findings and recommendations can facilitate communication with the attending physician, the director of nursing, the remainder of the IDT, the medical director, the resident and his or her legal representative, the ombudsman, and surveyors.

**Response to Irregularities Identified in the MRR**

The medical record must show documentation that the attending physician reviewed any irregularities identified by the pharmacist. For those issues that require physician intervention, the attending physician either accepts and acts upon the report and recommendations or rejects all or some of the report and should document his or her rationale of why the recommendation is rejected in the resident's medical record. It is not acceptable for an attending physician to document only that he/she disagrees with the report, without providing some clinical basis for disagreeing.

The facility should have a procedure for how to resolve situations where:

- The attending physician does not concur with or take action on identified irregularities, and;
- The attending physician is also the medical director.

## KEY ELEMENTS OF NONCOMPLIANCE

To cite deficient practice at F756, the surveyor's investigation will generally show that:

- The MRR was not conducted by a licensed pharmacist; or
- The pharmacist failed to conduct a complete MRR, at least monthly (or more frequently, as indicated by the resident's condition) for every resident of the facility; or
- The pharmacist's findings in the MRR did not show evidence that the pharmacist also reviewed the resident's chart, for example, the pharmacist did not reference the resident response to a particular medication that was cited as an irregularity; or
- The pharmacist failed to identify or report the absence of or inadequate indications for use of a medication, or a medication or medication combination with significant potential for adverse consequences or medication interactions; or
- The pharmacist failed to identify and/or report medications prescribed or administered in excessive dose (including but not limited to duplicate therapy); or
- The pharmacist failed to identify and/or report medications prescribed or administered for excessive duration; or
- The pharmacist failed to identify and/or report medications prescribed or administered without adequate monitoring; or
- The pharmacist failed to identify or report medications in a resident's regimen that could (as of the review date) be causing or associated with new, worsening, or progressive signs and symptoms; or
- The pharmacist failed to identify and report the absence of any explanation as to why or how the benefit of a medication(s) with potential for clinically significant adverse consequences outweighs the risk; or
- The attending physician failed to document that he or she reviewed the pharmacist's identified irregularities and/or failed to document the action taken or not taken to address the irregularities; or
- The facility failed to develop, maintain, and implement policies and procedures which address the time frames for the steps in the MRR process; or
- The facility failed to develop and implement policies and procedures which address steps the pharmacist must take when he or she identifies an irregularity that requires urgent action to protect the resident.

## PROCEDURE

Use the Unnecessary Medications, Psychotropic Medications, and Medication Regimen Review Critical Element Pathway, as appropriate, along with the above interpretive guidelines when determining if the facility meets the requirements for, or investigating concerns related to Medication Regimen Review.

## DEFICIENCY CATEGORIZATION

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

**Examples of noncompliance that demonstrate severity at Level 4 include, but are not limited to**:

- Despite identifying irregularities with the potential for serious harm or death in a resident's medication regimen, the pharmacist did not report the irregularities to the attending physician, DON, and medical director or action was not taken on the irregularities reported.
- On the MRR, the pharmacist identified that a resident was prescribed an antipsychotic medication without a clinical indication. This placed the resident at likely risk for harm such as experiencing a fall, mental status changes, or sustained negative psychosocial outcomes. The medical record did not show evidence that the attending physician had reviewed and responded to the identified irregularity.

**Examples of Level 3, Actual harm (physical or psychosocial) that are not immediate jeopardy, include, but are not limited to:**

- The pharmacist's MRR failed to identify the indication for continued use for opioid analgesics that had been prescribed for a resident's acute pain which had resolved. As a result of prolonged duration of use, the resident continued to be or became more lethargic and/or withdrawn.
- The pharmacist's MRR identified that the staff were crushing medications that should not be crushed. As a result of facility failure to act upon the notification, the resident experienced clinically significant adverse consequences such as hypoglycemia or hypotension that required medical intervention.
- The attending physician failed to act in response to the pharmacist's MRR which identified the indefinite continuation of an antidepressant in a resident who had no history of depression, who had been placed on the antidepressant without an evaluation to confirm presence of depression, and whose function and mood were not monitored while getting the medication for months. The resident experienced clinically significant adverse consequences such as falls without serious injury, constipation, or change in weight.

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

- The facility failed to respond to the pharmacist's notification that the resident was not receiving an over-the-counter (OTC) dietary supplement that had been prescribed. Currently, there was no change in the resident's condition, such as a weight loss.

- The pharmacist's MRR failed to evaluate and report on the potential adverse consequences of a medication that may increase the possible side effects of another clinically appropriate medication that had been prescribed. The resident had not yet experienced side effects from the combined medications.

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

**Severity Level 1 does not apply for this regulatory requirement because the failure to perform the MRR according to the regulatory provisions creates the potential for more than minimal harm.**

**POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION**

Examples of some of the related requirements that should be considered when concerns have been identified include the following:

- 42 CFR §483.10(g)(14), F580, Notification of Changes
  - Review whether a member of the IDT contacted the attending physician regarding a significant change in the resident's condition in relation to a potential adverse consequence of a medication, or a need to alter treatment significantly (i.e., a need to discontinue an existing form of treatment due to adverse consequences, or to commence a different form of treatment).
- 42 CFR §483.45(d), F757, Unnecessary Drugs and 42 CFR §483.45(e), F758, Psychotropic Medications
  - Review whether the resident is receiving any medications without an indication for use, in excessive dose or duration, with inadequate monitoring, or in the presence of any adverse consequences that indicate that the dose should be reduced or discontinued.
- 42 CFR §483.30(a), F710, Physician Supervision
  - Review whether the attending physician supervised the resident's medical treatment, including assessing the resident's condition, identifying the need for and continuing use of medication to address the resident's needs, and identifying and addressing adverse consequences related to medications.
- 42 CFR §483.30(b), F711 Physician Visits and 42 CFR §483.30(c), F712, Frequency of Physician Visits
  - Review whether the attending physician or another designated practitioner reviewed the resident's total program of care including the beneficial and adverse effects of medications and treatment, and provided a relevant progress note at each visit.
- 42 CFR §483.45(a), (b)(1)-(3), F755, Pharmacy Services
  - Review whether the licensed pharmacist has provided consultation regarding all aspects of pharmaceutical services.

- 42 CFR §483.70(*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.

## F758

*(Rev. 225; Issued: 08-08-24; Effective: 08-08-24; Implementation: 08-08-24)*

**§483.45(c)(3) A psychotropic drug is any drug that affects brain activities associated with mental processes and behavior. These drugs include, but are not limited to, drugs in the following categories:**

**(i) Anti-psychotic;**
**(ii) Anti-depressant;**
**(iii) Anti-anxiety; and**
**(iv) Hypnotic.**

**§483.45(e) Psychotropic Drugs. Based on a comprehensive assessment of a resident, the facility must ensure that--**

**§483.45(e)(1) Residents who have not used psychotropic drugs are not given these drugs unless the medication is necessary to treat a specific condition as diagnosed and documented in the clinical record;**

**§483.45(e)(2) Residents who use psychotropic drugs receive gradual dose reductions, and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs;**

**§483.45(e)(3) Residents do not receive psychotropic drugs pursuant to a PRN order unless that medication is necessary to treat a diagnosed specific condition that is documented in the clinical record; and**

**§483.45(e)(4) PRN orders for psychotropic drugs are limited to 14 days. Except as provided in §483.45(e)(5), if the attending physician or prescribing practitioner believes that it is appropriate for the PRN order to be extended beyond 14 days, he or she should document their rationale in the resident's medical record and indicate the duration for the PRN order.**

**§483.45(e)(5) PRN orders for anti-psychotic drugs are limited to 14 days and cannot be renewed unless the attending physician or prescribing practitioner evaluates the resident for the appropriateness of that medication.**

**INTENT: (F757) §483.45(d) Unnecessary drugs and (F758) §483.45(c)(3) and (e)Psychotropic Drugs**

The intent of these requirements is that:

- each resident's entire drug/medication regimen is managed and monitored to promote or maintain the resident's highest practicable mental, physical, and psychosocial well-being;
- the facility implements gradual dose reductions (GDR) and non-pharmacological interventions, unless contraindicated, prior to initiating or instead of continuing psychotropic medication; and
- PRN orders for psychotropic medications are only used when the medication is necessary and PRN use is limited.

**NOTE: For concerns related to unnecessary medications, excluding psychotropic medications, surveyors should assess compliance with §483.45(d), F757.**

**For concerns related to psychotropic medications only, including the unnecessary medication requirements, surveyors should assess compliance with §§483.45(c) and (e), F758.**

**The Guidance for these two tags is combined to avoid unnecessary duplication.**

Although the regulatory language refers to "drugs," the guidance in this document generally will refer to "medications," except in those situations where the term "drug" has become part of an established pharmaceutical term (e.g., adverse drug event, and adverse drug reaction or consequence).

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

The surveyor's review of medication use is not intended to constitute the practice of medicine. However, surveyors are expected to investigate the basis for decisions and interventions affecting residents.

**DEFINITIONS (F757) §483.45 (d) Unnecessary Drugs and (F758) §483.45(c)(3) and (e) Psychotropic Drugs**

Definitions are provided to clarify terminology related to medications and to the evaluation and treatment of residents.

**"Adverse consequence"** is a broad term referring to unwanted, uncomfortable, or dangerous effects that a drug may have, such as impairment or decline in an individual's mental or physical condition or functional or psychosocial status. It may include various types of adverse drug reactions and interactions (e.g., medication-medication, medication-food, and medication-disease) (adapted from The Merck Manual Professional Version, http://www.merckmanuals.com/professional/clinical-pharmacology/adverse-drug-reactions/adverse-drug-reactions.)

**NOTE:** Adverse drug reaction (ADR) is a form of adverse consequences. It may be either a secondary effect of a medication that is usually undesirable and different from the therapeutic effect of the medication or any response to a medication that is noxious and unintended and occurs in doses for prophylaxis, diagnosis, or treatment. The term "side effect" is often used interchangeably with ADR; however, side effects are but one of five ADR categories, the others being hypersensitivity, idiosyncratic response, toxic reactions, and adverse medication interactions. A side effect is an expected, well-known reaction that occurs with a predictable frequency and may or may not constitute an adverse consequence.

**"Anticholinergic side effect"** is an effect of a medication that opposes or inhibits the activity of the parasympathetic (cholinergic) nervous system to the point of causing symptoms such as dry mouth, blurred vision, tachycardia, urinary retention, constipation, confusion, delirium, hallucinations, flushing, and increased blood pressure. Types of medications that may produce anticholinergic side effects include:

- Antihistamines, antidepressants, anti-psychotics, antiemetics, muscle relaxants; and
- Certain medications used to treat cardiovascular conditions, Parkinson's disease, urinary incontinence, gastrointestinal issues and vertigo.

**"Behavioral interventions"** are individualized, non-pharmacological approaches to care that are provided as part of a supportive physical and psychosocial environment, directed toward understanding, preventing, relieving, and/or accommodating a resident's distress or loss of abilities, as well as maintaining or improving a resident's mental, physical or psychosocial well-being.

**"Clinically significant"** refers to effects, results, or consequences that materially affect or are likely to affect an individual's mental, physical, or psychosocial well-being either positively by preventing, stabilizing, or improving a condition or reducing a risk, or negatively by exacerbating, causing, or contributing to a symptom, illness, or decline in status.

**"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.

**"Duplicate therapy"** refers to multiple medications of the same pharmacological class/category or any medication therapy that substantially duplicates a particular effect of another medication that the individual is taking.

**"Excessive dose"** means the total amount of any medication (including duplicate therapy) given at one time or over a period of time that is greater than the amount

recommended by the manufacturer's label, package insert, and accepted standards of practice for a resident's age and condition.

**"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)"** are neurological side effects that can occur at any time from the first few days of treatment with antipsychotic medication to years later. EPS includes various syndromes such as:

- Akathisia, which refers to a distressing feeling of internal restlessness that may appear as constant motion, the inability to sit still, fidgeting, pacing, or rocking.
- Medication-induced Parkinsonism, which refers to a syndrome of Parkinson-like symptoms including tremors, shuffling gait, slowness of movement, expressionless face, drooling, postural unsteadiness and rigidity of muscles in the limbs, neck and trunk.
- Dystonia, which refers to an acute, painful, spastic contraction of muscle groups (commonly the neck, eyes and trunk) that often occurs soon after initiating treatment and is more common in younger individuals.

**"Gradual Dose Reduction (GDR)"** is the stepwise tapering of a dose to determine if symptoms, conditions, or risks can be managed by a lower dose or if the dose or medication can be discontinued.

**"Indications for use"** is the identified, documented clinical rationale for administering a medication that is based upon an assessment of the resident's condition and therapeutic goals and is consistent with manufacturer's recommendations and/or clinical practice guidelines, clinical standards of practice, medication references, clinical studies or evidence-based review articles that are published in medical and/or pharmacy journals.

**"Neuroleptic Malignant Syndrome (NMS)"** is a syndrome related to the use of medications, mainly antipsychotics, that typically presents with a sudden onset of diffuse muscle rigidity, high fever, labile blood pressure, tremor, and notable cognitive dysfunction. It is potentially fatal if not treated immediately, including stopping the offending medications.

**"Psychotropic drug"** is defined in the regulations at §483.45(c)(3), as "any drug that affects brain activities associated with mental processes and behavior." Psychotropic drugs include, but are not limited to the following categories: anti-psychotics, anti-depressants, anti-anxiety, and hypnotics.

**"Serotonin Syndrome"** is a potentially serious clinical condition resulting from overstimulation of serotonin receptors. It is commonly related to the use of multiple

serotonin-stimulating medications (e.g., SSRIs, SNRIs, triptans, certain antibiotics). Symptoms may include restlessness, hallucinations, confusion, loss of coordination, fast heartbeat, rapid changes in blood pressure, increased body temperature, overactive reflexes, nausea, vomiting and diarrhea.

**"Tardive dyskinesia"** refers to abnormal, recurrent, involuntary movements that may be irreversible and typically present as lateral movements of the tongue or jaw, tongue thrusting, chewing, frequent blinking, brow arching, grimacing, and lip smacking, although the trunk or other parts of the body may also be affected.

**GUIDANCE (F757) §483.45(d) Unnecessary Drugs and (F758) §483.45(c)(3) and (e) 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.

Proper medication selection and prescribing (including dose, duration, and type of medication(s)) may help stabilize or improve a resident's outcome, quality of life and functional capacity. Any medication or combination of medications—or the use of a medication without adequate indications, in excessive dose, for an excessive duration, or without adequate monitoring—may increase the risk of a broad range of adverse consequences such as medication interactions, depression, confusion, immobility, falls, hip fractures, and death. The Beers Criteria for Potentially Inappropriate Medication Use in Older Adults provides information on safely prescribing medications for older adults, http://www.healthinaging.org/medications-older-adults/.

**NOTE:** References to non-CMS sources do not constitute or imply endorsement of these organizations or their programs by CMS or the U.S. Department of Health and Human Services and were current as of the date of this publication.

Intrinsic factors including physiological changes accompanying the aging process, multiple comorbidities, and certain medical conditions may affect the absorption, distribution, metabolism or elimination of medications from the body and may also increase an individual's risk of adverse consequences.

While assuring that only those medications required to treat the resident's assessed condition are being used, reducing the need for and maximizing the effectiveness of medications are important considerations for all residents. Therefore, as part of all medication management (especially psychotropic medications), it is important for the IDT to implement non-pharmacological approaches designed to meet the individual needs of each resident. Educating facility staff and providers about the importance of implementing individualized, non-pharmacological approaches to care prior to the use of medications may minimize the need for medications or reduce the dose and duration of those medications. Additional information as well as examples of non-pharmacological

interventions may be found in other guidance for regulations at (F741) §483.40, Behavioral Health Services and (F679) §483.24, Quality of Life.

The indications for initiating, withdrawing, or withholding medication(s), as well as the use of non-pharmacological approaches, are determined by assessing the resident's underlying condition, current signs, symptoms, and expressions, and preferences and goals for treatment. This includes, where possible, the identification of the underlying cause(s), since a diagnosis alone may not warrant treatment with medication. Orders from multiple prescribers or providers can increase the resident's chances of receiving unnecessary medications.

Staff and practitioner access to current medication references and pertinent clinical protocols helps to promote safe administration and monitoring of medications. One of the existing mechanisms to warn prescribers about risks associated with medications is the Food and Drug Administration (FDA) requirement that manufacturers include within the medication labeling warnings about adverse reactions and potential safety hazards identified both before and after approval of a medication, and what to do if they occur (Visit: 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 update labels to warn about newly identified safety hazards—regardless of whether causation has been proven and whether the medication is prescribed for a disease or condition that is not included in the "Indications and Usage" section of the labeling (so-called "off-label" or unapproved use). Federal regulations at 21 CFR 201.57 (a)(4) and (c)(1) also require manufacturers to place statements about serious problems or contraindications in a prominently displayed box that appears on the medication labelling and in greater detail in the full prescribing information that accompanies the medication. The boxed warning is reserved for prescription drugs that pose a significant risk of serious or life-threatening adverse effects, based on medical studies.

The facility's pharmacist is a valuable source of information about medications. Listings or descriptions of most significant risks, recommended doses, medication interactions, cautions, etc. can be found in widely available, standard references, and computer software and systems that provide up-to-date information. It is important to note that some of the medication information found in many of these references is not specific to older adults or individuals residing in nursing homes. A list of resources and tools is provided at the end of this guidance.

**MEDICATION MANAGEMENT**

Medication management is based in the care process and includes recognition or identification of the problem/need, assessment, diagnosis/cause identification, management/treatment, monitoring, and revising interventions, as warranted as well as documenting medication management steps. The attending physician plays a key leadership role in medication management by developing, monitoring, and modifying the

medication regimen in conjunction with residents, their families, and/or representative(s) and other professionals and direct care staff (the IDT).

When selecting medications and non-pharmacological approaches, members of the IDT, including the resident, his or her family, and/or representative(s), participate in the care process to identify, assess, address, advocate for, monitor, and communicate the resident's needs and changes in condition. This guidance is intended to help the surveyor determine whether the facility's medication management supports and promotes:

- Involvement of the resident, his or her family, and/or the resident representative in the medication management process.
- Selection of medications(s) based on assessing relative benefits and risks to the individual resident;
- Evaluation of a resident's physical, behavioral, mental, and psychosocial signs and symptoms, in order to identify the underlying cause(s), including adverse consequences of medications;
- Selection and use of medications in doses and for the duration appropriate to each resident's clinical conditions, age, and underlying causes of symptoms and based on assessing relative benefit and risks to, and preferences and goals of, the individual resident;
- The use of non-pharmacological approaches, unless contraindicated, to minimize the need for medications, permit use of the lowest possible dose, or allow medications to be discontinued; and
- The monitoring of medications for efficacy and adverse consequences.
- Resident Choice –If a resident declines treatment, the facility staff and physician should inform the resident about the risks related to the lack of the medication, and discuss appropriate alternatives such as offering the medication at another time or in another dosage form, or offer an alternative medication or non-pharmacological approach.
- Advance Directives – A resident's advance directives may include withdrawing or withholding medications. Whether or not a resident has an advance directive, the facility is responsible for giving treatment, support, and other care that is consistent with the resident's condition and applicable care instructions, according to the resident's care plan. If there are concerns regarding Resident Choice or Advance Directives, consider investigating the requirements at §483.10, Resident Rights and §483.21, Care Planning.

The resident's medical record documents and communicates to the entire team the basic elements of the care process and the resident's goals and preferences. Information about aspects of the care process related to medications may be found in various locations within the record, such as: hospital discharge summaries and transfer notes, progress notes and interdisciplinary notes, history and physical examination, Resident Assessment Instrument (RAI), plan of care, laboratory reports, professional consults, medication orders, Medication Regimen Review (MRR) reports, and Medication Administration Records (MAR).

The regulations associated with medication management include consideration of:

- Indication and clinical need for medication;
- Dose (including duplicate therapy);
- Duration;
- Adequate monitoring for efficacy and adverse consequences; and
- Preventing, identifying, and responding to adverse consequences.

With regard to psychotropic medications, the regulations additionally require:

- Giving psychotropic medications only when necessary to treat a specific diagnosed and documented condition;
- Implementing GDR and other non-pharmacologic interventions for residents who receive psychotropic medications, unless contraindicated; and
- Limiting the timeframe for PRN psychotropic medications, which **are not** antipsychotic medications, to 14 days, unless a longer timeframe is deemed appropriate by the attending physician or the prescribing practitioner.
- Limiting PRN psychotropic medications, which **are** antipsychotic medications, to 14 days and not entering a new order without first evaluating the resident.

**NOTE:** While there may be isolated situations where a pharmacological intervention is required first, these situations do not negate the obligation of the facility to develop and implement non-pharmacological interventions. For additional information related to situations where a non-pharmacological intervention may be contraindicated, refer to §483.40(a)(2), Implementing non-pharmacological interventions.

**Indication for Use**

The resident's medical record must show documentation of adequate indications for a medication's use and the diagnosed condition for which a medication is prescribed. An evaluation of the resident by the IDT helps to identify his/her needs, goals, comorbid conditions, and prognosis to determine factors (including medications and new or worsening medical conditions) that are affecting signs, symptoms, and test results. This evaluation process is important when selecting initial medications and/or non-pharmacological approaches and when deciding whether to modify or discontinue a current medication. The evaluation also clarifies:

- Whether other causes for the symptoms (including expressions or indications of distress that could mimic a psychiatric disorder) have been ruled out;
- Whether the physical, mental, behavioral, and/or psychosocial signs, symptoms, or related causes are persistent or clinically significant enough (e.g., causing functional decline) to warrant the initiation or continuation of medication therapy;
- Whether non-pharmacological approaches are implemented, unless clinically contraindicated for the resident or declined by the resident;
- Whether a particular medication is clinically indicated to manage the symptom or condition; and

- Whether the intended or actual benefit is understood by the resident and, if appropriate, his/her family and/or representative(s) and is sufficient to justify the potential risk(s) or adverse consequences associated with the selected medication, dose, and duration.

The content and extent of the evaluation may vary with the situation and may employ various assessment instruments and diagnostic tools. Examples of information to be considered and evaluated may include, but are not limited to, the following:

- An appropriately detailed evaluation of mental, physical, psychosocial, and functional status, including comorbid conditions and pertinent psychiatric symptoms and diagnoses and a description of resident complaints, symptoms, and signs (including the onset, scope, frequency, intensity, precipitating factors, and other important features);
- Each resident's goals and preferences;
- Allergies to medications and foods and potential for medication interactions;
- A history of prior and current medications and non-pharmacological interventions (including therapeutic effectiveness and any adverse consequences);
- Recognition of the need for end-of-life or palliative care; and
- The basis for declining care, medication, and treatment and the identification of pertinent alternatives.
- Documentation of indications of distress, delirium, or other changes in functional status.

Circumstances that warrant evaluation of the resident and medication(s) include:

- Admission or re-admission;
- A clinically significant change in condition/status;
- A new, persistent, or recurrent clinically significant symptom or problem;
- A worsening of an existing problem or condition;
- An unexplained decline in function or cognition;
- A new medication order or renewal of orders; and
- An irregularity identified in the pharmacist's medication regimen review. See F756 for guidance related to the medication regimen review.
- Orders for PRN psychotropic and/or antipsychotic medications which are not prescribed to treat a diagnosed specific condition or do not meet the PRN requirements for psychotropic and antipsychotic medications.

Specific considerations related to these circumstances may include the following:

- Admission (or Readmission) – Some residents may be admitted on medications for an undocumented chronic condition or without a clear indication as to why a medication was begun or should be continued. It is expected that the attending physician, pharmacist, and staff subsequently determine if continuing the

medication is justified by evaluating the resident's clinical condition, risks, existing medication regimen, preferences, goals, and related factors.

- Multiple prescribers – Regardless of who the prescribers are, the continuation of a medication needs to be evaluated to determine if the medication is still warranted in the context of the resident's other medications and comorbidities. Medications prescribed by a specialist or begun in another care setting, such as the hospital, need to have a clinically pertinent documented rationale in the resident's medical record.
- New medication order as an emergency measure – When a resident is experiencing an acute medical problem or psychiatric emergency (e.g., the resident's expression or action poses an immediate risk to the resident or others), medications may be required. In these situations, it is important to identify and address the underlying causes of the problem or symptoms. Once the acute phase has stabilized, the staff and prescriber consider whether medications are still relevant. Subsequently, the medication is reduced or discontinued as soon as possible or the clinical rationale for continuing the medication is documented. If the new medication is a psychotropic or antipsychotic medication ordered on a PRN basis, the PRN order(s) must be consistent with the requirements for PRN use of psychotropic and antipsychotic medications at §483.45(e)(3), (4), and (5). When psychopharmacological medications are used as an emergency measure, adjunctive approaches, such as individualized, non-pharmacological approaches and techniques must be implemented. Longer term management options should be discussed with the resident, their family, and/or representative(s).
- Psychiatric disorders or expressions and/or indications of distress – As with all symptoms, it is important to seek the underlying cause of the distress. Some examples of potential causes include delirium, pain, psychiatric or neurological illness, environmental or psychological stressors, dementia, or substance intoxication or withdrawal. Non-pharmacologic approaches, unless clinically contraindicated, must be implemented to address expressions or indications of distress. However, medications may be effective when the underlying cause of a resident's distress has been determined, non-pharmacologic approaches to care have been ineffective, or expressions of distress have worsened. Medications may be unnecessary and are likely to cause harm when given without a clinical indication, at too high of a dose, for too long after the resident's distress has been resolved, or if the medications are not monitored. All approaches to care, including medications, need to be monitored for efficacy, risks, benefits, and harm and revised as necessary.

**NOTE**: Permission given by or a request made by the resident and/or representative does not serve as a sole justification for the medication itself.

**Dose**

Medications are prescribed based on a variety of factors including the resident's diagnoses, signs and symptoms, current condition, age, coexisting medication regimen, review of lab and other test results, input from the IDT about the resident, including the

resident's preferences and goals, the type of medication(s), and therapeutic goals being considered or used.

The route of administration influences a medication's absorption and ultimately the dose received. Examples of factors that can affect the absorption of medications delivered by transdermal patches include skin temperature and moisture, and the integrity of the patch. Similarly, the flow rate of intravenous solutions affects the amount received at a given time.

Duplicate therapy is generally not indicated, unless current clinical standards of practice and documented clinical rationale confirm the benefits of multiple medications from the same class or with similar therapeutic effects. Some examples of potentially problematic duplicate therapy include use of more than one product containing the same medication, concomitant use of drugs within the same class, or medications from different therapeutic categories with similar effects or properties. Additionally, the risk for duplication is particularly high during transitions of care, especially if medications are not tracked closely between locations or within the care settings. Documentation is necessary to clarify the rationale for and benefits of duplicate therapy and the approach to monitoring for benefits and adverse consequences.

**Duration**

Periodic re-evaluation of the medication regimen is necessary to determine whether prolonged or indefinite use of a medication is indicated. The clinical rationale for continued use of a medication(s) may have been demonstrated in the clinical record, or the staff and prescriber may present pertinent clinical reasons for the duration of use. Regarding PRN medications, it is important that the medical record include documentation related to the attending physician's or other prescriber's evaluation of the resident and of indication(s), specific circumstance(s) for use, and the desired frequency of administration for each medication. As part of the evaluation, gathering and analyzing information helps define clinical indications and provide baseline data for subsequent monitoring. Common considerations for appropriate duration may include:

- A medication initiated as a result of a time-limited condition (for example, delirium, pain, infection, nausea and vomiting, cold and cough symptoms, or itching) is then discontinued when the condition has resolved, or there is documentation indicating why continued use is still relevant. Failure to review whether the underlying cause has resolved may lead to excessive duration.
- A medication administered beyond the stop date established by the prescriber, without evidence of clinical justification for continued use of the medication, may be considered excessive duration.

- A medication, which is prescribed on a PRN basis, is requested by the resident and/ or/administered by staff on a regular basis, indicating a more regular schedule or other change in medication regimen may be needed.

**Monitoring for Efficacy and Adverse Consequences**

The information gathered during the initial and ongoing evaluations and through conversations with the resident and, as appropriate, his or her family or representative is essential to:

- Verify or differentiate the underlying diagnoses or other underlying causes of signs and symptoms.
- Incorporate into a comprehensive care plan that reflects person-centered medication related goals and parameters for monitoring the resident's condition, including the likely medication effects and potential for adverse consequences. Examples of this information may include the FDA boxed warnings or warnings of adverse consequences that may be rare, but have sudden onset, or that may be irreversible. If the facility has established protocols for monitoring specific medications and the protocols are accessible for staff use, the care plan may refer staff to these protocols;
- Optimize the therapeutic benefit of medication therapy and minimize or prevent potential adverse consequences;
- Establish parameters for evaluating the ongoing need for the medication; and
- Track progress and/or decline towards the therapeutic goal.

Sources of information to facilitate defining the monitoring criteria or parameters may include cautions, warnings, and identified adverse consequences from:

- Manufacturers' package inserts and boxed warnings;
- Facility policies and procedures;
- Pharmacists;
- Clinical practice guidelines or clinical standards of practice;
- Medication references; and
- Clinical studies or evidence-based review articles that are published in medical and/or pharmacy journals.

Monitoring and accurate documentation of the resident's response to any medication(s) is essential to evaluate the ongoing benefits as well as risks of various medications. Monitoring should also include evaluation of the effectiveness of non-pharmacological approaches, such as prior to administering PRN medications.

Monitoring involves several steps, including:

- Identifying the essential information and how it will be obtained and reported-- It is important to consider who is responsible for obtaining the information, which information should be collected, and how the information will be documented. The information that is collected depends on therapeutic goals, detection of potential or actual adverse consequences, and consideration of risk factors, such as:

- Medication-medication, medication-food interactions;
- Clinical condition (for example renal disease);
- Properties of the medication;
- Boxed warnings; and
- Resident's history of adverse consequences related to a similar medication.

- Determining the frequency of monitoring-- The frequency and duration of monitoring needed to identify therapeutic effectiveness, achievement of resident goals, and adverse consequences will depend on factors such as clinical standards of practice, facility policies and procedures, manufacturer's specifications, and the resident's clinical condition and choices. Monitoring involves three aspects:
  - Periodic planned evaluation of progress toward the therapeutic goals;
  - Continued vigilance for adverse consequences; and
  - Evaluation of identified adverse consequences.
- Defining the methods for communicating, analyzing, and acting upon relevant information-- The monitoring process needs to identify who is to communicate with the prescriber, what information is to be conveyed, and when to ask the prescriber to evaluate and consider modifying the medication regimen.
- If the therapeutic goals are not being met or the resident is experiencing adverse consequences, it is essential for the prescriber in collaboration with facility staff, the pharmacist, and the resident to consider whether current medications and doses continue to be appropriate or should be reduced, changed, or discontinued. Serum concentration monitoring may be necessary for some medications. Abnormal or toxic serum concentrations must be evaluated for dosage adjustments. If serum concentrations are within normal ranges, each resident should still be evaluated for effectiveness and side effects.
- Re-evaluating and updating monitoring approaches-- Modification of monitoring may be necessary when the resident experiences changes, such as:

  - Acute onset of signs or symptoms or worsening of chronic disease;
  - Addition or discontinuation of medications and/or non-pharmacological approaches, for example, a resident who takes warfarin regularly starts on a medication that interacts with warfarin, therefore more frequent blood work may be needed;
  - Addition or discontinuation of care and services such as enteral feedings; and
  - Significant changes in diet that may affect medication absorption or effectiveness or increase adverse consequences.

Additional examples of circumstances that may indicate a need to modify the monitoring include: changes in manufacturer's specifications, FDA warnings, pertinent clinical practice guidelines, or other literature about how and what to monitor.

Adverse consequences related to medications are common enough to warrant serious attention and close monitoring. An HHS Office of the Inspector General (OIG) report released in February 2014 found approximately one in five SNF residents

experienced at least one adverse event during their SNF stay. Thirty-seven percent of these events were related to medications and were often preventable. See the full report, "Adverse Events in Skilled Nursing Facilities: National Incidence among Medicare Beneficiaries" at http://oig.hhs.gov/oei/reports/oei-06-11-00370.pdf.

Some adverse consequences may be avoided by:

- Following relevant clinical guidelines and manufacturer's specifications for use, dose, administration, duration, and monitoring of the medication;
- Defining appropriate indications for use;
- Determining that the resident:
  - Has no known allergies to the medication;
  - Is not taking other medications, nutritional supplements including herbal products, or foods that would be incompatible with the prescribed medication; and
  - Has no condition, history, or sensitivities that would preclude use of that medication.
- Responding to the resident's reported experience with medications and treatments they have received.

The risk for adverse consequences increases with both the number of medications being taken regularly and with medications from specific pharmacological classes, such as anticoagulants, diuretics, psychotropic medications, anti-infectives, and anticonvulsants.[1] Adverse consequences can range from minimal harm to functional decline, hospitalization, permanent injury, and death. Use of a tool, such as the CMS Adverse Drug Event Trigger Tool, may assist in identifying resident risk factors and triggers for adverse drug events as well as in determining whether a facility has systems and processes in place to minimize risk factors and mitigate harm to residents. The tool is available on the CMS Nursing Home Quality Assurance and Performance Improvement website, https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/QAPI/Downloads/Adverse-Drug-Event-Trigger-Tool.pdf. 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.

One common adverse consequence is delirium, which presents as an alteration in attention and awareness associated with a change in cognition not explained by a current or emerging neurocognitive disorder. Delirium may result from medications as well as other factors including electrolyte imbalances or infections. While delirium is not always preventable, identifying and addressing risk factors may reduce the occurrence. In many facilities, a majority of the residents have dementia. Individuals who have dementia may be more sensitive to medication effects and may be at greater risk for delirium.[2]

Delirium may go undiagnosed, be misinterpreted as dementia, or misdiagnosed as a psychiatric disorder, such as bipolar disorder. Delirium develops rapidly over a short period of time, such as hours or days, and usually follows a fluctuating course throughout

the day. Additionally, the resident may have difficulty paying attention and be less aware of his or her surroundings. Delirium can be characterized as hyperactive (e.g., extreme restlessness, climbing out of bed), hypoactive (e.g., sluggish and lethargic), or mixed (e.g., normal level of activity with lowered awareness). Delirium is particularly common post-hospitalization; signs and symptoms may be subtle and therefore are often missed. Although generally thought to be short lived, delirium can persist for months. Recognizing delirium is critical, as failure to act quickly to identify and treat the underlying causes may result in poor health outcomes or death.

Negative psychosocial outcomes can also occur in relation to unnecessary medications, including psychotropic medications. These adverse consequences may include: suicidal ideation, recurrent debilitating anxiety, extreme aggression or agitation, significant decline in former social patterns, social withdrawal, psychomotor agitation or retardation, inability to think or concentrate, and apathy.

**Psychotropic Medications and Antipsychotic Medications (F758 Only Guidance)**

In accordance with §483.45(d)(4) and as clarified in the section above on Indication for Use, residents must not receive any medications which are not clinically indicated to treat a specific condition. The medical record must show documentation of the diagnosed condition for which a psychotropic medication is prescribed (§483.45(e)(1)). All medications included in the psychotropic medication definition may affect brain activities associated with mental processes and behavior. Use of psychotropic medications, other than antipsychotics, should not increase when efforts to decrease antipsychotic medications are being implemented. Risks associated with psychotropic medications still exist regardless of the indication for their use (e.g., nausea, insomnia, itching), therefore the requirements pertaining to psychotropic medications 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 as anti-psychotic, anti-depressant, anti-anxiety, or hypnotic medications 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, pseuodobulbar 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 and the medical record shows no history of seizures but there is documentation that the medication is being used to treat agitation or other expressions of distress, then the use of valproic acid should be consistent with the psychotropic medication requirements under §483.45(e). Residents who take

these medications must be monitored for any adverse consequences, specifically increased confusion or over-sedation, as required by §483.45(d)(3). Concerns related to the use of the medications noted here would be investigated at F757, Unnecessary Medications, if the medication is being used for its original or approved indication and not primarily as a psychotropic medication.

The regulations and guidance concerning psychotropic medications are not intended to supplant the judgment of a physician or prescribing practitioner in consultation with facility staff, the resident and his/her representatives and in accordance with appropriate standards of practice. Rather, the regulations and guidance are intended to ensure psychotropic medications are used only when the medication(s) is appropriate to treat a resident's specific, diagnosed, and documented condition and the medication(s) is beneficial to the resident, as demonstrated by monitoring and documentation of the resident's response to the medication(s). Concerns related to inappropriate prescribing of psychotropic medications may require referrals by the facility and/or the survey team to State Medical Boards or Boards of Nursing.

**Note:** CMS is aware of situations where practitioners have potentially misdiagnosed residents with a condition for which antipsychotics are an approved use (e.g., new diagnosis of schizophrenia) which would then exclude the resident from the long-stay antipsychotic quality measure.

For these situations, please refer to the following regulations:

- §483.21(b)(3)(i), F658, to determine if the **practitioner's diagnostic practices** meet professional standards.
- §483.20(g), F641 to determine if the **facility completed an assessment** which accurately reflects the resident's status.

**Use of Psychotropic Medications in Specific CircumstancesAcute or Emergency Situations**:

When a psychotropic medication is being initiated or used to treat an emergency situation (i.e., acute onset or exacerbation of symptoms or immediate threat to health or safety of resident or others) related to a documented condition or diagnosis, a clinician in conjunction with the IDT must evaluate and document the situation to identify and address any contributing and underlying causes of the acute condition and verify the need for a psychotropic medication. Use of psychotropic medication to treat an emergency situation must be consistent with the requirements regarding PRN orders for psychotropic and antipsychotic medications and any continued use must be consistent with the requirements for gradual dose reduction (GDR).

**Enduring Conditions**: Psychotropic medications may be used to treat an enduring (i.e., non-acute; chronic or prolonged) condition. Before initiating or increasing a psychotropic medication for enduring conditions, the resident's symptoms and therapeutic goals must

be clearly and specifically identified and documented. Additionally, the facility should ensure that the resident's expressions or indications of distress are:

- Not due to a medical condition or problem (e.g., pain, fluid or electrolyte imbalance, infection, obstipation, medication side effect or poly-pharmacy) that can be expected to improve or resolve as the underlying condition is treated or the offending medication(s) are discontinued;
- Not due to environmental stressors alone (e.g., alteration in the resident's customary location or daily routine, unfamiliar care provider, hunger or thirst, excessive noise for that individual, inadequate or inappropriate staff response), that can be addressed to improve the symptoms or maintain safety;
- Not due to psychological stressors alone (e.g., loneliness, taunting, abuse), anxiety or fear stemming from misunderstanding related to his or her cognitive impairment (e.g., the mistaken belief that this is not where he/she lives or inability to find his or her clothes or glasses, unaddressed sensory deficits) that can be expected to improve or resolve as the situation is addressed; and
- Persistent--The medical record must contain clear documentation that the resident's distress persists and his or her quality of life is negatively affected and, unless contraindicated, that multiple, non-pharmacological approaches have been attempted and evaluated in any attempts to discontinue the psychotropic medication.

**New Admissions:** Many residents are admitted to a SNF/NF already on a psychotropic medication. The medication may have been started in the hospital or the community, which can make it challenging for the IDT to identify the indication for use. However, the attending physician in collaboration with the consultant pharmacist must re-evaluate the use of the psychotropic medication and consider whether or not the medication can be reduced or discontinued upon admission or soon after admission. Additionally, the facility is responsible for:

- Preadmission screening for mental illness and intellectual disabilities, see §483.20(k), F645 and F646; and
- Obtaining physician's orders for the resident's immediate care, see §483.20(a), F635.

**Monitoring of Psychotropic Medications:** When monitoring a resident receiving psychotropic medications, the facility must evaluate the effectiveness of the medications as well as look for potential adverse consequences. After initiating or increasing the dose of a psychotropic medication, the behavioral symptoms must be reevaluated periodically (e.g., at least during quarterly care plan review, if not more often) to determine the potential for reducing or discontinuing the dose based on therapeutic goals and any adverse effects or functional impairment.

If the record shows evidence of prescribing multiple psychotropic medications, or switching from one type of psychotropic medication to another category of psychotropic

medication, surveyors must review the medical record to determine whether the prescribing practitioner provided a rationale.

**Potential Adverse Consequences:** The facility assures that residents are being adequately monitored for adverse consequences such as:

- **General**: anticholinergic effects which may include flushing, blurred vision, dry mouth, altered mental status, difficulty urinating, falls, excessive sedation, constipation
- **Cardiovascular:** signs and symptoms of cardiac arrhythmias such as irregular heart beat or pulse, palpitations, lightheadedness, shortness of breath, diaphoresis, chest or arm pain, increased blood pressure, orthostatic hypotension
- **Metabolic:** increase in total cholesterol and triglycerides, unstable or poorly controlled blood sugar, weight gain
- **Neurologic:** agitation, distress, EPS, neuroleptic malignant syndrome (NMS), parkinsonism, tardive dyskinesia, cerebrovascular event (e.g., stroke, transient ischemic attack (TIA).

If psychotropic medication(s) are identified as possibly causing or contributing to adverse consequences as identified above, the facility and prescriber must determine whether the medication(s) should be continued and document the rationale for the decision. Use of multiple psychotropic medications can increase the risk of adverse consequences and/or confound the effects of individual medications although there may be infrequent times when use of multiple psychotropic medications is indicated, such as to treat multiple symptoms of a condition or to address side effects. Additionally, the medical record should show evidence that the resident, family member or representative is aware of and involved in the decision. In some cases, the benefits of treatment may outweigh the risks or burdens of treatment, so the medication(s) may be continued.

**Antipsychotic Medications**

As with all medications, the indication for any prescribed first generation (also referred to as typical or conventional antipsychotic medication) or second generation (also referred to as atypical antipsychotic medication) antipsychotic medication must be thoroughly documented in the medical record. While antipsychotic medication may be prescribed for expressions or indications of distress, the IDT must first identify and address any medical, physical, psychological causes, and/or social/environmental triggers. Any prescribed antipsychotic medication must be administered at the lowest possible dosage for the shortest period of time and is subject to the GDR requirements for psychotropic medications.

Antipsychotic medications (both first and second generation) have serious side effects and can be especially dangerous for elderly residents. When antipsychotic medications are used without an adequate rationale, or for the sole purpose of limiting or controlling expressions or indications of distress without first identifying the cause, there is little chance that they will be effective, and they commonly cause complications such as

movement disorders, falls with injury, cerebrovascular adverse events (cerebrovascular accidents (CVA, commonly referred to as stroke), and transient ischemic events) and increased risk of death. The FDA Boxed Warning which accompanies second generation anti-psychotics states, "Elderly patients with dementia-related psychosis treated with atypical anti-psychotic drugs are at an increased risk of death," https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm053171.htm. The FDA issued a similar Boxed Warning for first generation antipsychotic drugs, https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm124830.htm. .

Diagnoses alone do not necessarily warrant the use of an antipsychotic medication. Antipsychotic medications may be indicated if:

- behavioral symptoms present a danger to the resident or others;
- expressions or indications of distress that are significant distress to the resident;
- if not clinically contraindicated, multiple non-pharmacological approaches have been attempted, but did not relieve the symptoms which are presenting a danger or significant distress; and/or [3]
- GDR was attempted, but clinical symptoms returned.

If antipsychotic medications are prescribed, documentation must clearly show the indication for the antipsychotic medication, the multiple attempts to implement care-planned, non-pharmacological approaches, and ongoing evaluation of the effectiveness of these interventions.

**Gradual Dose Reduction for Psychotropic Medications**

The requirements underlying this guidance emphasize the importance of seeking an appropriate dose and duration for each medication and minimizing the risk of adverse consequences. The purpose of 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. Tapering may be indicated when the resident's clinical condition has improved or stabilized, the underlying causes of the original target symptoms have resolved, and/or non-pharmacological approaches have been effective in reducing the symptoms.

There are various opportunities during the care process to evaluate the effects of medications on a resident's physical, mental, and psychosocial well-being, and to consider whether the medications should be continued, reduced, discontinued, or otherwise modified. Examples of these opportunities include:

- During the monthly medication regimen review, the pharmacist evaluates resident-related information for dose, duration, continued need, and the emergence of adverse consequences for all medications;
- When evaluating the resident's progress, the attending physician or prescribing practitioner reviews the total plan of care, orders, the resident's response to

medication(s), and determines whether to continue, modify, or stop a medication; and

- During the quarterly MDS review, the facility evaluates mood, function, behavior, and other domains that may be affected by medications.

The time frames and duration of attempts to taper any medication must be consistent with accepted standards of practice and depend on factors including the coexisting medication regimen, the underlying causes of symptoms, individual risk factors, and pharmacologic characteristics of the medications. Some medications (e.g., antidepressants, sedative/hypnotics, opioids) require more gradual tapering so as to minimize or prevent withdrawal symptoms or other adverse consequences. Close monitoring while medications are tapered will enable facility staff to determine whether a resident is experiencing side effects, changes in behavior, or withdrawal symptoms that originally prompted prescribing of the drug. However, some residents with specific, enduring, progressive, or terminal conditions such chronic depression, Parkinson's disease psychosis, or recurrent seizures may need specific types of psychotropic medications or other medications which affect brain activity indefinitely.

**NOTE:** If the resident's condition has not responded to treatment or has declined despite treatment, it is important to evaluate both the medication and the dose to determine whether the medication should be discontinued or the dosing should be altered, whether or not the facility has implemented GDR as required, or tapering.

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).

For any individual who is receiving a psychotropic medication to treat expressions or indications of distress related to dementia, the GDR may be considered clinically contraindicated for reasons that include, but that are not limited to:

- The resident's target symptoms returned or worsened after the most recent attempt at a GDR within the facility; and
- The physician has documented the clinical rationale for why any additional attempted dose reduction at that time would be likely to impair the resident's function or increase distressed behavior.

For any individual who is receiving a psychotropic medication to treat a disorder other than expressions or indications of distress related to dementia (for example, schizophrenia, bipolar mania, depression with psychotic features, or another medical condition, other than dementia, which may cause psychosis), the GDR may be considered clinically contraindicated for reasons that include, but that are not limited to:

- The continued use is in accordance with relevant current standards of practice and the physician has documented the clinical rationale for why any attempted dose reduction would be likely to impair the resident's function or exacerbate an underlying medical or psychiatric disorder; or
- The resident's target symptoms returned or worsened after the most recent attempt at a GDR within the facility and the physician has documented the clinical rationale for why any additional attempted dose reduction at that time would be likely to impair the resident's function or exacerbate an underlying medical or psychiatric disorder.

**PRN Orders for Psychotropic and Antipsychotic Medications**

In certain situations, psychotropic medications may be prescribed on a PRN basis, such as while the dose is adjusted, to address acute or intermittent symptoms, or in an emergency. However, residents must not have PRN orders for psychotropic medications unless the medication is necessary to treat a diagnosed specific condition. The attending physician or prescribing practitioner must document the diagnosed specific condition and indication for the PRN medication in the medical record. (§483.45(e)(3))

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 practitioner believes it is appropriate to extend the order. | Attending physician or prescribing practitioner should document the rationale for the extended time period in the medical record and indicate a specific duration. |
| PRN orders for antipsychotic medications only | 14 days | None | If the attending physician or prescribing practitioner wishes to write a new order for the PRN antipsychotic, the |

| Type of PRN order | Time Limitation | Exception | Required Actions |
|---|---|---|---|
| | | | attending physician or prescribing practitioner must first evaluate the resident to determine if the new order for the PRN antipsychotic is appropriate. |

The required evaluation of a resident before writing a new PRN order for an antipsychotic entails the attending physician or prescribing practitioner directly examining the resident and assessing the resident's current condition and progress to determine if the PRN antipsychotic medication is still needed. As part of the evaluation, the attending physician or prescribing practitioner should, at a minimum, determine and document the following in the resident's medical record:

- Is the antipsychotic medication still needed on a PRN basis?
- What is the benefit of the medication to the resident?
- Have the resident's expressions or indications of distress improved as a result of the PRN medication?

**NOTE:** Report of the resident's condition from facility staff to the attending physician or prescribing practitioner does not constitute an evaluation.

**KEY ELEMENTS OF NONCOMPLIANCE**

**If any of the elements the sections below involve psychotropic medications, investigate F758. For all other medications, investigate F757.**

To cite deficient practice at F757and/or F758, the surveyor's investigation will generally show:

**Inadequate Indications for Use**

- Failure to document a clinical reason or a clinically pertinent rationale, for using medication(s) for a specific resident or for continuing medication(s) that may be causing an adverse consequence; or
- Prescribing or administering a medication despite an allergy to that medication, or without clarifying whether a true allergy existed; or
- Failure to consider relative risks and benefits or potentially lower risk medications before initiating medication(s) that present clinically significant risks; or
- Failure to provide a clinically pertinent explanation for concomitant use of two or more medications in the same pharmacological class; or
- Failure to consider other factors that may be causing expressions or indications of

distress before initiating a psychotropic medication, such as an underlying medical condition (e.g., urinary tract infection, dehydration, delirium), environmental (lighting, noise) or psychosocial stressors; or

- Administering a psychotropic medication(s), which the resident has not previously received, when it is not necessary to treat a specific condition that has been diagnosed and documented in the clinical record; or
- Failure to attempt non-pharmacological approaches, unless clinically contraindicated, in efforts to discontinue psychotropic medications.

**NOTE:** For concerns related to a medication that involves an inadequate indication for use and evidence shows the medication is also being used for the purpose of discipline or staff convenience rather than to treat the resident's medical symptoms, surveyors should evaluate whether evidence shows the medication is being used to sedate the resident or restrict the resident's movement or cognition and assess compliance with §483.10(e)(1) and §483.12(a)(2), F605, Right to Be Free From Chemical Restraints, instead of citing both at F605 and F757 or F758 for the same evidence.

**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).

**Inadequate Monitoring** –

- Failure to monitor the responses to or effects of a medication, or
- Failure to respond when monitoring indicates a lack of progress toward the therapeutic goal (e.g., relief of pain or normalization of thyroid function) or the emergence of an adverse consequence; or
- Failure to monitor for changes in psychosocial engagement resulting from adverse consequences of medications, (e.g., resident no longer participates in activities because medication causes confusion or lethargy); or
- Failure to monitor a medication consistent with the current standard of practice or manufacturer's guidelines; or
- Failure to carry out the monitoring that was ordered or failure to monitor for potential adverse consequences; or
- Failure to consider whether the onset or worsening of symptoms, or a change of condition, may be related to a medication; or
- Failure to monitor effectiveness of non-pharmacological approaches, unless clinically contraindicated, before prescribing and administering medications.

**NOTE:** Additional information as well as examples of non-pharmacological approaches may be found in other guidance for regulations at §483.40, Behavioral Health Services and §483.25, Quality of Care and Quality of Life.

**Excessive Dose (including duplicate therapy)** –

- Giving a total amount of any medication at one time or over a period of time that exceeds the amount prescribed by the prescribing practitioner, the amount recommended by the manufacturer's recommendations, clinical practice guidelines, evidence-based studies from medical/pharmacy journals, or standards of practice for a resident's age and condition, without a documented clinically pertinent rationale; or
- Failure to consider periodically the continued necessity of the dose or the possibility of tapering a medication; or
- Failure to provide and/or document a clinical rationale for using multiple medications from the same pharmacological class.
- Failure to consider each resident's clinical condition as a factor in determining an appropriate dose, as adverse consequences may occur even when medication serum concentration levels are in the therapeutic range.

**Excessive Duration** –

- Continuation beyond the manufacturer's recommended time frames, the stop date or duration indicated on the medication order, facility-established stop order policies, or clinical practice guidelines, evidence-based studies from medical/pharmacy journals, or current standards of practice, without documented clinical justification; or
- Continuation of a medication after the desired therapeutic goal has been achieved, without evaluating whether there is a continued need for the medication, for example, use of an antibiotic beyond the recommended clinical guidelines or the facility policy without adequate reassessment and evaluation of the resident.

**Adverse Consequences**

- Failure to act upon (i.e., discontinue a medication or reduce the dose or provide clinical justification for why the benefit outweighs the adverse consequences) or report the presence of adverse consequence(s); or
- Failure to monitor for the presence of adverse consequences related to the use of medications (e.g., particularly high risk medications, such as warfarin, insulin, opioids, or medications requiring monitoring of blood work); or
- Failure to respond to the presence of adverse consequences related to the use of medications (e.g., particularly high risk medications, such as warfarin, insulin, or opioids).

**Psychotropic Medications**

- Failure to present to the attending physician or prescribing practitioner the need to attempt GDR in the absence of identified and documented clinical contraindications; or
- Use of psychotropic medication(s) without documentation of the need for the medication(s) to treat a specific diagnosed condition; or

- PRN psychotropic medication ordered for longer than 14 days, without a documented rationale for continued use; or
- Failure to implement person-centered, non-pharmacological approaches in the attempt to reduce or discontinue a psychotropic medication (§§483.40(a)(2) and 483.45(e)(2)); or
- Administering a new PRN antipsychotic medication for which the resident had a previous PRN order (for 14 days) but the medical record does not show that the attending physician or prescribing practitioner evaluated the resident for the appropriateness of the new order for the medication.

**PROCEDURES: §483.45(d) Unnecessary drugs and §§483.45(c)(3) and (e) Psychotropic Drugs**
**Investigating Concerns Related to Medication Regimen Review, Unnecessary Medications, and Psychotropic Medications**

Use the Unnecessary Medications, Psychotropic Medications, and Medication Regimen Review Critical Element (CE) Pathway along with the interpretive guidelines when determining if the facility meets the requirements for, and when investigating concerns related to, Medication Regimen Review, Unnecessary Medications, and Psychotropic Medications.

Review the medications (prescription, over-the-counter medications, and nutritional supplements such as herbal products) currently ordered and/or discontinued by the prescriber at least back to the most recent signed recapitulation of all medications. Obtain a copy of the current orders if necessary. Gather information regarding the resident's mental, physical, functional, and psychosocial status and the medication-related therapeutic goals identified in the care plan as the basis for further review.

Use the table below to guide observations, record review, and interviews with the resident or representative and relevant staff. Symptoms and signs described in the table may also be related to a resident's condition or disease. The surveyor may seek clarification about the basis of specific signs and symptoms from the attending physician and/or pharmacist.

| SYMPTOMS, SIGNS, AND CONDITIONS THAT MAY BE ASSOCIATED WITH MEDICATIONS | REVIEW FOR HOW THE IDT MANAGED MEDICATIONS FOR THE RESIDENT |
|---|---|
| Determine if the resident has been transferred to acute care since the last survey and/or has recently (e.g., the previous 3 months) experienced a change in condition or currently has signs and symptoms, such as:<br><br>• Anorexia and/or unplanned weight loss, or weight gain<br>• Apathy | 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:<br><br>• Clinical indications for use of the medication |

| SYMPTOMS, SIGNS, AND CONDITIONS THAT MAY BE ASSOCIATED WITH MEDICATIONS | REVIEW FOR HOW THE IDT MANAGED MEDICATIONS FOR THE RESIDENT |
|---|---|
| • Behavioral changes, unusual patterns (including increased expressions or indications of distress, social isolation or withdrawal)<br>• Bleeding or bruising, spontaneous or unexplained<br>• Bowel dysfunction including diarrhea, constipation and impaction<br>• Dehydration, fluid/electrolyte imbalance<br>• Depression, mood disturbance<br>• Dysphagia, swallowing difficulty<br>• Falls, dizziness, or evidence of impaired coordination<br>• Gastrointestinal bleeding<br>• Headaches, muscle pain, generalized or nonspecific aching or pain<br>• Lethargy<br>• Mental status changes, (e.g., new or worsening confusion, new cognitive decline, worsening of dementia (including delirium), inability to concentrate)<br>• Psychomotor agitation (e.g., restlessness, inability to sit still, pacing, hand-wringing, or pulling or rubbing of the skin, clothing, or other objects).<br>• Psychomotor retardation (e.g., slowed speech, thinking, and body movements)<br>• Rash, pruritus<br>• Respiratory difficulty or changes<br>• Sedation (excessive), insomnia, or sleep disturbance<br>• Seizure activity<br>• Urinary retention or incontinence<br><br>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. | • Implementation of person-centered, non-pharmacological approaches to care<br>• Dose, including excessive dose and duplicate therapy<br>• Duration, including excessive duration<br>• Consideration of potential for tapering/GDR or rationale for clinical contraindication<br>• Monitoring for and reporting of:<br>  ○ Response to medications and progress toward therapeutic goals and resident's goals<br>  ○ Emergence of medication-related adverse consequences<br>• Adverse consequences, if present and potentially medication-related, note if there was:<br>  ○ Recognition, evaluation, reporting, and management by the IDT<br>  ○ Physician action regarding potential medication-related adverse consequences<br>• The residents goals and preferences for medications and treatments |

Interview the resident, his or her family, and representative(s) and the IDT, as needed to gather information about use of medications and any possible side effects in the nursing

home. 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 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.

**NOTE:** This review is not intended to direct medication therapy. However, surveyors are expected to review factors related to the implementation, use, monitoring, and documentation of medications.

The surveyor is not expected to prove that an adverse consequence was directly caused by a medication or combination of medications, but rather that there was a failure in the care process related to considering and acting upon such possibilities.

If during the course of this review, the surveyor needs to contact the attending physician regarding questions related to the medication regimen, it is recommended that the facility's staff have the opportunity to provide the necessary information about the resident and the concerns to the physician for his/her review prior to responding to the surveyor's inquiries.

**POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION**

Examples of some of the related requirements that may be considered when concerns have been identified include the following:

- 42 CFR 483.10(g)(14), F580, Notification of Changes
  - Review whether the facility contacted the attending physician regarding a significant change in the resident's condition in relation to a potential adverse consequence of a medication, or if the resident has not responded to medication therapy as anticipated and/or indicated.
- 42 CFR 483.10 (c), F552, Planning and Implementing Care
  - Determine whether the resident was advised of her/his medical condition and therapy and was informed about her/his treatment including medications and the right to refuse treatments.

- 42 CFR 483.24(c), F679, Activities
  - Review whether the facility provides activities that address a resident's needs and may permit discontinuation or reduction of psychotropic medications. Review also whether adverse consequences of medications interfere with a resident's ability to participate in activities.
- 42 CFR 483.24(a), F676, Activities of Daily Living
  - Review whether the facility had identified, evaluated, and responded to a new or rapidly progressive decline in function, development or worsening of movement disorders, increased fatigue and activity intolerance that affected the resident's ADL ability in relation to potential medication adverse consequences.
- 42 CFR 483.40, F740, Behavioral Health Services
  - Review whether the facility had identified, evaluated, and responded to a change in behavior and/or psychosocial changes, including depression or other mood disturbance, distress, restlessness, increasing confusion, or delirium in relation to potential medication adverse consequences.
- 42 CFR 483.30(a), F710, Physician Supervision
  - Review if the attending physician supervised the resident's medical treatment, including assessing the resident's condition and medications, identifying the clinical rationale, and monitoring for and addressing adverse consequences.
- 42 CFR 483.30(b), F711, Physician Visits and 42 CFR 483.30(c), F712, Frequency of Physician Visits
  - Review if the attending physician or designee reviewed the resident's total program of care and wrote, signed, and dated progress notes covering pertinent aspects of the medication regimen and related issues.
- 42 CFR 483.70(*g*), F841, Medical Director
  - Review whether the medical director, when requested by the facility, interacted with the attending physician regarding a failure to respond or an inadequate response to identified or reported potential medication irregularities and adverse consequences; and whether the medical director collaborated with the facility to help develop, implement, and evaluate policies and procedures for the safe and effective use of medications in the care of residents.
- 42 CFR §483.80(a)(3), F881, Antibiotic Stewardship Program
  - Review whether the facility has developed and implemented their antibiotic stewardship program (e.g., antibiotic use protocols that utilize an infection assessment tool, monitoring of antibiotic use, feedback and education to prescribing providers).

**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 noncompliance that demonstrate severity at Level 4 immediate jeopardy to resident health or 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.
- Failure to recognize that use of an antipsychotic medication, originally prescribed for agitation, has caused significant changes in the resident's quality of life. The resident no longer participates in activities that they previously enjoyed, has difficulty concentrating and carrying on conversations, and spends most of the day isolated in his or her room, sleeping in a recliner or in bed. Continued use of the antipsychotic medication without an adequate clinical indication, GDR attempts, and evidence of non-pharmacological approaches resulted in psychosocial harm.
- Failure to re-evaluate the appropriateness of continued administration of a PRN antipsychotic medication, originally prescribed for acute delirium, which resulted in the likelihood of significant side effects from the medication.

**Examples of Level 3, Actual harm (physical or psychosocial) that are not immediate jeopardy, include, but are not limited to:**

- The facility failed to evaluate a resident's new medication regimen as the source of a resident's recent nausea. The prescriber then added a medication to treat the nausea, which caused agitation and insomnia.
- Failure to evaluate a resident for a GDR for a psychotropic medication originally prescribed to treat delirium. Delirium symptoms subsided but the resident remained drowsy and inactive.

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

- Facility failure to identify and act upon minor symptoms of allergic response to medications, such as a rash with mild itching to the abdomen and no other symptoms, causing minimal discomfort.

- Facility failure to monitor for response or for the emergence or presence of adverse consequences for a resident who has not yet experienced an adverse consequence or decline in function, such as by monitoring hydration status and basic metabolic profile for a resident receiving diuretics or ACE inhibitors.

**Severity Level 1: No Actual Harm with Potential for Minimal Harm**
Severity Level 1 does not apply for this regulatory requirement because the failure of the facility to provide appropriate care and services to manage the resident's medication regimen to avoid unnecessary medications and minimize negative outcome places residents at risk for more than minimal harm.

**RESOURCES AND TOOLS**

The following resources and tools provide information on medications including box warnings, appropriate dosing, medication categories, drug interactions, and medication safety information. Some of these resources also assist in identifying the correct class of a medication (e.g., identifying whether a medication is an antipsychotic or other category of psychotropic medication). Additionally, the list includes some of the recognized clinical resources available for understanding the overall treatment and management of medical problems, symptoms and medication consequences and precautions.

- U.S. Department of Health and Human Services, National Institute of Mental Health Web site, which includes publications and clinical research information www.nimh.nih.gov
- MedlinePlus, https://www.nlm.nih.gov/medlineplus/druginformation.html
- National Library of Medicine Drug Information Portal, http://druginfo.nlm.nih.gov/drugportal/drug/categories (medication class information).
- 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 publicatio

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delirium and dementia in elderly adults. The Lancet, 14, pp.823-832. Retrieved from http://thelancet.com/journals/laneur/article/PIIS1474-4422(15)00101-5/fulltext.

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## F770

*(Rev. 225; Issued: 08-08-24; Effective: 08-08-24; Implementation: 08-08-24)*

**§483.50(a) Laboratory Services.**
**§483.50(a)(1) The facility must provide or obtain laboratory services to meet the needs of its residents. The facility is responsible for the quality and timeliness of the services.**

**(i) If the facility provides its own laboratory services, the services must meet the applicable requirements for laboratories specified in part 493 of this chapter.**

**DEFINITIONS §483.50(a)(1)(i)**

**"Laboratory service "** as referenced in §493.2, is any examination of materials derived from the human body for purposes of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of human beings.

**GUIDANCE §483.50(a)(1)(i)**
If a facility provides its own laboratory services or performs any laboratory tests directly (e.g., blood glucose monitoring, etc.) the provisions of 42 CFR Part §493 apply and the facility must have a current Clinical Laboratory Improvement Amendment (CLIA) certificate appropriate for the level of testing performed within the facility.

Facilities collecting and/or preparing specimens and not performing testing are not considered to be providing laboratory services and do not need to meet the requirements of 42 CFR Part §493.

Surveyors should only verify that the facility has a current CLIA certificate and not attempt to determine compliance with the requirements in 42 CFR part 493; rather, refer questions or concerns to CLIA surveyors.

**POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION**

If noncompliance with §483.50(a)(1)(i) has been identified, the surveyor may have identified concerns with related structure, process, and/or outcome requirements. If an additional concern has been identified, the surveyor must investigate the identified concern. Do not cite any related or associated requirements before first conducting an investigation to determine compliance or non-compliance with the related or associated requirement. Examples include, but are not limited to, the following:

- §483.30 - Physician Services
- §483.35 - Nursing Services
- §483.70(*f*) - Use of Outside Resources
- §483.70(*g*) - Medical Director
- §483.75 - Quality Assessment and Performance Improvement

**KEY ELEMENTS OF NONCOMPLIANCE**

To cite deficient practice at F770, the surveyor's investigation will generally show that the facility failed to do any one or more of the following:

- Have a current CLIA certificate appropriate for the level of testing it performs; **OR**
- Meet the needs of residents with regard to the quality and/or timeliness of providing laboratory services and reporting laboratory results: **OR**
- Provide or obtain laboratory services, to meet the needs of its residents.

## F771

***(Rev. 225; Issued: 08-08-24; Effective: 08-08-24; Implementation: 08-08-24)***

**§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 Regional Office CLIA surveyors that requirements in part 493 were not met cite a deficiency under this Tag F771.

The facility must have procedures for preventing transfusion reactions and promptly identify, investigate, and report blood and blood product transfusion reactions to the laboratory that provided the blood or blood products and as appropriate, to Federal and State authorities.

If the facility provides transfusion services, determine whether they have policies, procedures, and protocols for:

(a) Transfusion processes that include adverse reaction identification and corrective actions to be taken;

(b) Investigating all transfusion reactions; and
(c) Reporting all transfusion reactions to the appropriate officials and agencies.

Review the facility's procedures to ensure their process includes the positive identification of the blood or blood components to be transfused into the intended recipient.

If a facility has not established policies as referenced above **do not** cite here but cite under §483.70(d) Governing body, F837. Also consider requirements at §483.70(*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 Regional Office for appropriate follow-up by CLIA surveyors.

## F775

*(Rev. 225; Issued: 08-08-24; Effective: 08-08-24; Implementation: 08-08-24)*

**§483.50(a)(2) The facility must—**

**(iv) File in the resident's clinical record laboratory reports that are dated and contain the name and address of the testing laboratory.**

**PROCEDURES**

Review the resident's clinical record to determine laboratory reports are included and that the reports are dated and contain the name and address of the testing laboratory. If there are other medical record documentation concerns, refer to §483.70(*h*) - Medical Records.

**KEY ELEMENTS OF NONCOMPLIANCE**

To cite deficient practice at F775, the surveyor's investigation will generally show that the facility failed to do any one or more of the following:

- Have laboratory reports filed in the resident's clinical record; **OR**
- Laboratory reports were not dated; **OR**
- Laboratory reports did not contain the name and address of the testing laboratory.

## F776

*(Rev. 225; Issued: 08-08-24; Effective: 08-08-24; Implementation: 08-08-24)*

**§483.50(b) Radiology and other diagnostic services.**

**§483.50(b)(1) The facility must provide or obtain radiology and other diagnostic services to meet the needs of its residents. The facility is responsible for the quality and timeliness of the services.**

**(i) If the facility provides its own diagnostic services, the services must meet the applicable conditions of participation for hospitals contained in §482.26 of this subchapter.**

**(ii) If the facility does not provide its own diagnostic services, it must have an agreement to obtain these services from a provider or supplier that is approved to provide these services under Medicare.**

**GUIDANCE §483.50(b)(1)(i)(ii)**

If the facility provides its own radiologic or other diagnostic services, the services must meet the applicable requirements for radiologic services contained at §482.26 – Conditions of Participation for Hospitals- Radiologic Services. If there are questions or concerns refer to State Agency or CMS Regional Office for appropriate discussion and follow-up with surveyors trained in assessing compliance with §482.26 (i.e., hospital surveyors).

If the facility does not provide its own radiologic or diagnostic services, it must have a written agreement to obtain these services from a provider or supplier that is approved to provide these services under Medicare. For concerns regarding this agreement, refer to §483.70(*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.

## F779

***(Rev. 225; Issued: 08-08-24; Effective: 08-08-24; Implementation: 08-08-24)***

**§483.50(b)(2)(iv) File in the resident's clinical record signed and dated reports of radiologic and other diagnostic services.**

**PROCEDURES**

Review resident clinical records to determine if reports of radiologic and other diagnostic services reports are filed and that they are signed and dated. If there are other medical record documentation concerns, refer to §483.70(*h*) - Medical Records.

**KEY ELEMENTS OF NONCOMPLIANCE**

To cite deficient practice at F779, the surveyor's investigation will generally show that the facility failed to do any one or more of the following:

- Have reports filed in the resident's clinical record; **OR**
- Reports were not dated or signed.

## F790

***(Rev. 225; Issued: 08-08-24; Effective: 08-08-24; Implementation: 08-08-24)***

**§483.55 Dental services.**
**The facility must assist residents in obtaining routine and 24-hour emergency dental care.**

**§483.55(a) Skilled Nursing Facilities**
**A facility—**

**§483.55(a)(1) Must provide or obtain from an outside resource, in accordance with with §483.70(*f*) of this part, routine and emergency dental services to meet the needs of each resident;**

**§483.55(a)(2) May charge a Medicare resident an additional amount for routine and emergency dental services;**

**§483.55(a)(3) Must have a policy identifying those circumstances when the loss or damage of dentures is the facility's responsibility and may not charge a resident for the loss or damage of dentures determined in accordance with facility policy to be the facility's responsibility;**

**§483.55(a)(4) Must if necessary or if requested, assist the resident;**
**(i) In making appointments; and**
**(ii) By arranging for transportation to and from the dental services location; and**

**§483.55(a)(5) Must promptly, within 3 days, refer residents with lost or damaged dentures for dental services. If a referral does not occur within 3 days, the facility must provide documentation of what they did to ensure the resident could still eat and drink adequately while awaiting dental services and the extenuating circumstances that led to the delay.**

## F791

***(Rev. 225; Issued: 08-08-24; Effective: 08-08-24; Implementation: 08-08-24)***

**§483.55 Dental Services**
**The facility must assist residents in obtaining routine and 24-hour emergency dental care.**

**§483.55(b) Nursing Facilities.**
**The facility—**

**§483.55(b)(1) Must provide or obtain from an outside resource, in accordance with §483.70(*f*) of this part, the following dental services to meet the needs of each resident:**

**(i) Routine dental services (to the extent covered under the State plan); and**
**(ii) Emergency dental services;**

**§483.55(b)(2) Must, if necessary or if requested, assist the resident—**

**(i) In making appointments; and**
**(ii) By arranging for transportation to and from the dental services locations;**

**§483.55(b)(3) Must promptly, within 3 days, refer residents with lost or damaged dentures for dental services. If a referral does not occur within 3 days, the facility must provide documentation of what they did to ensure the resident could still eat and drink adequately while awaiting dental services and the extenuating circumstances that led to the delay;**

**§483.55(b)(4) Must have a policy identifying those circumstances when the loss or damage of dentures is the facility's responsibility and may not charge a resident for the loss or damage of dentures determined in accordance with facility policy to be the facility's responsibility; and**

**§483.55(b)(5) Must assist residents who are eligible and wish to participate to apply for reimbursement of dental services as an incurred medical expense under the State plan.**

**INTENT of §483.55(a)[F790] & (b) [F791]**

To ensure that residents obtain needed dental services, including routine dental services; to ensure the facility provides the assistance needed or requested to obtain these services; to ensure the resident is not inappropriately charged for these services; and if a referral does not occur within three business days, documentation of the facility's to ensure the resident could still eat and drink adequately while awaiting dental services and the extenuating circumstances that led to the delay.

**DEFINITIONS for §483.55(a)[F790] & (b) [F791]**

**"Emergency dental services"** includes services needed to treat an episode of acute pain in teeth, gums, or palate; broken, or otherwise damaged teeth, or any other problem of the oral cavity that required immediate attention by a dentist.

**"Promptly"** means within 3 business days or less from the time the loss or damage to dentures is identified unless the facility can provide documentation of extenuating circumstances that resulted in the delay.

**"Routine dental services"** means an annual inspection of the oral cavity for signs of disease, diagnosis of dental disease, dental radiographs as needed, dental cleaning, fillings (new and repairs), minor partial or full denture adjustments, smoothing of broken teeth, and limited prosthodontic procedures, e.g., taking impressions for dentures and fitting dentures.

**GUIDANCE for §483.55(a)[F790] & (b) [F791]**

A dentist must be available for each resident. The dentist can be directly employed by the facility or the facility can have a written contractual agreement with a dentist. The facility may also choose to have a written agreement for dentist services from a dental clinic,

dental school or a dental hygienist all of whom are working within Federal and State laws and under the direct supervision of a dentist.

For Medicare and private pay residents, facilities are responsible for having the services available, but may bill an additional charge for the services.

For Medicaid residents, the facility must provide all emergency dental services and those routine dental services to the extent covered under the Medicaid state plan. The facility must inform the resident of the deduction for the incurred medical expense available under the Medicaid State plan and must assist the resident in applying for the deduction.

If any resident is unable to pay for dental services, the facility should attempt to find alternative funding sources or delivery systems so that the resident may receive the services needed to meet their dental needs and maintain his/her highest practicable level of well-being. This can include finding other providers of dental services, such as a dental school or the provision of dental hygiene services on site at a facility.

The facility must assist residents in making arrangements for transportation to their dental appointments when necessary or requested. The facility should attempt to minimize the financial burden on the resident by finding the lowest cost or no cost transportation option to dental health care appointments.

The facility must have a policy identifying those instances when the loss or damage of partial or full dentures is the facility's responsibility, such as when facility staff discards dentures placed on a meal tray. A blanket policy of facility non-responsibility for the loss or damage of dentures or a policy stating the facility is only responsible when the dentures are in actual physical possession of facility staff would not meet the requirement. In addition, the facility is prohibited from requesting or requiring residents or potential residents to waive any potential facility liability for losses of personal property. See §483.15(a)(2)(iii), F620, Admissions Policy.

Prompt referral means no later than three (3) business days from the time the partial or full dentures are lost or damaged. Referral does not mean that the resident must see the dentist at that time. It does mean that an earliest possible appointment (referral) is made, or that the facility is aggressively working to have the dentures repaired or replaced if the dentist was contacted timely and determined the dentures could be repaired or replaced without a dental visit.

If there is a delay in making the referral, the facility must document the circumstances that led to the delay. The facility must also be able to provide documentation demonstrating what they did to ensure the resident could still adequately eat and drink while waiting for the issue with their dentures to be addressed.

If concerns are identified regarding providing ADL assistance for oral hygiene (such as assistance with brushing, flossing, denture cleaning), do not cite here. See guidance under §483.24(a), F677, Activities of Daily Living.

**Summary of Procedures for §483.55(a)[F790] & (b) [F791]**
**The process to review concerns are outlined in the Dental Care Area Pathway.**

**Record Review**
Review the resident's records for identification of the resident's dental needs and the resident's responsiveness to dental services. The information found in the resident's assessment and care plans should be used to guide resident observations, and to determine whether the facility has met or is meeting related regulatory requirements including, but not limited to, person-centered care planning, resident assessment, and dental services. Finally, determine the resident's payer status (Medicare, Medicaid or private pay) for service eligibility determinations.

**Observation**
Observe the resident to determine if his or her dental status is consistent with the comprehensive assessment or if the resident exhibited signs of dental health concerns that may not have been identified.

**Resident/Resident Representative Interview**

Interview the resident and/or resident representative to determine if any concerns identified since the last survey were promptly addressed to the resident's or the resident representative's satisfaction. This includes determining if the facility provided the assistance to obtain dental services needed or requested by the resident or resident representative and whether the facility assisted the resident with arranging transportation to the dental appointment. If the identified concern is related to missing or damaged dentures, interview the resident and family/resident representative to determine if a referral was promptly (within three business days) made, if an explanation was provided if a referral was not promptly made, and if the facility took measures to ensure the resident was able to continue to eat or drink adequately while awaiting dental services.

**KEY ELEMENTS OF NONCOMPLIANCE**

To cite deficient practice, the surveyor's investigation will generally show that the facility any of the following:

**For residents receiving Medicare and private pay residents, F790:**

- Failed to provide or obtain from an outside resource, in accordance with §483.70(*f*), routine and emergency dental services to meet the needs of each resident; **or**
- Did not assist the resident as necessary or requested to make appointments for dental services and/or arrange for transportation to and from the dental service location; **or**
- Did not promptly, within three business days, refer a resident with lost or damaged partial or full dentures and/or documented the extenuating circumstances that led to a delay; **or**

- Did not document what the facility did to ensure a resident with missing or damaged dentures could still eat and drink adequately while awaiting dental services; **or**
- Charged a resident for the loss or damage of partial or full dentures determined to by facility policy to be the facility's responsibility.

**For residents receiving Medicaid, F791:**

- Failed to provide or obtain from an outside resource, in accordance with §483.70(*f*), routine (to the extent covered by the State plan) and emergency dental services for each resident; **or**
- Did not assist the resident as necessary or requested to make appointments for dental services or arrange for transportation to and from dental services locations; **or**
- Did not promptly, within three days, refer a resident with lost or damaged partial or full dentures and/or documented the extenuating circumstances that led to a delay; **or**
- Did not document what the facility did to ensure a resident with missing or damaged partial or full dentures could still eat and drink adequately while awaiting dental services; **or**
- Charged a resident for the loss or damage of partial or full dentures determined to by facility policy to be the facility's responsibility; **or**
- Failed to assist a resident(s) who are eligible to participate and/or wish to participate to apply for reimbursement of dental services as an incurred medical expense under the State plan; **or**
- Charged a Medicaid resident an added fee for routine dental services covered by the State plan or for emergency dental services.

**ADDITIONAL TAGS FOR CONSIDERATION MAY INCLUDE, BUT ARE NOT LIMITED TO:**

- §483.10(g)(14), F580, Notification of Change
  - Determine whether staff notified all necessary care providers and resident representatives of change in dental/oral condition when required.
- §483.20(b)(i), (iii), F636, Comprehensive Assessment
  - Determine if the facility comprehensively assessed the resident's risk and/or underlying causes (to the extent possible) of the resident's dental/oral condition and the impact upon the resident's function, mood and cognition.
- §483.20(g), F641, Accuracy of Assessments
  - Determine whether the assessment accurately reflected the dental condition of the resident at the time of the assessment.
- §483.21(b)(1), F656, Comprehensive Care Plan
  - Determine if the facility developed a care plan based on the comprehensive assessment to address the resident's dental/oral condition.
- §483.25(g)(1)-(3), F692, Assisted Nutrition and Hydration

- Determine if the staff ensured the resident maintained or did not experience an avoidable decline in nutritional status related to the resident's oral/dental condition.

- §483.25(k), F697, Pain Management
  - Determine whether staff have assessed, care-planned, and provided services to manage a resident's oral/dental pain.
- §483.35(a), F725, Sufficient and Competent Nursing Staff
  - Determine whether based on the resident's needs the facility had qualified staff in sufficient numbers and with the required competencies to identify dental concerns and provide necessary routine resident dental care.
- §483.40(d), F745, Social Services
  - Determine whether the facility provided medically-related social services by addressing any unmet needs related to dental/denture or oral care.
- §483.45(d), F757, Unnecessary Medications
  - Determine if the resident is experiencing an adverse dental/oral consequence of a medication which indicated the dose should have been reduced or discontinued, or any combination of the reasons stated in §§483.45(d)(1)-(5).
- §483.70(*h*)(*5*), F842, Medical Records
  - Determine whether the resident's records accurately and completely document the resident's dental/oral status and the care and services provided in accordance with current professional standards and practices.
- §483.70(*f*), F840, Use of Outside Resources
  - Determine whether dental services provided met professional standards and principles and the timeliness of those services.
- §483.70(*g*), F841, Medical Director
  - Determine if the medical director was involved in the development of dental/oral health policies/procedures and the coordination of care both on-site as well as availability of off-site providers and addressed any quality concerns.

## F801

***(Rev. 225; Issued: 08-08-24; Effective: 08-08-24; Implementation: 08-08-24)***

**§483.60(a) Staffing**

**The facility must employ sufficient staff with the appropriate competencies and skills sets to carry out the functions of the food and nutrition service, taking into consideration resident assessments, individual plans of care and the number, acuity and diagnoses of the facility's resident population in accordance with the facility assessment required at §483.7*1***

**This includes:**

**§483.60(a)(1) A qualified dietitian or other clinically qualified nutrition professional either full-time, part-time, or on a consultant basis. A qualified dietitian or other clinically qualified nutrition professional is one who—**

**(i) Holds a bachelor's or higher degree granted by a regionally accredited college or university in the United States (or an equivalent foreign degree) with completion of the academic requirements of a program in nutrition or dietetics accredited by an appropriate national accreditation organization recognized for this purpose.**

**(ii) Has completed at least 900 hours of supervised dietetics practice under the supervision of a registered dietitian or nutrition professional.**

**(iii) Is licensed or certified as a dietitian or nutrition professional by the State in which the services are performed. In a State that does not provide for licensure or certification, the individual will be deemed to have met this requirement if he or she is recognized as a "registered dietitian" by the Commission on Dietetic Registration or its successor organization, or meets the requirements of paragraphs (a)(1)(i) and (ii) of this section.**

**(iv) For dietitians hired or contracted with prior to November 28, 2016, meets these requirements no later than 5 years after November 28, 2016 or as required by state law.**

**§483.60(a)(2) If a qualified dietitian or other clinically qualified nutrition professional is not employed full-time, the facility must designate a person to serve as the director of food and nutrition services.**

**(i) The director of food and nutrition services must at a minimum meet one of the following qualifications—**

**(A) A certified dietary manager; or**

**(B) A certified food service manager; or**

**(C) Has similar national certification for food service management and safety from a national certifying body; or**

**D) Has an associate's or higher degree in food service management or in hospitality, if the course study includes food service or restaurant management, from an accredited institution of higher learning; or**

**(E) Has 2 or more years of experience in the position of director of food and nutrition services in a nursing facility setting and has completed a course of study in food safety and management, by no later than October 1, 2023, that includes topics integral to managing dietary operations including, but not limited to, foodborne illness, sanitation procedures, and food purchasing/receiving; and**

**(ii) In States that have established standards for food service managers or dietary managers, meets State requirements for food service managers or dietary managers, and**

**(iii) Receives frequently scheduled consultations from a qualified dietitian or other clinically qualified nutrition professional.**

**INTENT §483.60 (a)(1)-(2) -** To ensure there is sufficient and qualified staff with the appropriate competencies and skill sets to carry out food and nutrition services.

**DEFINITIONS §483.60(a)(1)-(2)**
**"Full-time"** means working 35 or more hours a week.

**"Part-time"** employees typically work fewer hours in a day or during a work week than full-time employees. The U.S. Department of Labor, Bureau of Statistics uses a definition of 34 or fewer hours a week as part-time work. Part-time workers may also be those who only work during certain parts of the year.

**"Consultants"** means an individual who gives professional advice or services. They are generally not direct employees of the facility and may work either full or part-time.

**GUIDANCE §483.60(a)(1)-(2)**
Cite F801 for concerns regarding the qualifications of the dietitian, other clinical nutrition professionals, or the food services director. For concerns regarding support personnel refer to F802, Sufficient Dietary Support Personnel.

In addition, cite F801 if staff, specifically the qualified dietitian or other clinically qualified nutrition professional did not carry out the functions of the food and nutrition services. While these functions may be defined by facility management, at a minimum they should include, but are not limited to:

- Assessing the nutritional needs of residents;
- Developing and evaluating regular and therapeutic diets, including texture of foods and liquids, to meet the specialized needs of residents;
- Developing and implementing person centered education programs involving food and nutrition services for all facility staff;
- Overseeing the budget and purchasing of food and supplies, and food preparation, service and storage; and,
- Participating in the quality assurance and performance improvement (QAPI), as described in §483.75, when food and nutrition services are involved.

The qualified dietitian or other clinically qualified nutrition professional can decide to oversee and delegate some of the activities listed above to the director of food and nutrition services.

**PROBES §483.60(a)(1)-(2)**
If the survey team finds concerns regarding a resident's food and/or nutritional status determine:

- If the practices of the dietitian, nutrition professional, and/or food services director contributed to the identified concerns. If so how?
- How facility management ensures that staff have the appropriate competencies and skills sets to carry out the functions of the food and nutrition service?

- If a food services director is employed by the facility, do they have frequent consultations with the dietitian or other nutrition professionals or consultants employed by the facility?

**POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION §483.60(a)(1)-(2)**

During the investigation of F801, the surveyor may have identified concerns with additional requirements related to outcome, process, and/or structure requirements. The surveyor is advised to investigate these related requirements before determining whether non-compliance may be present at these other tags. Examples of some of the related requirements that may be considered when non-compliance has been identified include, but are not limited to, the following but are not limited to:

- §483.25(b)(1), F686, Pressure Injury
  - Determine if the facility identified, evaluated, and responded to a change in a resident's skin integrity.
- §483.25(g)(1)-(3), F692, Nutrition/Hydration Status
  - Determine if the facility identified, evaluated, and responded to a change in nutritional parameters, anorexia, or unplanned weight loss, dysphagia, and/or swallowing disorders in relation to the resident's ability to eat.
- §483.25(g)(4)-(5), F693, Tube Feeding Management
  - Determine if the facility identified, evaluated, and responded to the use of a naso-gastric and gastrostomy tubes.

## F802

***(Rev. 225; Issued: 08-08-24; Effective: 08-08-24; Implementation: 08-08-24)***

**§483.60(a) Staffing**

**The facility must employ sufficient staff with the appropriate competencies and skills sets to carry out the functions of the food and nutrition service, taking into consideration resident assessments, individual plans of care and the number, acuity and diagnoses of the facility's resident population in accordance with the facility assessment required at §483.7*1*.**

**§483.60(a)(3) Support staff.**
**The facility must provide sufficient support personnel to safely and effectively carry out the functions of the food and nutrition service.**

**§483.60(b) A member of the Food and Nutrition Services staff must participate on the interdisciplinary team as required in § 483.21(b)(2)(ii).**

**DEFINITION §483.60(a)(3)-(b)**
"**Sufficient support personnel**" means having enough dietary and food and nutrition staff to safely carry out all of the functions of the food and nutrition services. This does

not include staff, such as licensed nurses, nurse aides or paid feeding assistants, involved in assisting residents with eating.

**PROCEDURES §483.60(a)(3) and (b)**

- Through observations and interviews determine if there are sufficient support personnel to safely and effectively carry out the meal preparation and other food and nutrition services as defined by facility management.
- Observe and interview residents to determine if their needs and preferences are met, if the food is palatable, attractive, served at the proper temperatures and at appropriate times? If concerns are identified, determine if they may be related to insufficient or inadequately trained personnel.
- Do observations and/or interviews indicate there are sufficient staff to prepare and serve meals in a timely manner and to maintain food safety and temperature?
- Determine who represents food and nutrition services at interdisciplinary team meetings.

When evaluating timeliness, factors that should be considered include but may not be limited to:

- Meals or nutritional supplements are provided in accordance with a resident's medication requirements;
- Meals intended to be "hot" are served as such and are maintained at the desired temperature when provided to the resident;
- Meals or nutritional supplements are provided to residents within 45 minutes of either a residents request or less depending on the facility's scheduled time for meals.

If a concern with having sufficient staff is identified, determine if the staffing levels provided were based on the facility assessment. If a concern with the facility assessment is identified, see §483.7*1*, F838, Facility Assessment.

## F811

***(Rev. 225; Issued: 08-08-24; Effective: 08-08-24; Implementation: 08-08-24)***

**§483.60(h) Paid feeding assistants-**
**§483.60(h)(1) State approved training course. A facility may use a paid feeding assistant, as defined in § 488.301 of this chapter, if—**

**(i) The feeding assistant has successfully completed a State-approved training course that meets the requirements of §483.160 before feeding residents; and**
**(ii) The use of feeding assistants is consistent with State law.**

**§483.60(h)(2) Supervision.**

**(i) A feeding assistant must work under the supervision of a registered nurse (RN) or licensed practical nurse (LPN).**
**(ii) In an emergency, a feeding assistant must call a supervisory nurse for help.**

**§483.60(h)(3) Resident selection criteria.**

**(i) A facility must ensure that a feeding assistant provides dining assistance only for residents who have no complicated feeding problems.**

**(ii) Complicated feeding problems include, but are not limited to, difficulty swallowing, recurrent lung aspirations, and tube or parenteral/IV feedings.**

**(iii) The facility must base resident selection on the interdisciplinary team's assessment and the resident's latest assessment and plan of care. Appropriateness for this program should be reflected in the comprehensive care plan.**

**NOTE:** Paid feeding assistants must complete a training program with the following minimum content as specified at §483.160.

a. Minimum training course contents. A State-approved training course for paid feeding assistants must include, at a minimum, 8 hours of training in the following:

   (1) Feeding techniques;
   (2) Assistance with feeding and hydration;
   (3) Communication and interpersonal skills;
   (4) Appropriate responses to resident behavior;
   (5) Safety and emergency procedures, including the Heimlich maneuver;
   (6) Infection control;
   (7) Resident rights; and
   (8) Recognizing changes in residents that are inconsistent with their normal behavior and the importance of reporting those changes to the supervisory nurse.

b. Maintenance of records. A facility must maintain a record of all individuals, used by the facility as feeding assistants, who have successfully completed the training course for paid feeding assistants.

**INTENT §483.60(h)(1)-(3) -** To ensure that residents are assessed for appropriateness for a feeding assistant program, receive services as per their plan of care, and feeding assistants are trained and supervised. The use of paid feeding assistants is intended to supplement certified nurse aides, not substitute for nurse aides or licensed nursing staff.

**DEFINITIONS §483.60(h)(1)-(3)**

**"Paid feeding assistant"** is defined in the regulation at 42 CFR §488.301 as "an individual who meets the requirements specified at 42 CFR §483.60(h)(1)(i) and who is paid by the facility to feed residents, or who is used under an arrangement with another agency or organization."

**NOTE:** The regulation uses the term "paid feeding assistant." While we are not using any other term, facilities and States may use whatever term they prefer, such as dining assistant, meal assistant, resident assistant, nutritional aide, etc. in order to convey more respect for the resident. Facilities may identify this position with other titles; however,

the facility must be able to identify those employees who meet the requirements under the paid feeding assistant regulation. While the facility is still responsible for ensuring the safety and care of all residents, this regulation does not apply to family members or to volunteers.

**GUIDANCE §483.60(h)(1)-(3)**

**NOTE:** The regulation requires that paid feeding assistants must work under the supervision of an RN or LPN, and they must call the supervisory nurse in case of an emergency. Therefore, a facility that has received a waiver and does not have either an RN or LPN available in the building cannot use paid feeding assistants during those times.

**Interdisciplinary Team Assessment of Resident Eligibility for Feeding Assistance**
When determining whether a resident may be assisted by a paid feeding assistant facility staff must base resident selection on the interdisciplinary team's current assessment of the resident's condition and the resident's latest comprehensive assessment and plan of care. Appropriateness should be reflected in the resident's comprehensive care plan.

Paid feeding assistants are only permitted to assist residents who have no complicated eating or drinking problems as determined by their comprehensive assessment. Examples of residents that a paid feeding assistant may assist include residents who are independent in eating and/or those who have some degree of minimal dependence, such as needing cueing or partial assistance, as long as they do not have complicated eating or drinking problems.

Paid feeding assistants are not permitted to assist residents who have complicated eating problems, such as (but not limited to) difficulty swallowing, recurrent lung aspirations, or who receive nutrition through parenteral or enteral means. Nurses or nurse aides must continue to assist residents who require the assistance of staff with more specialized training to eat or drink.

Paid feeding assistants may assist eligible residents to eat and drink at meal times, snack times, or during activities or social events as needed, whenever the facility can provide the necessary supervision.

**Supervision of Paid Feeding Assistants -** Paid feeding assistants must work under the supervision of an RN or LPN. While we are not prescribing the exact means by which facility RNs and LPNs assert their supervisory responsibilities, we expect that facilities will do so in a way that avoids negative outcomes for their residents. If a facility chooses to use paid feeding assistants, it is the facility's responsibility to ensure that adequate supervisory nursing staff are available to supervise these assistants.

Adequate supervision by a supervising nurse does not necessarily mean constant visual contact or being physically present during the meal/snack time, especially if a feeding assistant is assisting a resident to eat in his or her room. However, in the event that an

emergency should occur, the feeding assistant must be aware of and know how to access the supervisory nurse immediately and the nurse must be located close enough to the resident that he or she can promptly respond. Should an emergency arise, a paid feeding assistant must immediately call a supervisory nurse for help.

Supervisory nurses should monitor the provision of the assistance provided by paid feeding assistants to evaluate on an ongoing basis:

- Their use of appropriate feeding techniques;
- Whether they are assisting assigned residents according to their care planned eating and drinking needs;
- Whether they are providing assistance in recognition of the rights and dignity of the resident; and
- Whether they are adhering to safety and infection control practices.

**Use of Existing Staff as Paid Feeding Assistants -** Facilities may use existing staff, i.e., licensed nurses, certified nursing assistants, to assist residents in feeding. However, other employees for example, administrative, clerical, housekeeping, dietary staff, or activity specialists, etc. must have successfully completed a State-approved training course for paid feeding assistants, as required in §483.160.

**Maintenance of Training Records -** The facility must maintain a record of all employees used as paid feeding assistants. The record should include verification that they have successfully completed a State-approved training course as required in §483.160.

**INVESTIGATIVE PROTOCOL - Use of Paid Feeding Assistants**
**Objectives -** To determine if:

- Individuals used as paid feeding assistants successfully completed a State-approved training course;
- Sampled residents who were selected to receive assistance from paid feeding assistants were assessed and determined to be eligible to receive these services based on the latest assessment and plan of care;
- Paid feeding assistants are supervised by an RN or LPN; and,
- Paid feeding assistants know how to obtain assistance in emergencies.

**Use -** When through observation, record review, or interview(s) with residents, family, or staff, a surveyor identifies concerns that the facility may not be following the requirements regarding paid feeding assistants, including proper training and supervision, and proper assessment and selection of residents for feeding assistance.

**Procedures -** Review the resident's comprehensive assessment and interdisciplinary care plan to guide observations and interviews.

**Observations -** If a concern was discovered through resident or family interview(s), observe the resident while he or she is being assisted to eat and drink by a paid feeding assistant. Determine if the assistant is using proper feeding technique and is providing the type of assistance specified in the resident's care plan. Note the resident's condition and observe for the presence of complicated feeding problems that may require the assistance of a nurse aide or licensed nursing staff. The use of paid feeding assistants is intended to supplement, not substitute for, nursing staff. Also, during observation note whether:

- A paid feeding assistant was observed assisting a resident in a location without a call system available or other means of emergency notification;
- A resident who was assessed as ineligible for services due to complicated eating/drinking problems, or a resident who has not been assessed for eligibility, is being assisted by a paid feeding assistant; and,
- RN or LPN staff members assigned to supervise paid feeding assistants were observed to be unavailable (for example, not available in case of emergency).

If the concern was discovered through observations that were already made, only conduct additional observations if necessary to complete the investigation.

**Resident and Family Interviews -** If a resident is selected for this protocol through surveyor observation that he or she is having difficulties in eating or drinking and he or she is being assisted by a paid feeding assistant, interview the resident if the resident is interviewable. Ask questions to gain information about why the resident is receiving these services and the resident's experience with receiving assistance to eat and drink. If concerns are identified, inquire if the resident has reported these problems to a nurse. If the resident is not interviewable, ask these questions of a family member or the resident's representative.

If the concern was discovered through resident, resident representative or family interviews already conducted, focus any additional interview on questions specific to complete the investigation.

**Paid Feeding Assistant Interviews -** Interview paid feeding assistants assisting the selected resident. Determine whether there are concerns with their training, supervision, or the selection of the resident such as:

- What training did you successfully complete in providing feeding assistance?
- What information did you receive about this resident's needs for assistance (type of assistance needed, any precautions)?
- In what manner and by whom are you supervised while assisting residents?
- What issues/problems do you report (such as coughing, choking, changes in the resident's usual responses, or level of alertness) and to whom do you report?
- What would you do if an emergency occurred while you were assisting a resident to eat or drink? Who would you contact and how would you contact them?

**Interdisciplinary Team Interview -** Interview the nurse or other member(s) of the interdisciplinary team responsible for assessing if the resident is eligible and appropriate to receive assistance by a paid feeding assistant. Ask:

- How they determined that this resident has no complicated feeding problems and is eligible to be assisted by a paid feeding assistant?
- If a resident is appropriate to receive assistance from a paid feeding assistant, how is this resident's needs reflected in his or her comprehensive care plan?
- How they determine that each eligible resident remains free of emergent complicated feeding problems?
- Who supervises paid feeding assistants and how is the supervision accomplished?
- Describe the processes in place to handle emergencies when a supervisor is not present in the area where paid feeding assistants are assisting residents.

**Review of Resident Assessment of Eligibility to Receive Assistance from a Paid Feeding Assistant -** Determine whether the resident's assessment regarding his or her ongoing eligibility to be assisted by a paid feeding assistant is based on identification of the current condition of the resident and any additional or new risk factors or condition changes that may impact on the resident's ability to eat or drink. This information may be contained in the RAI or in other supporting documents such as progress notes, etc. The assessment of eligibility to receive assistance from a paid feeding assistant is ongoing and should be reflected in a resident's comprehensive care plan.

**Requirements for Training of Paid Feeding Assistants -** Determine how the facility identifies that paid feeding assistants have successfully completed a State-approved training course that meets the requirements at 42 CFR §483.160 before they are allowed to assist eligible residents with eating and drinking. If the facility uses temporary (agency) staff as paid feeding assistants, request documentation that these staff have met the minimum training requirements at 42 CFR §483.160. Review facility's records for all employees used as paid feeding assistants to verify their completion of a State approved training course (it is recommended the survey team coordinator assign one surveyor to obtain and verify these records).

**NOTE:** If the facility has not ensured any paid feeding assistant has completed a State-approved training course, **do not** cite here. Cite 42 CFR §483.95(h), F948, Required training of feeding assistants.

**POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION §483.60(h)(1)-(3)**
During the investigation of F811, the surveyor may have identified concerns with additional requirements related to outcome, process, and/or structure requirements. The surveyor is cautioned to investigate these related requirements before determining whether non-compliance may be present at these other tags. Examples of some of the related requirements that may be considered when non-compliance has been identified include, but are not limited to, the following:

- §483.10, F550, Resident Rights

- Determine if staff are attentive and responsive to the resident's requests, and if they provide assistance to eat in a manner that respects the resident's dignity, meets needs in a timely manner, and minimizes potential feelings of embarrassment, humiliation, and/or isolation related to inability to assist themselves with food or fluid intake.

- §483.10(c), F552 and F578, Planning and Implementing Care
  - Determine if the facility addressed the resident's right to choose or refuse treatment, including receiving assistance to eat or drink by a paid feeding assistant.
- §483.20(b), F636, Comprehensive Assessments
  - Review whether facility staff initially and periodically conducted a comprehensive, accurate assessment of the resident's ability to eat and drink with or without assistance and/or identified a condition that makes the resident ineligible for this service.
- §483.21(b)(1), F656, Comprehensive Care Plans
  - Review whether facility staff developed or implemented a comprehensive care plan that was based on the assessment of the resident's conditions, needs, and behaviors, and was consistent with the resident's goals in order to provide assistance with nutrition and hydration as necessary.
- §483.21(b)(2)(iii), F657, Comprehensive Care Plan Revision
  - Determine if the care plan was reviewed and revised periodically, as necessary, related to eligibility to eat and drink with assistance of a paid feeding assistant.
- §483.25(g)(1)-(3), F692, Nutrition/Hydration Status
  - Review if facility staff had identified, evaluated, and responded to a change in nutritional parameters, anorexia, or unplanned weight loss, dysphagia, and/or swallowing disorders in relation to the resident's ability to eat.
  - Review if facility staff had identified, evaluated, and responded to a change in the resident's ability to swallow liquids.
- §483.25 (b)(4), F676, ADL Assistance for Dependent Residents
  - Determine if staff identified and implemented appropriate measures to provide food and fluids for the resident who cannot perform relevant activities of daily living.
- §483.35(a), F725, Sufficient Staff
  - Determine if the facility has qualified staff in sufficient numbers to provide assistance to eat or drink to those residents who require such assistance. For residents who are not eligible to receive assistance from paid feeding assistants, determine if there are sufficient staff to provide this assistance to these residents in a timely fashion.
- §483.70(g), F841, Medical Director
  - Determine whether the medical director collaborates with the facility to help develop, implement, and evaluate resident care policies and procedures based on current standards of practice, e.g., the use of paid feeding assistants, their supervision, and the criteria for determining which residents are eligible to receive assistance to eat or drink from paid feeding assistants.
- §483.95(h), F948, Required training of feeding assistants.

- Determine if the facility has ensured the paid feeding assistant(s) has completed a State-approved training course prior to employment.

**KEY ELEMENTS OF NONCOMPLIANCE:**

To cite F811, the surveyor's investigation will generally show the facility failed to do any one or more of the following:

- Prohibit an employee who did not complete a State-approved training to assist a resident to eat or drink; **or**
- Ensure all paid feeding assistants (permanent or temporary) are used consistent with State law; **or**
- Maintain documentation of a paid feeding assistant's successful completion of a State-approved paid feeding training course; **or**
- Ensure paid feeding assistants were supervised by a licensed nurse; **or**
- Ensure a paid feeding assistant called a supervisory nurse in an emergency; **or**
- Ensure paid feeding assistants are assisting only those residents without complicated feeding problems and who have been selected as eligible to receive these services from a paid feeding assistant; **or**
- Ensure the interdisciplinary team assessed the resident's appropriateness for paid feeding assistance and this need is reflected in the comprehensive care plan.

**DEFICIENCY CATEGORIZATION**

- **An example of Level 4, immediate jeopardy to resident health and safety, includes, but is not limited to:**

  - A resident is being assisted to eat by a paid feeding assistant and begins to experiencing choking. The assistant was not trained to provide abdominal thrusts or the Heimlich maneuver and the supervising nurse or other qualified staff were not available to assist.

- **An example of Level 3, Actual harm (physical or psychological) that is not immediate jeopardy, includes, but is not limited to:**

  - A resident who did not have a complicated feeding problem and who was assessed to have the potential to improving his or her eating ability was assisted to eat by a paid feeding assistant. The assistant provided too much food too quickly and the resident was pocketing the food in their cheeks. The assistant did not notice this was happening and as a result the resident experienced coughing and subsequently vomited.

- **Examples of Level.2 - No actual harm with a potential for more than minimal harm (physical or psychological) that is not immediate jeopardy, includes but are not limited to:**

- Residents are being assisted to eat by individuals who have not successfully completed a State-approved paid feeding assistant training course and who otherwise by State law would not be allowed to feed residents (note that RNs, LPNs or CNAs **are** permitted to feed residents), and there were no resident negative outcomes.
- Paid feeding assistants are assisting eligible residents; however supervising nurses are not nearby or immediately available to promptly respond to an emergency, but there have been no negative resident outcomes.

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

## F825

***(Rev. 225; Issued: 08-08-24; Effective: 08-08-24; Implementation: 08-08-24)***

**§483.65 Specialized rehabilitative services.**
**§483.65(a) Provision of services.**
**If specialized rehabilitative services such as but not limited to physical therapy, speech-language pathology, occupational therapy, respiratory therapy, and rehabilitative services for mental illness and intellectual disability or services of a lesser intensity as set forth at §483.120(c), are required in the resident's comprehensive plan of care, the facility must—**

**§483.65(a)(1) Provide the required services; or**

**§483.65(a)(2) In accordance with §483.70(*f*), obtain the required services from an outside resource that is a provider of specialized rehabilitative services and is not excluded from participating in any federal or state health care programs pursuant to section 1128 and 1156 of the Act.**

**INTENT §483.65(a)(1)-(2)**
The intent of this regulation is to ensure that every resident receives specialized rehabilitative services as determined by their comprehensive plan of care to assist them to attain, maintain or restore their highest practicable level of physical, mental, functional and psycho-social well-being. The intent is also to ensure that residents with a Mental Disorder (MD), Intellectual Disability (ID) or a related condition receive services as determined by their Preadmission Screening and Resident Review (PASARR).

**GUIDANCE §483.65(a)(1)-(2)**
Regulations governing PASARR are found at 42 CFR §483.100-138. For any questions or concerns regarding PASARR do not cite here but refer to §483.20(e) and (k), F644, F645 and/or F646.

**"Specialized Rehabilitative Services"** includes but is not limited to physical therapy, speech-language pathology, occupational therapy, or respiratory therapy and are provided or arranged for by the nursing home. They are "specialized" in that they are provided based on each resident's individual assessed rehabilitative needs based on their

comprehensive plan of care and can only be performed by or under the supervision of qualified personnel.

These services must be provided by the facility or an outside resource and delivered by qualified personnel as defined below in the guidance under tag F826 and who are acting within the State's scope of practice laws and regulations.

The facility must provide or arrange for the provision of specialized rehabilitative services to all residents that require these services for the appropriate length of time as assessed in their comprehensive plan of care. These services are considered a facility service provided to all residents who need them based on their comprehensive plan of care and are included within the scope of facility services.

Care provided by all facility staff must be coordinated and consistent with the specialized rehabilitative services provided by qualified personnel, which is defined under tag F826.

**Restorative services are not considered Specialized Rehabilitative Service - As referenced in Section O of the MDS/RAI manual - Restorative services** refers to nursing interventions that promote the resident's ability to adapt and adjust to living as independently and safely as possible. This concept actively focuses on achieving and maintaining optimal physical, mental, and psychosocial functioning. A resident may be started on a restorative nursing program when he or she is admitted to the facility with restorative needs, but is not a candidate for formalized rehabilitation therapy, or when restorative needs arise during the course of a longer-term stay, or in conjunction with formalized rehabilitation therapy. Generally, restorative nursing programs are initiated when a resident is discharged from formalized physical, occupational, or speech rehabilitation therapy.

**PROBES §483.65(a)(1)-(2)**

Physical and occupational therapy:

- How did these services maintain, improve, or restore the individual's muscle strength, balance, range of motion, functional mobility or prevent or slow decline or deterioration in the individual's muscle strength?
- How are these services maintaining, improving or restoring the amount of activity the individual could do to maintain, improve or restore their independence?
- Do these services assist an individual in minimizing pain to enhance function and independence?
- How are these services maintaining, increasing or decreasing the amount of assistance needed by the individual to perform a task?
- How are these services maintaining, improving or restoring gross and fine motor coordination, including sensory awareness, visual-spatial awareness, and body integration?
- Do these services assist to maintain, improve or restore memory, problem solving, attention span, and the ability to recognize safety hazards?

Speech-language pathology:

- How are these services maintaining, improving or restoring auditory comprehension such as understanding common functional words, concepts of time and place, and conversation?
- How are these services maintaining, improving or restoring the functional abilities of individuals with moderate to severe hearing loss? For example, is the individual instructed how to effectively and independently use environmental controls to compensate for hearing loss such as eye contact, preferential seating, and use of the better ear or hearing aid?
- How are individuals who cannot speak or hear assessed for devices such as a communication board or an alternate means of communication?
- How are these services maintaining, improving or restoring the functional abilities of individuals with swallowing disorders? For example, are muscle re-education, swallowing, positioning, or food consistency modification techniques being employed to restore, improve, or maintain safe swallowing function?
- How are these services maintaining, improving or restoring the functional abilities of individuals with speech disorders? For example, are muscle re-education, positioning, breathing, or other techniques being employed to maintain, improve or restore the individual's ability to communicate verbally?

Respiratory Therapy:

- How are residents assessed to determine which factor or factors may be involved in their underlying causes for ventilator dependence?
- How does the clinical team design and implement an individualized comprehensive pulmonary rehabilitation program to include resident assessment, exercise training, education, and psychosocial support?
- Are qualified personnel caring for mechanically ventilated residents aware of risk factors for ventilator-associated pneumonia (VAP) (e.g., nebulizer therapy, manual ventilation, and patient transport) and how do they practice prevention for these factors?
- How do facility staff implement practices to prevent VAP and other potential infections for residents on ventilator care? Refer to §483.80 (Infection Control).
- What precautions do facility staff take to avoid accidental drainage of condensate into the resident's airway and to avoid contamination of caregivers during ventilator disconnection or during disposal of condensate? Refer to §483.80 (Infection Control).
- If the conditions that warranted placing the resident on the ventilator stabilize and begin to resolve, does the clinical team determine the patient's readiness for subsequent discontinuation of ventilator support and, ultimately, extubation? Is a gradual process implemented according to the physician's orders to wean the resident from the ventilator?

- How and to whom do facility staff report ventilator malfunction? Does the facility have a system in place to provide ventilator services for residents in the event of a malfunction of equipment?
- Does the facility have back-up power to assure ventilators and other respiratory devices are operable in the event of a power failure? Refer to §483.90 (Physical environment).

**PROCEDURES §483.65(a)(1)-(2)**

For each of the services noted above, surveyors should determine through information obtained by observations, interviews and record reviews, that the facility not only delivered these services, but that the services and interventions:

(1) Were monitored for their effectiveness; and
(2) Assisted residents to attain or maintain their highest practicable level of physical, mental, functional and psycho-social well-being or to prevent or slow a decline in condition.

If the facility did not provide or obtain the required services, cite that here under tag F825. However, if the services provided were not appropriately assessed or delivered in accordance with a resident's plan of care, do not cite here but refer to the section below, Potential Requirements for Additional Investigation.

**POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION §483.65(a)(1)-(2)**

For residents with MI or ID, their assessment and comprehensive plan of care must be coordinated with their PASARR. If this coordination is not done, or where it is clear that the resident needs a service according to their comprehensive plan of care and facility staff failed to adequately assess the resident or has failed to care plan for the service, do not cite here but refer to §483.20 Resident Assessment and §483.21 Comprehensive person-centered care planning.

Regulations governing PASARR are found at 42 CFR §483.100-138. For any questions or concerns regarding PASARR do not cite here but refer to §483.20(e) and (k), F644, F645 and/or F646.

If noncompliance with F825, has been identified, the surveyor may have identified concerns with related structure, process, and/or outcome requirements. If an additional concerns have been identified, the surveyor must investigate the identified concern. Do not cite any related or associated requirements before first conducting an investigation to determine compliance or non-compliance with the related or associated requirement.

Other Potential Tags

- Use of Outside Resources,§483.70(*f*);
- Self-determination, §483.10;

- Quality of Life, §483.24;
- Quality of Care, §483.25;
- Resident Rights, §483.10 (for example if there are concerns regarding charges to the resident for any of these services refer to §483.10(f)(11));
- If an assistive device is needed for food and nutrition, refer to §483.60;
- Behavioral Health Services,§483.40;
- Infection Control,§483.80;
- Physical Environmental, §483.90

**KEY ELEMENTS OF NONCOMPLIANCE**

To cite deficient practice at F825, the surveyor's investigation will generally show that the facility failed to do any one or more of the following:

- Provide specialized rehabilitative services based on a resident's comprehensive plan of care; **OR**
- Obtain specialized rehabilitative services from an outside resource that is a provider of specialized rehabilitation services that is NOT excluded from participating in any federal or state health care programs pursuant to section 1128 and 1156 of the Social Security Act.

## F826

***(Rev. 225; Issued: 08-08-24; Effective: 08-08-24; Implementation: 08-08-24)***

**§483.65(b) Qualifications**
**Specialized rehabilitative services must be provided under the written order of a physician by qualified personnel.**

**DEFINITIONS §483.65(b)**
**"Qualified Personnel"** means a physical therapist, occupational therapist, respiratory therapist, speech-language pathologist, physician, nurse practitioner, clinical nurse specialist, or physician's assistant, who is licensed or certified by the state to furnish therapy services. Qualified personnel may also include a physical therapist assistant (PTA), or an occupational therapy assistant (OTA) when furnishing services under the supervision of a qualified therapist.

**GUIDANCE §483.65(b)**
The facility must employ either directly or contract with an outside resource the appropriate qualified personnel as defined above, and additional support staff to ensure the needs of the residents are met in accordance with their comprehensive plan of care.

In addition to meeting the specific competency requirements as part of their license and certification requirements defined under State law or regulations, these personnel must have the training, competencies and skill sets to care for residents as identified through resident assessments, and described in the plan of care.

**NOTE:** For residents receiving physical therapy (PT), occupational therapy (OT) and/or speech-language pathology (SLP) services under the Medicare Part B benefit, an order is not required An order from a physician may substitute for the required plan of care (although orders from therapists are not recognized). Although §483.30(e)(3) allows a resident's attending physician to delegate the task of writing therapy orders to a qualified therapist, Medicare Part B does not currently recognize an order written by a therapist. Under current Part B requirements, when a therapy order is written by a qualified therapist, for that therapy to be covered and paid under the Part B benefit, a physician or recognized non-physician practitioner including a nurse practitioner, clinical nurse specialist or physician assistant – not a therapist − must sign and date the PT, OT, or SLP plan of care which may be established by the therapist.

In situations where there are differences between federal and state supervision requirements, the requirement with the greater level of supervision will apply. Only physical therapists may supervise physical therapy assistants, and only occupational therapists may supervise occupational therapy assistants. All speech-language pathology services must be provided by a licensed speech-language pathologist, or by a physician, nurse practitioner, clinical nurse specialist, or physician's assistant, who is licensed or certified by the state to furnish therapy services.

**PROCEDURES §483.65(b)**

During the record review, determine that these services are provided under the written order of a physician (or therapist as delegated by the physician in accordance with §483.30(e)(3)) and provided by qualified personnel.

If individuals providing specialized rehabilitative services, i.e., physical, occupational, speech or respiratory therapy are not qualified cite here. If a problem in a resident's care or services is related to the qualifications, competencies or training, of personnel (i.e., facility staff, contractors, temporary staff, etc.), also refer to:

- Nursing services not related to behavioral health care or dementia care, tag F725 or 726, §483.35(a),(c);
- Any staff caring for residents with dementia or a history of trauma and/or post-traumatic stress disorder, tag F741, §483.40;
- Administration, tag F839, §483.70(*e*).

If there are any problems in quality of care related to restoring, maintaining or improving a resident's functional abilities, determine if these problems are attributable in part to the qualifications, competencies or training of specialized rehabilitative services staff. Also refer to §483.25 (Quality of Care) and §483.24 (Quality of Life).

**KEY ELEMENTS OF NONCOMPLIANCE**

To cite deficient practice at F826, the surveyor's investigation will generally show that the facility failed to do any one or more of the following:

- Obtain a written order from a physician (or therapist as delegated by the physician in accordance with §483.30(e)(3)), except as otherwise permitted with regard to residents receiving these services under the Medicare Part B benefit (as explained above); **OR**,
- Ensure that services were provided by qualified personnel.

## F837

***(Rev. 225; Issued: 08-08-24; Effective: 08-08-24; Implementation: 08-08-24)***

**§483.70(d) Governing body.**
**§483.70(d)(1) The facility must have a governing body, or designated persons functioning as a governing body, that is legally responsible for establishing and implementing policies regarding the management and operation of the facility; and**

**§483.70(d)(2) The governing body appoints the administrator who is—**
**(i) Licensed by the State, where licensing is required;**
**(ii) Responsible for management of the facility; and**
**(iii) Reports to and is accountable to the governing body.**

**§483.70(d)(3) The governing body is responsible and accountable for the QAPI program, in accordance with §483.75(f).**

**INTENT §483.70(d)**
This regulation is intended to ensure that the facility has an active (engaged and involved) governing body that is responsible for establishing and implementing policies regarding the management of the facility.

**DEFINITIONS §483.70(d)**
**"Governing body"** refers to individuals such as facility owner(s), Chief Executive Officer(s), or other individuals who are legally responsible to establish and implement policies regarding the management and operations of the facility.

**GUIDANCE**
**§483.70(d)**
The facility must determine:

- A process and frequency by which the administrator reports to the governing body, the method of communication between the administrator and the governing body including, how the governing body responds back to the administrator and what specific types of problems and information (i.e., survey results, allegations of abuse or neglect, complaints, etc.) are reported or not reported directly to the governing body;

- How the administrator is held accountable and reports information about the facility's management and operation (i.e., audits, budgets, staffing, supplies, etc.).; and
- How the administrator and the governing body are involved with the facility wide assessment in §483.7*1* Facility assessment at F838.

**PROCEDURES §483.70(d)**
Request the names and contact information of the members of the governing body at the Entrance Conference. If there are concerns, conduct an interview with the administrator and if possible with one or more members of the governing body or designated person(s) functioning as the governing body.

## F838
***(Rev. 225; Issued: 08-08-24; Effective: 08-08-24; Implementation: 08-08-24)***

**§483.7*1* Facility assessment.**
**The facility must conduct and document a facility-wide assessment to determine what resources are necessary to care for its residents competently during both day-to-day operations *(including nights and weekends)* 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.**

**§483.7*1(a)* The facility assessment must address or include *the following*:**

**§483.7*1(a)*(1) The facility's resident population, including, but not limited to*:***
- **(i) Both the number of residents and the facility's resident capacity;**
- **(ii) The care required by the resident population*, using evidence-based, data-driven methods that* consider the types of diseases, conditions, physical and *behavioral health needs*, cognitive disabilities, overall acuity, and other pertinent facts that are present within that population*, consistent with and informed by individual resident assessments as required under § 483.20* ;**
- **(iii) The staff competencies *and skill sets* that are necessary to provide the level and types of care needed for the resident population;**
- **(iv)The physical environment, equipment, services, and other physical plant considerations that are necessary to care for this population; and**
- **(v) Any ethnic, cultural, or religious factors that may potentially affect the care provided by the facility, including, but not limited to, activities and food and nutrition services.**

**§483.7*1(a)*(2) The facility's resources, including but not limited to *the following:***
- **(i) All buildings and/or other physical structures and vehicles;**
- **(ii) Equipment (medical and non- medical);**
- **(iii) Services provided, such as physical therapy, pharmacy, *behavioral health,* and specific rehabilitation therapies;**

**(iv) All personnel, including managers, *nursing and other direct care* staff (both employees and those who provide services under contract), and volunteers, as well as their education and/or training and any competencies related to resident care;**

**(v) Contracts, memorandums of understanding, or other agreements with third parties to provide services or equipment to the facility during both normal operations and emergencies; and**

**(vi) Health information technology resources, such as systems for electronically managing patient records and electronically sharing information with other organizations.**

**§483.7*1(a)*(3) A facility-based and community-based risk assessment, utilizing an all-hazards approach *as required in §483.73(a)(1)*.**

***§ 483.71(b) In conducting the facility assessment, the facility must ensure:***
***§ 483.71(b)(1) Active involvement of the following participants in the process:***

***(i) Nursing home leadership and management, including but not limited to, a member of the governing body, the medical director, an administrator, and the director of nursing; and***

***(ii) Direct care staff, including but not limited to, RNs, LPNs/LVNs, NAs, and representatives of the direct care staff, if applicable.***

***(iii) The facility must also solicit and consider input received from residents, resident representatives, and family members.***

***§483.71(c) The facility must use this facility assessment to:***
***§483.71(c)(1) Inform staffing decisions to ensure that there are a sufficient number of staff with the appropriate competencies and skill sets necessary to care for its residents' needs as identified through resident assessments and plans of care as required in § 483.35(a)(3).***

***§483.71(c)(2) Consider specific staffing needs for each resident unit in the facility and adjust as necessary based on changes to its resident population.***

***§483.71(c)(3) Consider specific staffing needs for each shift, such as day, evening, night, and adjust as necessary based on any changes to its resident population.***

***§483.71(c)(4) Develop and maintain a plan to maximize recruitment and retention of direct care staff.***

***§483.71(c)(5) Inform contingency planning for events that do not require activation of the facility's emergency plan, but do have the potential to affect resident care, such as, but not limited to, the availability of direct care nurse staffing or other resources needed for resident care.***

**INTENT**

The intent of the facility assessment is for the facility to evaluate its resident population and identify the resources needed to provide the necessary care and services the residents require *during both day-to-day operations (including nights and weekends) and emergencies*.

**DEFINITIONS**

**"Competency"** *refers to* a measurable pattern of knowledge, skills, abilities, behaviors, and other characteristics in performing that an individual needs to perform work roles or occupational functions successfully.

***"Representative of direct care employees"*** *is an employee of the facility or a third party authorized by direct care employees at the facility to provide expertise and input on behalf of the employees for the purposes of informing a facility assessment.*

**GUIDANCE**

A facility assessment may be similar to common business practices for strategic and capital budget planning. Strategic planning is an organization's process of defining its strategy, or direction, and making decisions on allocating its resources to pursue this strategy. However, while a facility may include input from its corporate organization, the facility assessment must be conducted at the facility level.

The facility assessment will enable each nursing home to thoroughly assess the needs of its resident population and the required resources to provide the care and services the residents need *using evidence-based, data-driven methods*. It should serve as a record for staff and management to understand the reasoning for decisions made regarding staffing and other resources, and may include the operating budget necessary to carry out facility functions.

To ensure the required thoroughness, individuals *actively* involved in the facility assessment *process must include, but are not limited to, the facility's leadership* (including a *member* of the governing body and the medical director), management (including the administrator and the director of nursing), *and direct care staff (including RNs, LPNs/LVNs, and NAs)*. The environmental operations manager, and other department heads (for example, the dietary manager, director of rehabilitation services, or other individuals*)* should be involved as needed.

*Additionally, the facility must solicit and consider* input from residents, their representative(s)*, family members, and representatives of direct care staff* when formulating their assessment. *We note there are a variety of ways facilities can solicit this input, such as by distributing a questionnaire related to staffing to residents/families, placing convenient suggestion boxes throughout the facility for anonymous input, or providing annual notices for soliciting input to residents and families prior to conducting the annual review and update of the facility assessment.*

An assessment of the resident population is the foundation of the facility assessment. *Therefore, the assessment must address the resident population including both the number of residents and the facility's resident capacity. In addition,* it must include an evaluation of diseases, conditions, physical *and behavioral health needs*, cognitive status, acuity of the resident population, and any other pertinent information *consistent with resident assessments* that may affect and plan for the services the facility must provide (e.g., MDS data). *Examples of other pertinent information about the resident population the facility serves may include race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, preferred language, health literacy or other factors that affect access to care and health outcomes related to health equity.* The assessment of the resident population will also contribute to identifying the physical *environment*, equipment *(medical and non-medical)*, assisted technology, individual communication devices, or other material resources that are needed to provide the required care and services to residents.

The regulation outlines that the individualized approach of the facility assessment is the foundation to determine staffing levels and competencies. Therefore, the facility assessment must include an evaluation of the overall number of facility staff needed to ensure sufficient number of qualified staff are available to meet each resident's needs *as identified through resident assessments and care plans*. Furthermore, the assessment must include a competency-based approach to determine the knowledge and skills required among staff *(including both employees and those who provide services under contract) and volunteers,* 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*, nutrition services*, and any other aspect of care identified. Finally, the assessment should consider a review of individual staff assignments and systems for coordination and continuity of care for residents within and across these staff assignments. Also refer to F553, §483.10 Resident Rights for more information and guidance on cultural competence.

The facility must review and update this assessment *as necessary, and at least* annually or whenever there is, or the facility plans for, any change that would require a modification to any part of this assessment. For example, if the facility decides to admit residents with care needs who were previously not admitted, such as residents on ventilators or dialysis, the facility assessment must be reviewed and updated to address how the facility staff, resources, physical environment, etc., meet the needs of those residents and any areas requiring attention, such as any training or supplies required to provide care. *Additionally, the facility must consider specific staffing needs for each shift (e.g., day, evening, night, weekend shifts) and for each resident unit in the facility based on changes to resident population.*

The assessment must include or address an evaluation of the facility's training program to ensure any training needs are met for all new and existing staff *including managers, nursing and other direct care staff*, individuals providing services under a contractual arrangement, and volunteers, consistent with their expected roles. The assessment should also include an evaluation of what policies and procedures may be required in the provision of care and that these meet current professional standards of practice. If there are any concerns regarding training refer to §483.95 Training.

*The facility assessment must be used to develop and maintain a plan to maximize direct care staff recruitment and retention.* The facility assessment must include an evaluation of any contracts, memorandums of understanding including third party agreements for the provision of goods, services or equipment to the facility during both normal operations and emergencies. The facility assessment must address their process for overseeing these services and how those services will meet resident needs and regulatory, operational, maintenance, and staff training requirements. For example, if the facility contracts for language translation, the assessment must address how those contractors will ensure services are provided both during normal operational hours and during emergencies.

The facility assessment must consider health information technology resources, such as managing resident records and electronically sharing information with other organizations. For example, the assessment should address how the facility will securely transfer health information to a hospital, home health agency, or other providers for any resident transferred or discharged from the facility.

The facility assessment must include an evaluation of the physical environment necessary to meet the needs of the residents. This must include an evaluation of how the facility needs to be equipped and maintained to protect and promote the health and safety of residents. This should also include an evaluation of building maintenance capital improvements, or structures, vehicles, or medical and non-medical equipment and supplies.

*The facility assessment must be used to create a contingency plan for events that do not require the activation of the facility emergency plan but have the potential to impact resident care, such as the availability of direct care nurse staffing or other resources needed for care of residents. For example, the use of contract licensed nurses to cover several shifts during a holiday.*

The facility based and community-based risk assessment, utilizing an all-hazards approach must evaluate the facility's ability to maintain continuity of operations and its ability to secure required supplies and resources during an emergency or natural disaster. For example, if the facility is located in a flood zone, the risk assessment must include an evaluation of how residents will be kept safe and needs met during a flood affecting the facility. Facility staff should consider involving their local/county Office of Emergency Preparedness when conducting this community based risk assessment. The facility's emergency preparedness plans as required under §483.73 *(a)(1)* should be integrated and compatible with the facility assessment. As one is updated, so should the other.

Risk Assessment is general terminology that is within the emergency preparedness regulations and preamble to the Final Rule (81 Fed. Reg. 63860, Sept. 16, 2016) which describes a process facilities are to use to assess and document potential hazards within their areas and the vulnerabilities and challenges which may impact the facility. Additional terms currently used by the industry are all-hazards risk assessments, also referred to as Hazard Vulnerability Assessments (HVAs), or all-hazards self-assessments. For the purposes of these guidelines, we are using the term "risk assessment," which may include a variety of current industry practices used to assess and document potential hazards and their impacts.

Hazard Vulnerability Assessments (HVAs) are systematic approaches to identifying hazards or risks that are most likely to have an impact on a healthcare facility and the surrounding community. The HVA describes the process by which a provider or supplier will assess and identify potential gaps in its emergency plan(s).

Potential loss scenarios should be identified first during the risk assessment. Once a risk assessment has been conducted and a facility has identified the potential hazards/risks they may face, the organization can use those hazards/risks to conduct a Business Impact Analysis.

This guidance is not specifying which type of generally accepted emergency preparedness risk assessment facilities should have, as the language used in defining risk assessment activities is meant to be easily understood by all providers and suppliers that are affected by this final rule and is aligned with the national preparedness system and terminology (81 Fed. Reg. 63860, at 63875). However, facilities are expected to conduct a full assessment of hazards based on geographical location and the individual facility dynamics, such as patient population.

## *INVESTIGATIVE* PROCEDURES

*Surveyors determine whether a facility assessment contains the required components under the regulation. However, they should not evaluate the quality of the assessment.* If systemic care concerns are identified that are related to the facility's planning, review the facility assessment to determine if these concerns were considered as part of the facility's assessment process. For example, if a facility recently started accepting bariatric residents, and concerns are identified related to providing bariatric services, did facility staff update its assessment before accepting residents with these needs to identify the necessary equipment, staffing, etc., needed to provide care that is effective and safe for the residents and staff? Questions surveyors should consider include, but are not limited to, the following:

- *Does* the facility assess*ment include an evaluation of* the resident population*, and its needs (e.g., acuity) based on evidence-based, data-driven methods?* Does this reflect the population observed?

*Does it address the facility's resident capacity?*

- *Does* the facility *assessment include information on* the staffing level*(s) needed for specific shifts, such as day, evening, and night and adjusted as necessary based on changes to resident population*?
- *Does* the facility *assessment address* what skills and competencies *are* required by those providing care?
- *Was* the facility assessment *conducted with input from the individuals stated in the regulation (483.71(b))*?
- *Does* the facility *assessment indicate* what *resources, including but not limited to,* equipment, supplies, *services, personnel, health information technology,* and physical environment *are* required to meet all resident needs?
- *Does the facility have a plan for maximizing recruitment and retention of direct care staff?*
- *Does* the facility *assessment include a contingency* plan *that is informed by the facility assessment*?

**KEY ELEMENTS OF NONCOMPLIANCE**

To cite deficient practice at F838, the surveyor's investigation will generally show that the facility failed to do any one of the following:

- Annually and as necessary, conduct, document, review and update a facility-wide assessment; **or**
- Address or include in the facility assessment the minimum requirements as described in sections *§ 483.71(a), (b), and (c)*.

**POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION**

If the survey investigation reveals that there are not sufficient or competent staff refer to:

- F639, §483.21(b)(3), Comprehensive Person-Centered Care Planning;
- F725 or 726, §483.35(a),(c) for any nursing services not related to behavioral health care or dementia care;
- F741, §483.40 for any staff caring for residents with dementia or a history of trauma and/or post-traumatic stress disorder;
- F801, §483.60(a) for Food and Nutrition staff;
- F826, §483.65(b), Specialized rehabilitative services;
- F839, §483.70(*e*), Staff qualifications;
- F837, §483.70(d), Governing Body
- F865, §483.75, QAPI/QA&A

***DEFICIENCY EXAMPLES***

- One of the sampled residents had experienced a fall while staff were transferring them *from the* bed to a chair *as a result of a faulty mechanical lift*. The resident's care plan indicates requiring a two-person assist using a mechanical lift. After the

fall, the resident was evaluated and although he did not suffer any physical harm, upon interview he did express psychological harm and stated he was afraid of using these lifts and would prefer to remain in bed. Interviews with *direct care* staff indicated that many of the lifts are old, in frequent need of repair, and often malfunction when used. A review of the *current* Facility Assessment did not include or address equipment necessary to provide for the needs of residents *and did not have active involvement of direct care staff in the process*.

- The facility recently admitted several individuals, some that follow a vegan diet and others that follow the Judaism faith, both of which include dietary restrictions. *These individuals did not previously reside in the facility and represents a substantial change in the resident population. The residents* expressed concerns that they are not always able to choose foods that are consistent with their cultural beliefs. Upon review of the facility assessment, the facility *did* not *review and update their assessment based on this change in their resident population. As a result,* the facility *did* not *adjust the menus for* these *newly admitted* residents. When reviewing the Facility Assessment, the survey team identified that while the assessment included all the required components, it had not been reviewed for any potential updates in the last 15 months. Facilities are required to review and update the assessment *as necessary and* at least annually. *Even though there were no changes to resident needs, staffing, or other resources,* the facility's failure to review the assessment within 12 months may result in the facility failing to identify a factor that would require a change to the assessment, thereby potentially placing the residents at risk for at least minimal harm.

## F839

***(Rev. 225; Issued: 08-08-24; Effective: 08-08-24; Implementation: 08-08-24)***

**§483.70(*e*) Staff qualifications.**

**§483.70(*e*)(1) The facility must employ on a full-time, part-time or consultant basis those professionals necessary to carry out the provisions of these requirements.**

**§483.70(*e*)(2) Professional staff must be licensed, certified, or registered in accordance with applicable State laws.**

**DEFINITIONS §483.70(*e*)**

**"Licensed health professional"** as defined at §483.5 is a physician; physician assistant; nurse practitioner; physical, speech, or occupational therapist; physical or occupational therapy assistant; registered professional nurse; licensed practical nurse; or licensed or certified social worker; or registered respiratory therapist or certified respiratory therapy technician.

**PROCEDURES §483.70(*e*)**

If there is reason to doubt the qualifications or competencies of **any personnel**, including temporary, agency and contracted individuals, verify qualifications with the appropriate State registry or practitioner professional licensing body.

If the survey investigation reveals that there are concerns with the qualifications or competencies of:

- Activities professionals refer to F679, §483.24(c)(2);
- Nursing Staff refer to F726, §483.35;
- Any staff caring for residents with dementia or a history of trauma and/or post-traumatic stress disorder refer to F741, §483.40;
- Food and Nutrition staff refer to F801, §483.60(a);
- Individuals providing Specialized rehabilitative services refer to F826, §483.65(b),;
- Social Workers refer to F850, §483.70(*o*);

**NOTE:** Only cite F839 for any staff not referenced above or if any professional staff is not licensed, certified, or registered in accordance with applicable State laws. This includes any physician or practitioner including the Medical director that does not hold a valid license to practice in the State where the Nursing Home is located.

If a facility has not designated a physician to serve as a Medical Director refer that citation under F841.

## F840

***(Rev. 225; Issued: 08-08-24; Effective: 08-08-24; Implementation: 08-08-24)***

**§483.70(*f*) Use of outside resources.**

**§483.70(*f*)(1) If the facility does not employ a qualified professional person to furnish a specific service to be provided by the facility, the facility must have that service furnished to residents by a person or agency outside the facility under an arrangement described in section 1861(w) of the Act or (with respect to services furnished to NF residents and dental services furnished to SNF residents) an agreement described in paragraph (g)(2) of this section.**

**§483.70(*f*)(2) Arrangements as described in section 1861(w) of the Act or agreements pertaining to services furnished by outside resources must specify in writing that the facility assumes responsibility for—**

**(i) Obtaining services that meet professional standards and principles that apply to professionals providing services in such a facility; and**

**(ii) The timeliness of the services.**

**DEFINITIONS §483.70(*f*)**

**"Timeliness"** means that services are completed and results are provided within the timeframe(s) specified in accordance with facility policies and procedures, the medical orders, or professional standards of practice; and that facility staff notifies the resident's physician, dentist, physician assistant, nurse practitioner or clinical nurse specialist as directed in the medical order.

## F841

*(Rev. 225; Issued: 08-08-24; Effective: 08-08-24; Implementation: 08-08-24)*

**§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 §483.70(*g*)**

**"Medical director"** means a physician who oversees the medical care and other designated care and services in a health care organization or facility. Under these regulations, the medical director is responsible for coordinating medical care and helping to implement and evaluate resident care policies that reflect current professional standards of practice.

**"Physician/practitioner" (physician assistant, nurse practitioner, clinical nurse specialist)** means the individual who has responsibility for the medical care of a resident.

**"Current professional standards of practice"** refers to approaches to care, procedures, techniques, treatments, etc., that are based on research and/or expert consensus and that are contained in current manuals, textbooks, or publications, or that are accepted, adopted or promulgated by recognized professional organizations or national accrediting bodies.

**"Resident care policies"** refers to the facility's overall goals, directives, and governing statements that direct the delivery of care and services to residents consistent with current professional standards of practice.

**GUIDANCE §483.70(*g*)**

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 all responsibilities of the medical director are effectively performed, regardless of how the task is accomplished or the technology used, to ensure residents attain or maintain their highest practicable physical, mental, and psychosocial well-being. For example, some, but not all, duties may be conducted remotely using various technologies (e.g., phone, email, fax, telehealth, etc., that is compliant with all confidentiality and privacy requirements).

It is important that the medical director's responsibilities require that he/she be knowledgeable about current professional standards of practice in caring for long term care residents, and about how to coordinate and oversee other practitioners.

If the medical director is also an attending physician, there should be a process to ensure there are no concerns with the individual's performance as a physician (i.e., otherwise, the medical director is monitoring his/her own performance). If there are concerns regarding his/her performance, the facility's administration should have a process for how to address these situations.

While medical directors who work for multi-facility organizations, such as corporate or regional offices, may be involved in policy development, the facility's individual policies must be based on the facility's unique environment and its resident's needs, and not based on a broad, multi-facility structure.

Although the medical director is not required to sign policies, the facility must be able to show that the development, review, and approval of resident care policies included his/her input.

Medical director responsibilities must include their participation in:

- Administrative decisions including recommending, developing and approving facility policies related to residents care. Resident care includes the resident's physical, mental and psychosocial well-being;
- Issues related to the coordination of medical care identified through the facility's quality assessment and assurance committee and other activities related to the coordination of care;
- Organizing and coordinating physician services and services provided by other professionals as they relate to resident care;
- Participate in the Quality Assessment and Assurance (QAA) committee or assign a designee to represent him/her. (Refer to F865).

**NOTE**: Having a designee does not change or absolve the Medical Director's responsibility to fulfill his or her role as a member of the QAA committee, or his or her responsibility for overall medical care in the facility.

In addition, the medical director responsibilities should include, but are not limited to:

- Ensuring the appropriateness and quality of medical care and medically related care;
- Assisting in the development of educational programs for facility staff and other professionals;
- Working with the facility's clinical team to provide surveillance and develop policies to prevent the potential infection of residents. Refer to Infection Control requirement at §483.80;
- Cooperating with facility staff to establish policies for assuring that the rights of individuals (residents, staff members, and community members) are respected;
- Supporting and promoting person-directed care such as the formation of advance directives, end-of-life care, and provisions that enhance resident decision making, including choice regarding medical care options;
- Identifying performance 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; and
- Assisting in developing systems to monitor the performance of the health care practitioners including mechanisms for communicating and resolving issues related to medical care and ensuring that other licensed practitioners (e.g., nurse practitioners) who may perform physician-delegated tasks act within the regulatory requirements and within the scope of practice as defined by State law.

**PROCEDURES §483.70(*g*)**

If a deficiency has been identified regarding a resident's care, also determine if the medical director had knowledge or should have had knowledge of a problem with care, or physician services, or lack of resident care policies and practices that meet current professional standards of practice and failed:

- To get involved or to intercede with other physicians or practitioners in order to facilitate and/or coordinate medical care; and/or
- To provide guidance for resident care policies.

Interview the medical director about his/her:

- Involvement in assisting facility staff with resident care policies, medical care, and physician issues;
- Understanding of his/her roles, responsibilities and functions and the extent to which he/she receives support from facility management for these roles and functions;
- Process for providing feedback to physicians and other health care practitioners regarding their performance and practices, including discussing and intervening (as appropriate) with a health care practitioner regarding medical care that is inconsistent with current professional standards of care;
- Input into the facility's scope of services including the capacity to care for residents with complex or special care needs, such as dialysis, hospice or end-of-life care, respiratory support with ventilators, intravenous medications/fluids,

dementia and/or related conditions, or problematic behaviors or complex mood disorders;
- His/her participation or involvement in conducting the Facility Assessment and the Quality Assessment and Assurance (QAA) Committee.

Interview facility leadership (e.g., Administrator, Director of Nursing, and others as appropriate) about how they interact with the medical director related to the coordination of medical care, the facility's clinical practices and concerns or issues with other physicians or practitioners.

Also, refer to §483.30 Physician Services for more information.

**KEY ELEMENTS OF NONCOMPLIANCE**

To cite deficient practice at F841, the surveyor's investigation will generally show that the facility failed to do any of the following:
- Designate a physician to serve as medical director; **or**
- Ensure the medical director fulfilled his/her responsibility for the implementation of resident care policies or the coordination of medical care in the facility.

**DEFICIENCY CATEGORIZATION**

- **An example of Level 4, immediate jeopardy to resident health and safety, includes, but is not limited to:**
  - The facility's medical director was aware of and did not intervene when a health care practitioner continued over several months to provide inappropriate medical care for infection prevention to a resident that was inconsistent with current professional standards of care. As a result this resident's health continued to decline, and was hospitalized with a severe infection.

- **An example of Level 3, Actual harm (physical or psychological) that is not immediate jeopardy, includes, but is not limited to:**

  - The Director of Nursing repeatedly requested the medical director's assistance in coordinating medical care with attending physicians for residents receiving psychotropic medications. In particular there were several physicians who had a known history of failing to provide justification for continued use of these medications and not attempting a gradual dose reduction for the residents under his/her care. As a result of the medical director's failure to intervene, several residents continued to receive these medications without medical/clinical justification. Based on record review and interviews with residents, their representative's and staff, there was no supporting evidence to indicate that an Immediate Jeopardy situation existed. However, due to the continuation of the use of these psychotropic medications, the residents withdrew from activities and from eating in the dining room. This caused

decreased appetite and substantial weight loss for several residents. Actual harm, both physical and psychosocial was indicated. Unnecessary Medications, was also cited for not ensuring the residents were receiving the lowest dose possible.

- **An example of Level 2 - No actual harm with a potential for more than minimal harm that is not immediate jeopardy, includes but is not limited to:**
  - The administrator had made multiple requests for the medical director to meet with physicians to ensure that they were familiar with the facility's resident care policies. At the time of the survey the medical director was interviewed and stated that she had not yet had an opportunity to introduce herself to or meet with physicians. Although no actual harm occurred, due the medical director's failure to ensure implementation of resident care policies, the potential for more than minimal harm existed.

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

## F842

***(Rev. 225; Issued: 08-08-24; Effective: 08-08-24; Implementation: 08-08-24)***

**§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 §483.70(*h*)**

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 Regional Office for assistance.

**KEY ELEMENTS OF NONCOMPLIANCE**

To cite deficient practice at F842, the surveyor's investigation will generally show that the facility failed to do any of the following:

- Ensure resident-identifiable information was not released to the public or any unauthorized entity as stated in §483.20(f)(5)(ii); or
- Ensure that any resident-identifiable information released to an agent, was to an agent in accordance with a contract under which the agent agreed not to disclose any information the facility would not also be able to release publicly; or
- Maintain medical records on each resident in accordance with accepted professional standards and practices that are:

    - Complete;
    - Accurately documented;
    - Readily accessible; and
    - Systematically organized.
- Keep all information in the resident's records confidential, except when release is:
    - To the resident, or resident representative where permitted by applicable law; or
    - Required by law; or
    - For treatment, payment, or health care operations permitted and in compliance with 45 CFR §164.512; or
    - Allowed under the conditions of §483.70(*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. 225; Issued: 08-08-24; Effective: 08-08-24; Implementation: 08-08-24)***

**§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), F622 and the facility's efforts to ensure safe and orderly transfers. In addition, the agreement should include the information in §483.15(c)(2)(iii), and consider other information that may be necessary for the safe and orderly transfer of the resident, and care and treatment of the resident at the receiving setting.

**KEY ELEMENTS OF NONCOMPLIANCE**

To cite deficient practice at F843, the surveyor's investigation will generally show that the facility failed to do any one of the following:

- Have a written transfer agreement in effect with one or more hospitals approved for participation in Medicare/Medicaid programs; or
- Ensure the transfer agreement(s) reasonably assured:
  - Residents will be transferred for timely admission to the hospital when medically appropriate; or
  - Medical or other information will be exchanged between the facility and the hospital:
    - Including, but not limited to the information required under §483.15(c)(2)(iii); or
    - Information needed for resident care/treatment; or
    - To determine whether the resident can be cared for in a less restrictive setting than either the facility or the hospital; or
- Attempt good faith efforts to enter into an agreement with a hospital sufficiently close to the facility to make the transfer safely and orderly.

## F844

***(Rev. 225; Issued: 08-08-24; Effective: 08-08-24; Implementation: 08-08-24)***

**§483.70(*j*) Disclosure of ownership.**

**§483.70(*j*)(1) The facility must comply with the disclosure requirements of §420.206 and 455.104 of this chapter.**

**§483.70(*j*)(2) The facility must provide written notice to the State Agency responsible for licensing the facility at the time of change, if a change occurs in—**

**(i) Persons with an ownership or control interest, as defined in §§420.201 and 455.101 of this chapter;**

**(ii) The officers, directors, agents, or managing employees;**
**(iii) The corporation, association, or other company responsible for the management of the facility; or**
**(iv) The facility's administrator or director of nursing.**

**§483.70(*j*)(3) The notice specified in paragraph (*j*)(2) of this section must include the identity of each new individual or company.**

The following hyperlinks are included for surveyor reference only.
42 CFR §420.201 Disclosure of Ownership and Control: Definitions
42 CFR §420.206 Disclosure of Persons Having Ownership, Financial, or Control Interest
42 CFR §455.101 Disclosure of Information by Providers and Fiscal Agents: Definitions
42 CFR §455.104 Disclosure by Medicaid Providers and Fiscal Agents: Information on Ownership and Control

## F845

***(Rev. 225; Issued: 08-08-24; Effective: 08-08-24; Implementation: 08-08-24)***

**§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 Regional Office (CMS RO) to ensure that appropriate procedures are implemented.

In a situation in which notice requirements were not met by the previous or current administrator, the State Survey Agency and the CMS RO may take action against the administrator as permitted under §488.446. Refer to Chapter 7 of the State Operations Manual for more information on enforcement actions in these situations.

For all impending closures, the facility needs to submit its closure plan to the State Survey Agency for review and approval. The closure plan must contain the information necessary to identify the steps for a safe and orderly facility closure, including the transfer, discharge or relocation of all residents and identify the individual(s) responsible for ensuring the plans and procedures are successfully carried out.

If CMS or the State Medicaid Agency involuntarily terminates the facility's participation in the Medicare and/or Medicaid programs, the facility's notifications must be no later than the date specified by CMS or the State Medicaid Agency. Notice must still be given if the facility remains open but CMS or the State Medicaid Agency involuntarily terminates the facility's participation in the Medicare and/or Medicaid programs.

In addition, the administrator or someone acting on behalf of the administrator should notify in writing, prior to the impending closure of the facility, the:

- Facility's Medical Director;

- Residents' primary physician;
- CMS Regional Office (RO ); and
- State Medicaid Agency.

Although not required, facilities are encouraged to provide notice to other entities that are impacted, such as employees, union representatives, vendors, community partners, hospitals, home health agencies, dialysis facilities and other providers as early as possible.

The facility's notifications should be developed with input from the facility's medical director and other management staff, and include details from the closure plan for the safe and orderly transfer, discharge or adequate relocation of all residents.

In addition to written notification, facility staff should discuss this information with residents, their families and/or legal representatives in order to provide a better understanding of the closure and their rights. Notice of facility closure to residents and their legal or other responsible parties must be provided in a language and manner they understand.

Facility staff should make every possible effort to lessen transfer trauma for residents, which may include:

- Reviewing the resident's care routines, needs, and preferences with staff at the receiving facility who will be caring for the resident, and
- Assisting residents and or their representatives with obtaining information required to make an informed decision about facility relocation.

Also refer to §483.15(c) Transfer and discharge requirements.

The notice must include:

- The name, address, and telephone number of the State LTC ombudsman;
- For residents with developmental disabilities, the mailing address and telephone number of the agency responsible for the protection and advocacy of developmentally disabled individuals established under Part C of the Developmental Disabilities Assistance and Bill of Rights Act; and
- For residents with mental illness, the mailing address and telephone number of the agency responsible for the protection and advocacy of individuals with mental illness established under the Protection and Advocacy for Mentally Ill Individuals Act.

In addition, the notice should include contact information for the primary facility contact(s) responsible for the daily operation and management of the facility during the facility's closure process.

**KEY ELEMENTS OF NONCOMPLIANCE**

To cite deficient practice at F845, the surveyor's investigation will generally show that the facility failed to do any one of the following:

- Provide prior notice of an impending closure to the appropriate parties as required; **or**
- Ensure no new residents continued to be admitted to the facility on or after the date of the notice of impending closure was submitted; **or**
- Ensure residents were transferred, discharged or relocated to the most appropriate and available facility or other setting in terms of quality, services, and location, taking into consideration the needs, choice, and best interests of each resident.

## F846

***(Rev. 225; Issued: 08-08-24; Effective: 08-08-24; Implementation: 08-08-24)***

**§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 Regional Office (RO), the State Medicaid Agency, and staff responsible for providing care and services to residents;
- How facility staff will identify available settings in terms of quality, services, and location, by taking into consideration each resident's individual needs, choices, and best interests. The facility may not close until all residents are transferred, relocated or discharged in a safe and orderly manner to the most appropriate setting; and
- Assurance that no new residents will be admitted to the facility on or after the date that the written notice of impending closure was provided to the State Survey Agency;

To ensure resident safety during a facility closure or termination of a facility's Medicare and/or Medicaid Provider Agreement, the policies and procedures should also address:

- How facility staff will ensure that all pertinent information about each resident is communicated to the receiving provider in accordance with §483.15(c)(2)(iii), and each resident's complete medical record information including archived files, Minimum Data Set (MDS) assessments, and all orders, recommendations or guidelines from the resident's attending physician;
- In addition to the administrator, the primary contact(s) responsible for the daily operation and management of the facility during the facility's closure process;
- The roles and responsibilities of the facility's owners, administrator, or their replacement(s) or temporary managers/monitors during the closure process, and their contact information;
- Provisions for ongoing operations and management of the facility and its residents and staff during the closure process that include:

    - Payment of salaries and expenses to staff, vendors, contractors, etc.;
    - Continuation of appropriate staffing and resources to meet the needs of each resident, including the provision of medications, services, supplies, and treatments as ordered by the resident's physician/practitioner;
    - Ongoing accounting, maintenance, and reporting of resident personal funds; and
    - Labeling, safekeeping and appropriate transfer of resident's personal belongings, such as clothing, medications, furnishings, etc. at the time of transfer or relocation, including contact information for missing items after the facility has closed.

The facility's policies and procedures should also consider certain provisions to prepare residents to ensure a safe and orderly transfer from the facility. These provisions include, but are not limited to:

- Interviewing residents and their legal or other responsible parties, to determine each resident's goals, preferences, and needs in planning for the services, location, and setting to which they will be moved;
- Offering each resident (in a manner and language understood by the resident) the opportunity to obtain information regarding their community options, including setting and location;
- Providing residents with information or access to information pertaining to the quality of the providers and/or services they are considering; psychological preparation or counseling of each resident as necessary; and
- Making every reasonable effort to accommodate each resident's goals, preferences and needs regarding receipt of services, location, and setting.

**PROCEDURES §483.70(*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. 225; Issued: 08-08-24; Effective: 08-08-24; Implementation: 08-08-24)***

**§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) - F622, 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), F622 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.

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[1] *Adapted from American Bar Association. "Dispute Resolution Processes: Arbitration." Americanbar.org,*

*Accessed 1/6/2021)*

[2] *Adapted from American Bar Association. "Dispute Resolution Processes: Arbitration." Americanbar.org, Accessed 1/6/2021)*

# F848 Arbitrator/Venue Selection and Retention of Agreements

*(Rev. 225; Issued: 08-08-24; Effective: 08-08-24; Implementation: 08-08-24)*

**§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*)(2) The facility must ensure that . . .**

**(iii) The agreement provides for the selection of a neutral arbitrator agreed upon by both parties; and**

**(iv)The agreement provides for the selection of a venue that is convenient to both parties. . .**

**§483.70(*m*)(6) When the facility and a resident resolve a dispute through arbitration, a copy of the signed agreement for binding arbitration and the arbitrator's final decision must be retained by the facility for 5 years after the resolution of that dispute on and be available for inspection upon request by CMS or its designee.**

**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 provide a neutral and fair arbitration process by ensuring both the resident or his or her representative, and the facility agree on the selection of a neutral arbitrator, and that the venue is convenient to both parties. In addition, the requirement to retain a copy of the signed agreement for binding arbitration and the arbitrator's final decision enables CMS to ensure that CMS can fully evaluate quality of care complaints that are addressed in arbitration and assess the overall impact of these agreements on the safety and quality of care provided in long-term care facilities.

## DEFINITIONS

**Arbitrator**: A third party who resolves a dispute between others by arbitration and pursuant to an arbitration agreement. Arbitrators are decision makers, with procedures set by the arbitration agreement and state law, except they may not be required to follow federal or state rules of evidence and their decisions may not be reviewable by a court absent extraordinary circumstances.

**Convenient Venue**: A location in which to carry out arbitration proceedings which should be agreed upon and suitable to both parties.

**Neutral Arbitrator**: An impartial, or unbiased third-party decision maker, contracted with, and agreed to by both parties to resolve their dispute.

**GUIDANCE**

The requirement at §483.70(*m*)(2)(iii) states **"the facility must ensure that the agreement provides for the selection of a neutral arbitrator agreed upon by both parties."** Facilities wishing to utilize binding arbitration agreements should make reasonable efforts to ensure that any arbitration agreement entered into with a resident or his or her representative provides for the selection of an arbitrator who is impartial, unbiased, and without the appearance of a conflict of interest. This ensures the integrity of the arbitration process, and also ensures that residents who choose this alternative dispute resolution are treated with the same fairness they would have if they chose to litigate.

Facilities may put forward suggestions for the use of specific arbitrators for residents (or their representatives) to select. The resident or his or her representative is not obligated to use the arbitrator (either an arbitration services company or an individual arbitrator) suggested by the facility, and may suggest an alternative arbitrator of their choosing. Facilities are expected to make a reasonable attempt to come to agreement with the resident or resident's representative on the selection of a neutral arbitrator and provide a fair process for selecting an arbitrator or arbitration services company.

To ensure a neutral arbitrator is selected, the facility should avoid even the appearance of bias, partiality, or a conflict of interest, and should promptly disclose to the resident or his or her representative the extent of any relationship which exists with an arbitrator or arbitration services company, including how often the facility has contracted with the arbitrator or arbitration service, and when the arbitrator or arbitration service has ruled for or against the facility.

The requirement at §483.70(*m*)(2)(iv) states **"the facility must ensure the agreement provides for the selection of a venue that is convenient to both parties."** The binding arbitration agreement **must** allow for the selection of a venue that is suitable in meeting the needs of both the resident or his or her representative, and the facility. The venue should be agreed upon by both parties. The venue is the geographical location of the arbitration proceeding that may be chosen, in part, on the basis of convenience. Convenience for the resident or resident's representative may be determined by his or her needs in terms of ability to get to the venue.

The requirements at §483.70(*m*)(6) state that **"when the facility and a resident resolve a dispute through arbitration, a copy of the signed agreement for binding arbitration and the arbitrator's final decision must be retained by the facility for 5 years after the resolution of that dispute on and be available for inspection upon request by CMS or its designee."** When a dispute is resolved through arbitration, facilities are accountable and responsible for retaining a copy of the signed binding arbitration agreement and final decision for a period of 5 years following resolution of the arbitrated dispute. These records must be made available for review to surveyors upon request.

**NOTE**: It is important for surveyors to focus on the record retention requirement, not the content of the arbitration agreement or final decision(s) in determining compliance with this requirement.

**PROCEDURES AND PROBES §483.70(*m*)(2)(iii) & (iv)**

Surveyors should verify with the facility whether arbitration agreements are used to resolve disputes. If so, determine compliance with F848 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 or Representative(s):** Interview the resident or their representative to determine the process for selecting a neutral arbitrator and convenient venue. Ask:

- How were you included in selecting the arbitrator?
- Were you given a choice in arbitrator?
- Were you given an opportunity to suggest an arbitrator?
- Do you agree with the arbitrator that was selected?
- Was more than one arbitrator suggested?
- Was a list of arbitrators to select from provided or alternatively were you made aware of how to search for arbitration companies?
- What did the facility tell you about the arbitrator or arbitration services company?
- Are you aware of any relationship or association between the facility and the arbitrator?
- How were you included in selecting the venue?
- Were you given a choice in venue?
- Was the agreed upon venue convenient to you and/or your representative?
- When were the arbitrator and venue selected? Under what circumstances?
- Did the facility reject any of your preferred arbitrators or venues? Why?
- Are you aware whether or not the facility used the same arbitrator or company in the past?

**b. Resident Council/Family Council:** For facilities having resident and/or family councils and 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:

- Are you aware of any concerns about the selection of a neutral arbitrator and/or the selection of a convenient venue? (Remind residents not to share personal, private information in the group setting.)

**c. Facility Staff:** Interview the facility staff responsible for facilitating the selection of a neutral arbitrator and convenient venue. Ask:

- How do you ensure that the resident or his or her representative has an equal role in selecting a neutral arbitrator?
- What is your process for selecting a neutral arbitrator?
- How do you ensure that the resident or his or her representative has an equal role in selecting a convenient venue?
- What is your process for selecting a convenient venue?
- When a resident or his or her representative do not agree with the arbitrator and/or venue, what are the next steps?
- How does the agreement provide for the selection of the arbitrator is agreed upon by both parties? What is the facility's policy on retention of the signed binding arbitration agreements and the final dispute documentation?
- When, and under what circumstances, do you approach residents or their representatives about selecting an arbitrator or venue?
- Are there any active complaints or grievances regarding the selection of an arbitrator or venue? How are you addressing these concerns?
- What information do you provide residents or their representatives regarding specific arbitrators or arbitration services companies (i.e., regarding parent corporation/owners using specific arbitration company)?
- Have you used more than one arbitrator/arbitration services company in the past few years? How many times have you contracted with the same company?

**d. State Long Term Care Ombudsmen (if available):** Interview the representative of the State Long-Term Care Ombudsman who serves resident of the facility. Ask:

- Did any resident or his or her representative ask your assistance to select an arbitrator or venue?
- Did any resident or his or her representative complain to you that he/she was forced or pressured to select a particular arbitrator/arbitration company or venue?
- Did any resident or his or her representative report that an arbitrator and/or venue was pre-selected (i.e., the resident or his or her representative did not have an opportunity to agree to an arbitrator and/or venue)?
- Did any resident or his or her representative complain the venue was inconvenient to them?

**Record Review:** Review the binding arbitration agreement, any other pertinent information relevant to the selection of the arbitrator and venue as well as the arbitrator's final decision after resolution of a dispute (if applicable) to identify the following:

- Is there evidence that the resident or his or her representative were provided with the opportunity to select a neutral arbitrator?
- Is there evidence that the resident or his or her representative were provided with the opportunity to select a convenient venue?
- Is there evidence the facility retained a copy of the signed agreement for binding arbitration and the arbitrator's final decision, after the resolution of a dispute through arbitration for five (5) years?

**KEY ELEMENTS OF NON-COMPLIANCE**

To cite deficient practice at F848, the surveyor's investigation will generally show that the facility failed to do **any one or more** of the following:

- Ensure that the arbitration agreement specifically provides for the selection of a neutral arbitrator; or
- Ensure that the arbitration agreement specifically provides for the selection of a venue that is convenient; or

For disputes resolved by arbitration, the facility failed to:

- Retain a copy of the signed agreement for binding arbitration and the arbitrator's final decision (for disputes resolved by arbitration) after the facility and a resident or their representative resolve a dispute through arbitration for five (5) years; or
- Refuse to make the signed agreement or final decision available for inspections upon request by CMS or its designee.

**Guidance on Identifying Noncompliance at F848:** In some cases, a resident or his or her representative may not be able to recall all the specifics about the selection of a neutral arbitrator or convenient venue. If a resident or their representative cannot recall the details of the selection of a neutral arbitrator or a convenient venue, this alone may not necessarily indicate noncompliance. However, if several residents do not recall the process of selecting a neutral arbitrator, or a convenient venue, the surveyor should conduct further investigation.

Conversely, if a resident or his or her representative actively asserts or complains that there is no process for the selection of a neutral arbitrator or a convenient venue to both parties, this **likely** constitutes 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 F848:** When determining the severity of noncompliance at F848, 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 F848 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.

If the surveyor identifies noncompliance at F848 for the failure to retain signed arbitration agreements and/or the arbitrator's final decision for residents that have resolved a dispute through arbitration for 5 years, Severity Level 1 may be the appropriate severity level for this regulatory requirement.

In other cases, noncompliance at the other requirements at F848 (failure for the agreement to provide for the selection of a neutral arbitrator or convenient location) would likely be cited at severity level 2, No Actual Harm with Potential for More than Minimal Harm that is not Immediate Jeopardy.

If the surveyor identifies that noncompliance at F848 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 State Operations Manual (SOM) Appendix Q for further information.

**Guidance on Correcting Noncompliance at F848:** When noncompliance exists at F848, the Plan of Correction (POC) is expected to include the required elements as identified in the SOM, Chapter 7, at 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 with F848, indicating a complete disregard or unawareness of the requirements, such as agreements, which make no provision for the selection of a neutral arbitrator or convenient venue, CMS has the following expectations (in addition to the requirements for POCs listed above) with regard to the accepted POC:

- The POC must ensure that all arbitration agreements allow for the selection of a neutral arbitrator and convenient venue; and
- There must be a process to ensure records are retained for 5 years.

## F849

***(Rev. 225; Issued: 08-08-24; Effective: 08-08-24; Implementation: 08-08-24)***

**§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:** Always observe for visual cues of psychosocial distress and harm (see Appendix P, Guidance on Severity and Scope Levels and Psychosocial Outcome Severity Guide).

If a concern is identified during the survey regarding hospice care and/or the timeliness of the hospice services, the survey team should review how the nursing home's QAA committee is monitoring the provision of hospice services, such as monitoring the response by the hospice for the timely provision of care, including onsite visits by hospice staff during a crisis or change in the resident's condition.

If noncompliance is identified related to the written agreement, cite at F849. If noncompliance is identified related to quality of care, cite at F685, Quality of Care.

**DEFICIENCY CATEGORIZATION**

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

    - The failure of the facility to assure that the resident received hospice care and services based upon a written agreement with a Medicare-certified hospice. For example, a deficiency was cited at Severity Level 4, at F697, when the resident has severe uncontrolled pain, or F675, acute respiratory distress and at F849, the facility fails to contact and consult with the hospice as per the written agreement for a change in condition.
    - The facility failed to establish a written agreement with a Medicare-certified hospice that was allowed to provide hospice services in the nursing home. In this example, a deficiency was cited at Severity Level 4, at F697, when the resident was administered medication for pain management by the hospice, and due to lack of coordination, the nursing home, unaware of the administration of the medication, also administered pain medication resulting in an overdose of opioids and hospitalization due to acute respiratory failure, and at F849, the facility failed to establish a written agreement with a Medicare-certified hospice that was allowed to provide hospice services in the nursing home, resulting in the lack of coordination.

- **Examples of Level 3 - Actual harm (physical or psychological) that is not immediate jeopardy include but are not limited to:**

    - The failure of the facility to assure that the resident received hospice care and services based upon a written agreement with a Medicare-certified hospice. For example, a deficiency was cited at Severity Level 3, at F697, when the resident has experienced pain that compromised his/her function (physical and/or psychosocial) and/or ability to reach his/her highest practicable well-being as a result of the facility's failure to recognize or address the situation, or failure to develop, implement, monitor, or modify a pain management plan to try to meet the resident's needs. For example, the pain was intense enough that the resident experienced recurrent insomnia, or reduced ability to move and perform ADLs, or a decline in mood or reduced ability to communicate/socialize with family and/ or participation in activities; and at

F849, the facility failed to contact and consult with the hospice as per the written agreement for reviewing the resident's care plan for pain management.
    - At F849, the facility failed to establish a written agreement with a Medicare-certified hospice that was allowed to provide hospice services in the nursing home. In addition, the facility failed to contact and consult with the hospice for concerns related to significant changes in the resident's physical condition or need to alter the plan of care which is a component of the written agreement regulation. For example, a deficiency was cited at Severity Level 3, at F697, when a resident experienced significant episodic pain (that was not all-consuming or overwhelming but was greater than minimal discomfort to the resident) related to care/treatment such as prior to wound care, exercise or physical therapy. The facility failed to involve the hospice and failed to develop, implement, monitor, or modify pain management interventions.

- **Examples of Level 2 - No actual harm with a potential for more than minimal harm that is not immediate jeopardy include but are not limited to:**

    - The failure of the facility to assure that the resident received hospice care and services based upon a written agreement with a Medicare-certified hospice. For example, a deficiency was cited at Severity Level 2, at F697, when the resident was on a pain management program utilizing opioids. The resident was experiencing episodic minimal discomfort and the facility failed to consult with the hospice regarding the bowel management plan as identified in the coordinated plan of care. The facility was cited at F849 for failure to contact and consult with the hospice as per the written agreement for communicating with the hospice for review and possible revision of the resident's care plan.
    - At F849, the facility failed to establish a written agreement with a Medicare-certified hospice that was allowed to provide hospice services in the nursing home. In addition, the facility failed to contact and consult with the hospice for concerns related to a need to alter the plan of care which is a component of the written agreement regulation. For example, a deficiency was cited at Severity Level 2, at F697, when a resident experienced daily or less than daily discomfort with no compromise in physical, mental, or psychosocial functioning as a result of the facility's failure to adequately recognize or address the pain management. The resident was able to participate in ADL's and/or activities of choice. The facility failed to involve the hospice in developing, implementing, monitoring, or modifying pain management interventions.
    - The facility failed to assure that the written agreement met one or more of the regulatory specifications resulting in the potential for negative resident outcomes.

- **An example of Level 1 - No actual harm with a potential for minimal harm includes but is not limited to:**

- There are components of the written agreement that were not met but they may have minimal impact to the resident. Failure to meet these elements will be cited at severity level 1. For example: The facility failed to implement provisions of the agreement regarding bereavement services for the LTC.

**POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION §483.70(*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.

## F850

***(Rev. 225; Issued: 08-08-24; Effective: 08-08-24; Implementation: 08-08-24)***

**§483.70(*o*) Social worker.**
**Any facility with more than 120 beds must employ a qualified social worker on a full-time basis. A qualified social worker is:**

**§483.70(*o*)(1) An individual with a minimum of a bachelor's degree in social work or a bachelor's degree in a human services field including, but not limited to, sociology, gerontology, special education, rehabilitation counseling, and psychology; and**

**§483.70(*o*)(2) One year of supervised social work experience in a health care setting working directly with individuals.**

**GUIDANCE §483.70(*o*)**

The regulations do not require a Social Worker when a facility has equal to or less than 120 beds.

If the facility has more than 120 beds and its full-time social worker does not provide on-site coverage on a full-time basis determine how these services are provided to meet the individual needs of the resident whenever needed. If social services deficiencies are identified refer to §483.40(d), F745, regardless of the number of beds.

**KEY ELEMENTS OF NONCOMPLIANCE**

To cite deficient practice at F850, the surveyor's investigation will generally show that the facility failed to do any one of the following:

- A facility with more than 120 beds did not employ a qualified social worker on a full-time basis; **or**
- The individual functioning as the social worker did not meet the qualifications specified in this regulation.

## F851

***(Rev. 225; Issued: 08-08-24; Effective: 08-08-24; Implementation: 08-08-24)***

**§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 §483.70(*p*)**

To ensure that long-term care facilities are electronically submitting direct care staffing information (including agency and contract staff) per day, based on payroll and other verifiable and auditable data. The staffing hours, when combined with census information, can then be used to not only report on the level of staff in each nursing home, but also to report on employee turnover and tenure.

**GUIDANCE §483.70(*p*)**

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.

The surveyors can obtain PBJ data from the Certification And Survey Provider Enhanced Reports (CASPER) report to determine if the facility submitted the required staffing information based on payroll data in a uniform format**. The facility's failure to submit PBJ data as required will be reflected on their CASPER report and result in a deficiency citation.**

If concerns were identified based on the CASPER report, or from any other source, refer to the critical element pathway "Sufficient and Competent Staffing."
Refer to the CMS Electronic Staffing Data Submission Payroll-Based Journal Policy Manual for submission guidelines. Please see the following link for more information: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Staffing-Data-Submission-PBJ.html
For questions related to F851, surveyors, providers, or other stakeholders should email NHStaffing@cms.hhs.gov.

**KEY ELEMENTS OF NONCOMPLIANCE**
To cite deficient practice at F851, the surveyor's investigation will generally show that the facility failed to do any one of the following:

- Complete data for the entire reporting period, such as hours paid for all required staff, each day; **or**
- Provide accurate data; **or**
- Provide data by the required deadline; or,

- Submit the required staffing information based on payroll data in a uniform format.

Noncompliance at F851 focuses on the submission of staffing data. If the surveyor identifies concerns related to sufficient staffing, surveyors would investigate these concerns using the Sufficient and Competent Staff Critical Element Pathway, and guidance at §483.35 Nursing Services (F725 & F727).

## *F867*

***(Rev. 225; Issued: 08-08-24; Effective: 08-08-24; Implementation: 08-08-24)***

**§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 §483.7*1* 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 §483.7*1*. 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:**

**(ii) Develop and implement appropriate plans of action to correct identified quality deficiencies;**
**(iii) Regularly review and analyze data, including data collected under the QAPI program and data resulting from drug regimen reviews, and act on available data to make improvements.**

**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"**: A written and implemented plan of action for correcting or improving performance in response to an identified quality deficiency. Use of the term corrective action in this guidance is not synonymous with a Plan of Correction (formal response to cited deficiencies). This is also separate from the written QAPI plan.

**"High-risk areas":** 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":** Refers to care or service areas performed frequently or affecting a large population, thus increasing the scope of the problem, e.g., transcription of orders; medication administration; laboratory testing.

**"Incidence":** is 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":** 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":** is a deviation from the process of care, which may or may not cause harm to the resident.

**"Near Miss":** is 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":** is 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)":** Nursing home QAPI is the coordinated application of two mutually-reinforcing aspects of a quality management system: Quality Assurance (QA) and Performance Improvement (PI). QAPI takes a systematic, interdisciplinary, comprehensive, and data-driven approach to

maintaining and improving safety and quality in nursing homes while involving residents and families, and all nursing home caregivers in practical and creative problem solving.

- **Quality Assurance (QA):** QA is the specification of standards for quality of care, service and outcomes, and systems throughout the facility for assuring that care is maintained at acceptable levels in relation to those standards. QA is on-going and both anticipatory and retrospective in its efforts to identify how the organization is performing, including where and why facility performance is at risk or has failed to meet standards.
- **Performance Improvement (PI):** PI (also called Quality Improvement - QI) is the continuous study and improvement of processes with the intent to improve services or outcomes, and prevent or decrease the likelihood of problems, by identifying opportunities for improvement, and testing new approaches to fix underlying causes of persistent/systemic problems or barriers to improvement. PI in nursing homes aims to improve facility processes involved in care delivery and enhanced resident quality of life. PI can make good quality even better.

**"Quality Deficiency (or Opportunity for Improvement)":** A deviation in performance resulting in an actual or potential undesirable outcome, or an opportunity for improvement. A quality deficiency is anything the facility considers to be in need of further investigation and correction or improvement. Examples include problems such as medical errors and accidents, as well as improvement opportunities such as responses to questionnaires showing decreased satisfaction. This term is not necessarily synonymous with a noncompliance deficiency cited by surveyors, but may include issues related to deficiencies cited on annual or complaint surveys.

**"Systematic":** describes a step by step process that is structured, so that it can be replicated.

**"Systemic":** 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.

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.

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 (§483.7*1*).

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.

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.

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:<br>• Pneumonia<br>• 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:<br>• Surgical Site Infections (SSIs)<br>• 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)<br>• Catheter Associated UTIs (CAUTIs)<br>• UTIs (non-catheter associated) |
| Bleeding related to use of antithrombotic medication | Respiratory distress related to inadequate monitoring and provision of tracheostomy/ventilator care | Infectious diarrhea<br>• Clostridium difficile<br>• Norovirus |

| Potentially Preventable Events Related to: | | |
|---|---|---|
| | | |
| 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 guidelines 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 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.

**Examples of Level 3, actual harm that is not immediate jeopardy include, but are 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.

## F868

***(Rev. 225; Issued: 08-08-24; Effective: 08-08-24; Implementation: 08-08-24)***

**§483.75(g) Quality assessment and assurance.**
**§483.75(g) Quality assessment and assurance.**
**§483.75(g)(1) A facility must maintain a quality assessment and assurance committee consisting at a minimum of:**

**(i) The director of nursing services;**
**(ii) The Medical Director or his/her designee;**
**(iii) At least three other members of the facility's staff, at least one of who must be the administrator, owner, a board member or other individual in a leadership role; and**
**(iv) The infection preventionist.**

**§483.75(g)(2) The quality assessment and assurance committee reports to the facility's governing body, or designated person(s) functioning as a governing body regarding its activities, including implementation of the QAPI program required under paragraphs (a) through (e) of this section. The committee must:**

**(i) Meet at least quarterly and as needed to coordinate and evaluate activities under the QAPI program, such as identifying issues with respect to which quality assessment and assurance activities, including performance improvement projects required under the QAPI program, are necessary.**

**§483.80(c) Infection Preventionist participation on quality assessment and assurance committee.**

**The individual designated as the IP, or at least one of the individuals if there is more than one IP, must be a member of the facility's quality assessment and assurance committee and report to the committee on the IPCP on a regular basis.**

## DEFINITIONS

**"Infection Preventionist (IP)":** Term used for the person(s) designated by the facility to be responsible for the infection prevention and control program**.** (Please refer to F882 for further information on the IP.)

**"Non-physician practitioner (NPP):** A nurse practitioner (NP), clinical nurse specialist (CNS), or physician assistant (PA).

**"Regular basis":** for the purpose of the infection preventionist reporting requirement, reporting should occur at the same frequency as the QAA committee meetings.

## GUIDANCE

### QAA Committee

QAA committee responsibilities include identifying and responding to quality deficiencies throughout the facility, and oversight of the QAPI program when fully implemented. Additionally, the committee must develop and implement corrective action, and monitor to ensure performance goals or targets are achieved, and revising corrective action when necessary.

The committee should be composed of staff who understand the characteristics and complexities of the care and services delivered by each unit, and/or department. The QAA Committee must be composed of, at a minimum:

- The director of nursing (DON),
- The Medical Director or his/her designee,
- The Infection Preventionist (IP), and
- At least three other staff, one of whom must be the facility's administrator, owner, board member, or other individual in a leadership role who has knowledge of facility systems and the authority to change those systems.

The facility may have a larger committee than required by the regulation. Residents and families may provide a valuable perspective to committee efforts, although their participation is not required. Representation by staff with responsibility for direct care and services provides perspectives that are valuable in identifying, analyzing and correcting problems in resident care areas. Additionally, departments such as maintenance, housekeeping, laundry services, and other service areas such as the business office should be provided opportunities to participate in the committee, when relevant

performance data is discussed. Consideration should be given as to how committee information is provided to and from staff who may not be members of the committee, but whose responsibilities include oversight of departments or services.

As noted above, the Medical Director is a required member of the QAA committee. This requirement stems from the Medical Director's responsibility for the overall medical care provided and the implementation of all resident care policies in the facility. There should be evidence of meaningful participation by the Medical Director in the QAPI program, such as reporting on trends identified during oversight and review of reports such as the report of irregularities from the medication regimen review, and other oversight activities. For additional guidance related to the Medical Director's role, see §483.70(*g*), Medical Director, F841.

The Medical Director's designee must not be another required member, such as the DON, but may be an NPP. The designee must have knowledge of the facility's policies, procedures and practices so that he/she can fully participate and can add value to the QAA committee comparable to the medical director. Having a designee for the QAA committee, does not change or absolve the Medical Director's responsibility to fulfill his or her role as a member of the QAA committee, or his or her responsibility for overall medical care in the facility. In addition, there must be evidence of communication of the content of the meeting to the Medical Director, with his/her acknowledgement of this information. The Medical Director, in conjunction with the QAA committee, may arrange for real-time alternative methods of participation, such as videoconferencing and teleconference calls. For additional guidance related to the Medical Director's responsibilities, see §483.70(*g*) Medical Director, F841.

**Infection Preventionist Participation on Quality Assessment and Assurance (QAA) Committee:**

The IP must be a participant on the facility's QAA committee and report on the IPCP and on incidents (e.g., healthcare-associated infections (HAIs)) identified under the program on a regular basis. Reporting may include, but is not limited to, facility process and outcome surveillance, outbreaks (ongoing and any since the last meeting) and control measures, occupational health communicable disease illnesses (e.g., TB, influenza) and the Antibiotic Stewardship Program (ASP) related to antibiotic use and resistance data. In order to be considered an active participant, the IP should attend each QAA meeting. If the IP cannot attend, another staff member should report on the IP's behalf but this does not change or absolve the IP's responsibility to fulfill the role of QAA committee member or reporting on the IPCP.

NOTE: Refer to §483.80(b), F882 for information on the infection preventionist's responsibilities and qualifications.

**QAA Committee and the Governing Body**

Functioning under the facility's governing body, the QAA committee is responsible for reporting its' activities, including the implementation of the QAPI program, to the governing body or designated person(s) functioning as the governing body.

**Note:** Small facilities might not have a Governing Body; there may only be an administrator who is already a required member of the QAA committee, and therefore, already apprised of QAPI activities.

**Frequency of Meetings**

QAA committee meetings must be held at least quarterly or more often as necessary to fulfill the committee's responsibilities to identify and correct quality deficiencies effectively. The QAA committee determines what performance data will be monitored and the schedule or frequency for monitoring this data. There is no expectation that all performance data will be monitored at each committee meeting, however, the data must be reviewed with enough frequency to enable the committee to know if improvement is needed or if improvement is occurring (for current corrective actions).

**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 guidelines when determining if the facility meets the requirements for, or investigating concerns related to the QAA Committee.

**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 NONCOMPLIANCE**

To cite deficient practice at F868, the surveyor's investigation must generally show that the facility failed to meet any one of the following:

- Establish and maintain a QAA committee;
- Ensure the QAA committee is composed of the required committee members;
- Ensure the QAA Committee reports its activities to the governing body; and/or
- Meet at least quarterly, and with enough frequency to conduct required QAPI activities.

## F880

*(Rev. 225; Issued: 08-08-24; Effective: 08-08-24; Implementation: 08-08-24)*

**§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 §483.7*1* and following accepted national standards;**

**§483.80(a)(2) Written standards, policies, and procedures for the program, which must include, but are not limited to:**

**(i) A system of surveillance designed to identify possible communicable diseases or infections before they can spread to other persons in the facility;**
**(ii) When and to whom possible incidents of communicable disease or infections should be reported;**
**(iii) Standard and transmission-based precautions to be followed to prevent spread of infections;**
**(iv) When and how isolation should be used for a resident; including but not limited to:**
  **(A) The type and duration of the isolation, depending upon the infectious agent or organism involved, and**
  **(B) A requirement that the isolation should be the least restrictive possible for the resident under the circumstances.**
**(v) The circumstances under which the facility must prohibit employees with a communicable disease or infected skin lesions from direct contact with residents or their food, if direct contact will transmit the disease; and**
**(vi) The hand hygiene procedures to be followed by staff involved in direct resident contact.**

**§483.80(a)(4) A system for recording incidents identified under the facility's IPCP and the corrective actions taken by the facility.**

**§483.80(e) Linens. Personnel must handle, store, process, and transport linens so as to prevent the spread of infection.**

**§483.80(f) Annual review. The facility will conduct an annual review of its IPCP and update their program, as necessary.**

**INTENT §483.80(a)(1), (a)(2), (a)(4), (e) and (f)**

The intent of this regulation is to ensure that the facility:

- Develops and implements an ongoing infection prevention and control program (IPCP) to prevent, recognize, and control the onset and spread of infection to the extent possible and reviews and updates the IPCP annually and as necessary. This would include revision of the IPCP as national standards change;

- Establishes facility-wide systems for the prevention, identification, 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.
- **"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 is based on the principle that all blood, body fluids, secretions, excretions except sweat, regardless of whether they contain visible blood, non-intact skin, and mucous membranes may contain transmissible infectious agents. Furthermore, equipment or items in the 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 §§483.80(a)(1), (a)(2), (a)(4), (e), and (f)**

**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 §483.7*1*; 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 §483.7*1* (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 §483.7*1* (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 §483.21(c)(2), Discharge Summary (F661) and §483.15(c)(2)(iii), Transfer and Discharge (F622) for further information on these requirements.

Additionally, as part of the overall IPCP for surveillance, the facility shall establish process and outcome surveillance.

**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.

**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 is 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:

- When a resident has wounds, secretions, or excretions that are unable to be covered or contained; and
- On units or in facilities where, despite attempts to control the spread of the MDRO, ongoing transmission is occurring.

These strategies may differ depending on the prevalence or incidence of the MDRO in the facility and region. For example, additional usage of PPE can be used for residents who do not meet criteria for contact precautions but are infected or colonized with MDROs (or have risk factors for MDRO acquisition). Staff can use gloves and gowns in order to prevent contamination of hands and clothing while performing high-contact

resident care activities that pose the highest risk for MDRO transmission. These high-contact activities include dressing, bathing or providing hygiene, transferring, changing briefs or assisting with toileting, changing linens, or providing any type of device or wound care. Use of additional PPE during resident care would not restrict a resident's ambulation, socialization, and use of common areas and participation in group activities.

**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: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/ucm227935.htm.

An excerpt from this guidance reads:

> "The disinfection solvent you choose should be effective against HIV, Hepatitis C, and Hepatitis B virus. Outbreak episodes have been largely due to transmission of Hepatitis B and C viruses. However, of the two, Hepatitis B virus is the most difficult to kill. Please note that 70% ethanol solutions are not effective against viral bloodborne pathogens and the use of 10% bleach solutions may lead to physical degradation of your device." A list of Environmental Protection Agency (EPA) registered disinfectants can be found at the following website: https://www.epa.gov/pesticide-registration/selected-epa-registered-disinfectants.

Furthermore, "healthcare personnel should consult the manufacturers of blood glucose meters in use at their facilities to determine what products, meeting the criteria specified by the FDA, are compatible with their meter prior to using any EPA-registered disinfectant for disinfection purposes. If manufacturers are unable to provide this information then the meter should not be used for multiple patients."[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 160ºF (71ºC) for 25 minutes; and

- For laundry that is not hot water compatible, low temperature washing at 71 to 77 ºF (22-25 ºC) 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 (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 §483.7*1*] 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.

**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.

**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.

**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.

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# F882

***(Rev. 225; Issued: 08-08-24; Effective: 08-08-24; Implementation: 08-08-24)***

**§483.80(b) Infection preventionist**
**The facility must designate one or more individual(s) as the infection preventionist(s) (IP)(s) who are responsible for the facility's IPCP. The IP must:**

**§483.80(b)(1) Have primary professional training in nursing, medical technology, microbiology, epidemiology, or other related field;**

**§483.80(b)(2) Be qualified by education, training, experience or certification;**

**§483.80(b)(3) Work at least part-time at the facility; and**

**§483.80(b)(4) Have completed specialized training in infection prevention and control.**

**INTENT §483.80(b)**

The intent of this regulation is to ensure that the facility designates a qualified individual(s) onsite, who is responsible for implementing programs and activities to prevent and control infections.

**GUIDANCE**

**Responsibility for the Infection Prevention and Control Program (including the Antibiotic Stewardship Program)**

The facility must designate one or more individuals as the infection preventionist (IP) who is responsible for assessing, developing, implementing, monitoring, and managing the IPCP. The IPCP includes content required in §§483.80(a)(1)-(4), (F880, Infection Prevention and

Control and at F881, Antibiotic Stewardship Program (ASP)). While the IP is responsible for the IPCP, other staff play important roles in infection prevention and control as well as antibiotic stewardship. For example, staff must appropriately implement standard precautions such as hand hygiene and transmission-based precautions. Furthermore, ASP development should include leadership support and accountability via the participation of the medical director, consulting pharmacist, nursing and administrative leadership and therefore, the IP should utilize and work collaboratively with these team members to also implement the ASP. While an ASP is a team effort, the IP is responsible for ensuring the program meets the requirements for ASPs (at §483.80(a)(3), F881). The IP should review and approve infection prevention and control training topics and content, as well as ensure facility staff are trained on the IPCP (for further information, see §483.95(e), F945, Infection Control Training). However, the IP is not required to perform the IPCP training, since some facilities may have designated staff development personnel.

**Primary Professional Training**

The IP must be professionally-trained in nursing, medical technology, microbiology, epidemiology, or other related field.

A professionally-trained nurse must have earned a certificate/diploma or degree in nursing.

A professionally-trained medical technologist (also known as clinical laboratory scientist) must have earned at least an associate's degree in medical technology or clinical laboratory science.

A professionally-trained microbiologist must have earned at least a bachelor's degree in microbiology.

A professionally-trained epidemiologist must have earned at least a bachelor's degree in epidemiology.

Examples of other related fields of training that are appropriate for the role of an IP include physicians, pharmacists, and physician's assistants.

**Qualifications**

The IP must be qualified by education, training, experience or certification. The IP must have the knowledge to perform the role. The IP should remain current with infection prevention and control issues and be aware of national organizations' guidelines as well as those from national/state/local public health authorities (e.g., emerging pathogens). The facility should ensure the individual selected as the IP has the background and ability to fully carry out the requirements of the IP based on the needs of the resident population, such as interpreting clinical and laboratory data. Examples of experience in infection prevention and control may include, but are not limited to, identification of infectious disease processes, surveillance and epidemiologic investigation, and preventing and controlling the transmission of infectious agents. An example of certification is the Certification in Infection Prevention and Control (CIC®) which is conducted by the Certification Board of Infection Control and

Epidemiology, Inc. (CBIC®) and accredited by the National Commission for Certifying Agencies (NCCA).

**IP Hours of Work**

Designated IP hours per week can vary based on the facility and its resident population. Therefore, the amount of time required to fulfill the role must be at least part-time and should be determined by the facility assessment, conducted according to §483.7*1*, to determine the resources it needs for its IPCP, and ensure that those resources are provided for the IPCP to be effective. Based upon the assessment, facilities should determine if the individual functioning as the IP should be dedicated solely to the IPCP. A facility should consider resident census as well as resident characteristics, types of units such as respiratory care units, memory care, skilled nursing and the complexity of the healthcare services it offers as well as outbreaks and seasonality of infections such as influenza in determining the amount of IP hours needed. The IP must have the time necessary to properly assess, develop, implement, monitor, and manage the IPCP for the facility, address training requirements, and participate in required committees such as QAA.

The IP must physically work onsite in the facility. He/she cannot be an off-site consultant or perform the IP work at a separate location such as a corporate office or affiliated short term acute care facility.

**Specialized Training in Infection Prevention and Control**

Infection prevention and control (IPC) training must be sufficient to perform the role of the IP. Specialized training in IPC may include care for residents with invasive medical devices, resident care equipment (e.g., ventilators), and treatment such as dialysis as well as high-acuity conditions. If a facility's resident population changes, the IP should re-evaluate his/her knowledge and skills, and may need to obtain additional training for the change in the facility's scope of care.

An IP must have obtained specialized IPC training beyond initial professional training or education prior to assuming the role. Training can occur through more than one course, but the IP must provide evidence of training through a certificate(s) of completion or equivalent documentation.

CMS recommends specialized training include the following topics:

- Infection prevention and control program overview,
- The infection preventionist's role,
- Infection surveillance,
- Outbreaks,
- Principles of standard precautions (e.g., content on hand hygiene, personal protective equipment, injection safety, respiratory hygiene and cough etiquette, environmental cleaning and disinfection, and reprocessing reusable resident care equipment),
- Principles of transmission-based precautions,
- Resident care activities (e.g., use and care of indwelling urinary and central venous catheters, wound management, and point-of-care blood testing),

- Water management,
- Linen management,
- Preventing respiratory infections (e.g., influenza, pneumonia),
- Tuberculosis prevention,
- Occupational health considerations (e.g., employee vaccinations, exposure control plan, and work exclusions),
- Quality assurance and performance improvement,
- Antibiotic stewardship, and
- Care transitions.

A free online training is available and was developed by a collaboration between CMS and the Centers for Disease Control and Prevention (CDC). The "Nursing Home Infection Preventionist Training Course" is located on CDC's TRAIN website (https://www.train.org/cdctrain/training_plan/3814). Other trainings may be available from entities such as associations, state public health, and universities.

**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, compliance with the infection preventionist requirement at §§483.80(b)(1)-(4) (i.e., role, qualifications, training, and allowed time for the position).

Instances of the facility not implementing transmission-based precautions when indicated should be cited at F880. These findings may support citing F882 as well, in which case the surveyor must also show that the facility did not ensure requirements at §483.80(b) were met. For example, F882 should be cited if the IP was not available to assist staff on multiple occasions with their questions on when transmission-based precautions should be initiated for a resident due to lack of sufficient time to perform the IP role, and this led to noncompliance with F880.

The facility may be cited at an infection control tag such as F880, but not at F882. For example, F882 should not be cited if all requirements at §483.80(b) are met, but a staff member did not clean and disinfect reusable resident care equipment (e.g., blood pressure cuff, thermometer) after use on a resident on transmission-based precautions and it was then used on the next resident, despite proper policies and procedures, staff training, and process surveillance of staff practices addressing this concern.

Conversely, the facility can be cited at F882 although not at F880, F881, or F945 in cases where a surveyor's investigation began with an infection control concern leading to a review of the IP, but in the end did not result in evidence of noncompliance at another infection control tag (e.g., F880, F881) or F945. For example, during the investigation, the surveyor found through record review that the IP did not have specialized training.

Surveyors should utilize the Quality Assessment and Assurance (QAA) and Quality Assurance and Performance Improvement (QAPI) Plan Review Facility Task to determine compliance with §483.80(c), IP participation on QAA committee.

**KEY ELEMENTS OF NONCOMPLIANCE**

To cite deficient practice at F882, the surveyor's investigation will generally show that the facility failed to ensure that the IPCP was overseen by a qualified individual, who:

- Meets the requirement for professional training; or
- Adequately assesses, develops, implements, monitors, and manages the IPCP; or
- Has the appropriate knowledge and skills to care for the IPC needs of the facility's resident population and to be responsible for the IPCP; or
- Has time to perform IP responsibilities; or
- Performs IP duties in the facility; or
- Completed specialized training in IPC.

**DEFICIENCY CATEGORIZATION**
**An example of Level 4, immediate jeopardy to resident health and safety includes, but is not limited to:**

- The facility failed to ensure the IP was qualified by education, training, experience or certification to identify a gastrointestinal outbreak in the facility and implement appropriate control measures. Surveyors identified that the IP did not ensure that appropriate control measures (e.g., transmission-based precautions, environmental cleaning and disinfection) and reporting to public health occurred. As a result, several residents became seriously ill with diarrheal illnesses resulting in dehydration.

**An example of Level 3, actual harm that is not immediate jeopardy includes, but is not limited to:**

- The facility failed to ensure the IP implemented the IPCP appropriately for a case of pediculosis (i.e., head lice) and the resident's roommate also became infested. Per the IPCP and CDC recommendations, the resident should have been placed on contact precautions until 24 hours after the application of an effective treatment. The IP participated in an interview and confirmed that she was aware of the diagnosis but did not ensure contact precautions were initiated.

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

- The facility failed to ensure the IP was performing the duties of the position and was qualified to perform the role. The IP did not ensure the facility had an antibiotic stewardship program. Based on record review, the facility could not provide documentation for an antibiotic stewardship program. During the interview, the IP demonstrated a lack of understanding of an effective program and how to implement an antibiotic stewardship program. Additionally, during the interview, the IP confirmed that she did not have training in antibiotic stewardship.

**An example of Level 1, no actual harm with potential for minimal harm includes, but is not limited to:**

- The facility failed to ensure the IP had appropriate time to perform IP responsibilities. Record review and interview(s) revealed that the IP failed to ensure that the IPCP was reviewed annually. The IP verified that she did not have enough time onsite to update the IPCP by its annual deadline and two months had passed since an update was required. There were no infection control findings outside of annual review and documentation.

**POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION**

- F838: for concerns related to the facility assessment;
- F867: for concerns related to the QAA committee's responsibility to identify or correct quality deficiencies, which may include systemic infection control concerns;
- F868: for concerns related to the QAA committee to include the IP's participation;
- F880: for concerns related to infection prevention and control;
- F881: for concerns related to the antibiotic stewardship program; and
- F945: for concerns related to staff training on the standards, policies, and procedures of the infection prevention and control program.

## F895

***(Rev. 225; Issued: 08-08-24; Effective: 08-08-24; Implementation: 08-08-24)***

**483.85 Compliance and ethics program.**

**§483.85(a) Definitions. For purposes of this section, the following definitions apply: Compliance and ethics program means, with respect to a facility, a program of the operating organization that—**

**§483.85(a)(1) Has been reasonably designed, implemented, and enforced so that it is likely to be effective in preventing and detecting criminal, civil, and administrative violations under the Act and in promoting quality of care; and**

**§483.85(a)(2) Includes, at a minimum, the required components specified in paragraph (c) of this section.**

**High-level personnel means individual(s) who have substantial control over the operating organization or who have a substantial role in the making of policy within the operating organization.**

**Operating organization means the individual(s) or entity that operates a facility.**

**§483.85(b) General rule.**

**Beginning November 28, 2019, the operating organization for each facility must have in operation a compliance and ethics program (as defined in paragraph (a) of this section) that meets the requirements of this section.**

**§483.85(c) Required components for all facilities.**
**The operating organization for each facility must develop, implement, and maintain an effective compliance and ethics program that contains, at a minimum, the following components:**

**§483.85(c)(1) Established written compliance and ethics standards, policies, and procedures to follow that are reasonably capable of reducing the prospect of criminal, civil, and administrative violations under the Act. and promote quality of care, which include, but are not limited to, the designation of an appropriate compliance and ethics program contact to which individuals may report suspected violations, as well as an alternate method of reporting suspected violations anonymously without fear of retribution; and disciplinary standards that set out the consequences for committing violations for the operating organization's entire staff; individuals providing services under a contractual arrangement; and volunteers, consistent with the volunteers' expected roles.**

**§483.85(c)(2) Assignment of specific individuals within the high-level personnel of the operating organization with the overall responsibility to oversee compliance with the operating organization's compliance and ethics program's standards, policies, and procedures, such as, but not limited to, the chief executive officer (CEO), members of the board of directors, or directors of major divisions in the operating organization.**

**§483.85(c)(3) Sufficient resources and authority to the specific individuals designated in paragraph (c)(2) of this section to reasonably assure compliance with such standards, policies, and procedures.**

**§483.85(c)(4) Due care not to delegate substantial discretionary authority to individuals who the operating organization knew, or should have known through the exercise of due diligence, had a propensity to engage in criminal, civil, and administrative violations under the Social Security Act.**

**§483.85(c)(5) The facility takes steps to effectively communicate the standards, policies, and procedures in the operating organization's compliance and ethics program to the operating organization's entire staff; individuals providing services under a contractual arrangement; and volunteers, consistent with the volunteers' expected roles. Requirements include, but are not limited to, mandatory participation in training as set forth at §483.95(f) or orientation programs, or disseminating information that explains in a practical manner what is required under the program.**

**§483.85(c)(6) The facility takes reasonable steps to achieve compliance with the program's standards, policies, and procedures. Such steps include, but are not limited to, utilizing monitoring and auditing systems reasonably designed to detect criminal, civil, and administrative violations under the Act by any of the operating organization's staff, individuals providing services under a contractual arrangement, or volunteers, having in place and publicizing a reporting system whereby any of these individuals could report violations by others anonymously within the operating organization without fear of retribution, and having a process for ensuring the integrity of any reported data.**

**§483.85(c)(7) Consistent enforcement of the operating organization's standards, policies, and procedures through appropriate disciplinary mechanisms, including, as appropriate, discipline of individuals responsible for the failure to detect and report a violation to the compliance and ethics program contact identified in the operating organization's compliance and ethics program.**

**§483.85(c)(8) After a violation is detected, the operating organization must ensure that all reasonable steps identified in its program are taken to respond appropriately to the violation and to prevent further similar violations, including any necessary modification to the operating organization's program to prevent and detect criminal, civil, and administrative violations under the Act.**

**§483.85(d) Additional required components for operating organizations with five or more facilities. In addition to all of the other requirements in paragraphs (a), (b), (c), and (e) of this section, operating organizations that operate five or more facilities must also include, at a minimum, the following components in their compliance and ethics program:**

**§483.85(d)(1) A mandatory annual training program on the operating organization's compliance and ethics program that meets the requirements set forth in §483.95(f).**

**§483.85(d)(2) A designated compliance officer for whom the operating organization's compliance and ethics program is a major responsibility. This individual must report directly to the operating organization's governing body and not be subordinate to the general counsel, chief financial officer or chief operating officer.**

**§483.85(d)(3) Designated compliance liaisons located at each of the operating organization's facilities.**

**§483.85(e) Annual review.**
**The operating organization for each facility must review its compliance and ethics program annually and revise its program as needed to reflect changes in all applicable laws or regulations and within the operating organization and its**

**facilities to improve its performance in deterring, reducing, and detecting violations under the Act and in promoting quality of care.**

## INTENT

To ensure that facilities have in operation an effective compliance and ethics program that uses internal controls to more efficiently monitor adherence to applicable statutes, regulations and program requirements to deter criminal, civil and administrative violations under the Act and promote quality of care for nursing home residents.

## DEFINITIONS

**"Due care"** generally means the care that a reasonable person would use under the same or similar circumstances.[1]

**"Entire staff"** includes all staff employed by the facility or operating organization, individuals providing services under a contractual arrangement, and volunteers, consistent with the volunteers' expected roles.[2]

## GUIDANCE

### Background

On March 16, 2000, the Department of Health and Human Services Office of the Inspector General (OIG) issued their Compliance Program Guidance for Nursing Facilities to promote "a higher level of ethical and lawful conduct throughout the entire health care industry" (65 FR 14289). The OIG previously issued guidance for other segments of the health care industry based on the belief that "a health care provider can use internal controls to more efficiently monitor adherence to applicable statutes, regulations, and program requirements." This guidance also provided the basis for Section 6102(b)(1) of the Patient Protection and Affordable Care Act of 2010 which amended the Act to add section 1128I(b) of the Social Security Act (the Act) requiring Medicare skilled nursing facilities and Medicaid nursing facilities to have a compliance and ethics program. The OIG guidance from 2000 recommended seven elements which should be included in an effective, comprehensive compliance and ethics program that are:

1. Implementing written policies, procedures and standards of conduct
2. Designation of a compliance officer and compliance committee
3. Conducting effective training and education
4. Developing effective lines of communication
5. Enforcing standards through well-publicized disciplinary guidelines
6. Conducting internal monitoring and auditing
7. Responding promptly to detected violations and corrective action

For further information, see the OIG publications regarding compliance and ethics programs in nursing facilities:

- Publication of the OIG Compliance and Ethics Program Guidance for Nursing Facilities (2000): https://oig.hhs.gov/compliance/compliance-guidance/index.asp.
- OIG Supplemental Compliance Program Guidance for Nursing Facilities (2008): https://oig.hhs.gov/compliance/compliance-guidance/index.asp

Common risk areas are mostly associated with the delivery of health care to nursing facility residents, including sufficient staffing, comprehensive care plans, medication management, infection prevention, appropriate use of psychotropic medications and resident abuse, neglect and safety.

Additional risk areas include, but are not limited to, resident rights, fraud prevention, billing and cost reporting, employee screening, resident assessment accuracy, creation and retention of records, falsification and modification of documentation, conflicts of interest, kickbacks, inducements and self-referrals.

The above background information and associated documents are provided as resources.

## REQUIREMENTS FOR ALL FACILITIES

### Compliance and Ethics Program

The operating organization of each facility must have a compliance and ethics program that has been reasonably designed, implemented, maintained and enforced, so that it is likely to be effective in preventing and detecting criminal, civil, and administrative violations under the Act and in promoting quality of care.

It is important for the facility to consider their facility assessment developed according to §483.7*1* in identifying risk areas, developing and maintaining their compliance and ethics program, and determining resources needed for the program.

### Written standards, policies and procedures

The operating organization must have written standards, policies and procedures for its compliance and ethics program, which include at a minimum:

- Designation of an appropriate compliance and ethics program contact to whom an individual can report suspected violations;
- An alternate method of reporting suspected violations anonymously without fear of retribution;
- Disciplinary standards that describe the consequences for committing violations for the entire staff.

### High-level Personnel Oversight

The operating organization must assign specific individuals within the high-level personnel of the organization with the overall responsibility of overseeing adherence to the compliance and ethics program's standards, policies, and procedures.

High-level personnel means individuals who have substantial control over the operating organization or who have a substantial role in the making of policy within the operating organization. The individuals considered ''high-level personnel'' will differ according to each operating organization's structure. Some examples include, but are not limited to, a director; executive officers including the chief executive officer (CEO); members of the board of directors; an individual in charge of a major business or functional unit of the operating organization; or an individual with a substantial ownership interest in the operating organization, as defined in section 1124(a)(3) of the Act.

**Sufficient Resources and Authority**

The program must include provisions ensuring that the specific individual(s) designated with oversight responsibility have sufficient resources and authority to assure compliance with program standards, policies, and procedures. The resources devoted should include both human and financial resources.

**Delegation of Substantial Discretionary Authority**

Organizations must exercise the care that a reasonable person would use under the same circumstances (due care) when delegating substantial discretionary authority to individuals, to ensure that the delegation is not made to an individual who the operating organization knew, or should have known, through the exercise of due diligence, had engaged in or had the predisposition to engage in unethical acts, or potential criminal, civil and/or administrative violations of the Act.

**Effectively Communicating Program Standards, Policies and Procedures**

The facility is required to effectively communicate to the entire staff, the standards, policies and procedures of the compliance and ethics program. Requirements include, but are not limited to, mandatory participation in training, as set forth in §483.95(f), orientation programs, and/or dissemination of information that explains what is required under the program, in a practical manner.

For information on compliance and ethics training requirements, see §483.95(f), (F946).

**Reasonable Steps to Achieve Program Compliance**

The facility must take reasonable steps to achieve compliance with the program's standards, policies and procedures. These steps include, but are not limited to:

1. Utilizing monitoring and auditing systems to detect criminal, civil, and administrative violations under the Act, by any of the facility's entire staff.
2. Publicizing a reporting system whereby any of the organization's entire staff could report violations anonymously within the operating organization without fear of retaliation.
3. Having a process for ensuring the integrity of any reported data.

**Consistent Enforcement through Disciplinary Mechanisms**

The compliance and ethics program must establish appropriate disciplinary mechanisms and effectively communicate those mechanisms, so that the operating organization's entire staff is clearly aware of the consequences of program violations.

The operating organization is required to consistently enforce its standards, policies, and procedures through appropriate disciplinary mechanisms, including, as appropriate, discipline of individuals responsible for failing to detect and report a violation to the appropriate party identified in the organization's compliance and ethics program.

**Response to Detected Violations**

After an operating organization detects a violation, it must ensure that all reasonable steps identified in its program are taken to respond appropriately to the violation and to prevent further similar violations. This includes any necessary modification to the organization's program to prevent and detect criminal, civil, and administrative violations under the Act.

The reasonable steps that should be taken when a violation is detected should be clearly identified in the operating organization's program. Such steps may include a corrective action plan, the return of overpayments, a report to the government and/or or a referral to criminal and/or civil law enforcement authorities. The steps will differ depending upon the size of the operating organization, the position of the individual reporting the violation, and the type of violation. For example, an operating organization's program may state that a staff member should immediately notify their immediate superior when he or she detects a violation. However, if it is the immediate superior or the operating organization's management whom the staff member believes is committing the violation, the staff member should have an alternative process to report the violation, such as, an executive officer of the organization, the Office of the State Long-Term Care Ombudsman or other appropriate agency or law enforcement authority.

Facilities should integrate the information and data they collect or which arises out of their compliance and ethics programs into their Quality Assurance and Performance Improvement (QAPI) program, see §483.75(g)(2)(iii), F868. The QAPI committee should work with the compliance officer to determine if there are trends or patterns of systemic problems.

**Annual review**

As an operating organization becomes aware of changes in laws and/or requirements, it should modify its program to ensure it is current with requirements. The operating organization's performance in prior years should also be used to improve its program. As an operating organization revises its program, it should ensure that those changes are communicated to its entire staff.

## ADDITIONAL REQUIREMENTS FOR OPERATING ORGANIZATIONS WITH FIVE OR MORE FACILITIES

### Mandatory Annual Training

For operating organizations with five or more facilities, the organization must have a mandatory annual training program. The annual training should be delivered in a practical manner based on its resources, the complexity of the operating organization and its facilities and in accordance with compliance and ethics training requirements in §483.95(f), (F946).

### Designated Compliance Officer

Operating organizations that operate five or more facilities must designate a compliance officer for whom the compliance and ethics program is a major responsibility.

The operating organization should ensure that the assigned compliance officer has sufficient time and other resources to fulfill all of his or her responsibilities under the operating organization's compliance and ethics program.

The compliance officer should be able to communicate with the governing body without being subject to any coercion or intimidation. This is to ensure that the compliance officer is not unduly influenced by other managers or executive officers, such as the general counsel, chief financial officer or chief operating officer.

### Designated Compliance Liaison

A designated compliance liaison must be located at each of the operating organization’s facilities. At a minimum, the facility-based liaison should be responsible for assisting the compliance officer with his or her duties under the operating organization’s program at their individual facilities.

## INVESTIGATIVE PROCEDURES

When concerns regarding the compliance and ethics program are identified, use the applicable probes below to assist with investigating and determining compliance.

## PROBES

- Does the operating organization have written standards, policies and procedures

for the compliance and ethics program that are reasonably capable of reducing the possibility of criminal, civil and administrative violations under the Act?

- Interview high-level personnel designated to oversee the organization's compliance and ethics program about their involvement in the program. Determine:
  - how the facility uses monitoring and auditing systems to detect criminal, civil, and administrative violations by staff;
  - if they are aware of the potential violation under investigation and what was their response.
- Ask staff if:
  - they are aware of the facility's compliance and ethics program;
  - there is a method for staff to anonymously report suspected violations;
  - they are confident in reporting compliance matters without fear of retaliation.
- When reports or reasonable suspicions of violations are identified, did the organization take prompt action to respond to the violation and prevent future occurrences, including enforcement of program standards, policies and procedures through disciplinary mechanisms, if appropriate?
- Did the operating organization delegate substantial discretionary authority to an individual it knew or should have known through due diligence, had a propensity to engage in criminal, civil and/or administrative violations?
- Does the operating organization review the program annually and as needed, in response to organization, facility and/or regulatory changes?
- If the operating organization has five or more facilities, have a compliance officer and a facility-based compliance liaison been designated and is mandatory annual training conducted?

## POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION

If a negative or potentially negative resident outcome is determined to be related to the facility's failure to meet compliance and ethics requirements it should also be investigated under the appropriate quality of care or other relevant requirement.

For concerns related to systems of care and management practices, written policies and procedures for feedback, data collections systems, monitoring, analyzing and acting on available data to make improvements, see Quality Assurance and Performance Improvement (QAPI) requirements in §483.75.

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[1] *http://thelawdictionary.org/due-care/ (accessed on April 17, 2015).*

[2] *Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities [CMS–3260–F], 81 FR 68688, at page 68814 (Oct. 4, 2016).*

**§483.90 Physical Environment.**

**The facility must be designed, constructed, equipped, and maintained to protect the health and safety of residents, personnel and the public.**

**§483.90(a) Life safety from fire.**

**§483.90(a)(1) Except as otherwise provided in this section –**

**§483.90(a)(1)(i) The LTC facility must meet the applicable provisions and must proceed in accordance with the Life Safety Code (NFPA 101 and Tentative Interim Amendments TIA 12-1, TIA 12-2, TIA 12-3, and TIA 12-4.)**

**§483.90(a)(1)(ii) Notwithstanding paragraph (a)(1)(i) of this section, corridor doors and doors to rooms containing flammable or combustible materials must be provided with positive latching hardware. Roller latches are prohibited on such doors.**

§483.90(a)(1)(iii) If a facility is Medicare- or Medicaid-certified before July 5, 2016 and the facility has previously used the Fire Safety Evaluation System for compliance, the facility may use the scoring values in the following Mandatory Values Chart:

**Mandatory Values—Nursing Homes**

| | Containment (Sa) | | Extinguishment (Sb) | | People Movement (Sc) | |
|---|---|---|---|---|---|---|
| Zone Location | New | Exist. | New | Exist. | New | Exist. |
| 1st story | 11 | 5 | **15(12)*** | 4 | **8(5)*** | 1 |
| 2nd or 3rd story | 15 | 9 | **17(14)*** | 6 | **10(7)*** | 3 |
| 4th story or higher | 18 | 9 | **19(16)*** | 6 | **11(8)*** | 3 |

* Use ( ) in zones that do not contain patient sleeping rooms.

**§483.90(a)(2) In consideration of a recommendation by the State survey agency or Accrediting Organization or at the discretion of the Secretary, may waive, for periods deemed appropriate, specific provisions of the Life Safety Code, which would result in unreasonable hardship upon a long-term care facility, but only if the waiver will not adversely affect the health and safety of the patients.**

**§483.90(a)(3) The provisions of the Life safety Code do not apply in a State where CMS finds, in accordance with applicable provisions of sections 1819(d)(2)(B)(ii) and 1919(d)(2)(B)(ii) of the Act, that a fire and safety code imposed by State law adequately protects patients, residents and personnel in long term care facilities.**

**§483.90(a)(4) A long-term care facility may install alcohol-based hand rub dispensers in its facility if the dispensers are installed in a manner that adequately protects against inappropriate access.**

**§483.90(a)(5) A long term care facility must:**

**§483.90(a)(5)(i) Install, at least, battery-operated single station smoke alarms in accordance with the manufacturer's recommendations in resident sleeping rooms and common areas.**

**§483.90(a)(5)(ii) Have a program for inspection, testing, maintenance, and battery replacement that conforms to the manufacturer's recommendations and that verifies correct operation of the smoke alarms.**

**§483.90(a)(5)(iii) Exception:**

**§483.90(a)(5)(iii)(A) The facility has system-based smoke detectors in patient rooms and common areas that are installed, tested, and maintained in accordance with NFPA 72, National Fire Alarm Code, for system-based smoke detectors; or**

**§483.90(a)(5)(iii)(B) The facility is fully sprinklered in accordance with NFPA 13, Standard for the Installation of Sprinkler Systems.**

**§483.90(a)(6) A long term care facility must:**

**§483.90(a)(6)(i) Install an approved, supervised automatic sprinkler system in accordance with the 1999 edition of NFPA 13, Standard for the Installation of Sprinkler Systems, as incorporated by reference, throughout the building by August 13, 2013. The Director of the Office of the Federal Register has approved the NFPA 13 1999 edition of the Standard for the Installation of Sprinkler Systems, issued July 22, 1999 for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the Code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269.**

**§483.90(a)(6)(ii) Test, inspect, and maintain an approved, supervised automatic sprinkler system in accordance with the 1998 edition of NFPA 25, Standard for the Inspection, Testing, and Maintenance of Water-Based Fire Protection Systems, as incorporated by reference. The Director of the Office of the Federal Register has approved the NFPA 25, Standard for the Inspection, Testing, and Maintenance of Water-Based Fire Protection Systems, 1998 edition, issued January 16, 1998 for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the Code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this**

**material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269.**

**§483.90(a)(6)(iii) Subject to approval by CMS, a long term care facility may be granted an extension of the sprinkler installation deadline for a time period not to exceed 2 years from August 13, 2013, if the facility meets all of the following conditions:**

**§483.90(a)(6)(iii)(A) It is in the process of replacing its current building, or undergoing major modifications to improve the living conditions for residents in all unsprinklered living areas that requires the movement of corridor, room, partition, or structural walls or supports, in addition to the installation of a sprinkler system; or, has had its planned sprinkler installation so impaired by a disaster or emergency, as indicated by a declaration under section 319 of the Public Health Service Act, that CMS finds it would be impractical to meet the sprinkler installation due date.**

**§483.90(a)(6)(iii)(B) It demonstrates that it has made the necessary financial commitments to complete the building replacement or modification; or pursuant to a declared disaster or emergency, CMS finds it impractical to make reasonable and necessary financial commitments.**

**§483.90(a)(6)(iii)(C) Before applying for the deadline extension, it has submitted plans to State and local authorities that are necessary for approval of the replacement building or major modification that includes the required sprinkler installation, and has received approval of the plans from State and local authorities.**

**§483.90(a)(6)(iii)(D) It agrees to complete interim steps to improve fire safety, as determined by CMS.**

**§483.90(a)(6)(iv) An extension granted under paragraph (a)(8)(iii) of this section may be renewed once, for an additional period not to exceed 1 year, if the following conditions are met:**

**§483.90(a)(6)(iv)(A) CMS finds that extenuating circumstances beyond the control of the facility will prevent full compliance with the provisions in paragraph (a)(8)(i) of this section by the end of the first waiver period.**

**§483.90(a)(6)(iv)(B) All other conditions of paragraph (a)(8)(iii) of this section are met.**

**§483.90(a)(8) When a sprinkler system is shut down for more than 10 hours, the LTC facility must:**

**§483.90(a)(8)(i) Evacuate the building or portion of the building affected by the system outage until the system is back in service, or**

**§483.90(a)(8)(ii) Establish a fire watch until the system is back in service.**

**GUIDANCE: §483.90(a)**
For additional guidance on life safety from fire and the survey procedures for these regulatory requirements, reference Appendix I in the SOM. Concerns regarding the above regulatory provisions would be addressed through the Life Safety Code survey (K-Tags).

**§483.90(b) Standard: Building safety.**

**Except as otherwise provided in this section, the LTC facility must meet the applicable provisions and must proceed in accordance with the Health Care Facilities Code (NFPA 99 and Tentative Interim Amendments TIA 12-2, TIA 12-3, TIA 12-4, TIA 12-5 and TIA 12-6).**

**§483.90(b)(1) Chapters 7, 8, 12, and 13 of the adopted Health Care Facilities Code do not apply to an LTC facility.**

**§483.90(b)(2) If application of the Health Care Facilities Code required under paragraph (b) of this section would result in unreasonable hardship for the LTC facility, CMS may waive specific provisions of the Health Care Facilities Code, but only if the waiver does not adversely affect the health and safety of residents.**

**GUIDANCE: §483.90(b)**
For additional guidance and procedures on building safety reference Appendix I in the SOM.

## F940
***(Rev. 225; Issued: 08-08-24; Effective: 08-08-24; Implementation: 08-08-24)***

**§483.95 Training Requirements**
**A facility must develop, implement, and maintain an effective training program for all new and existing staff; individuals providing services under a contractual arrangement; and volunteers, consistent with their expected roles. A facility must determine the amount and types of training necessary based on a facility assessment as specified at § 483.7*1*. Training topics must include but are not limited to—**

**INTENT**

Facilities are required to develop, implement, and maintain an effective training program for all staff. Appropriately trained staff can improve resident safety, create a more person-centered environment, and reduce the number of adverse events or other resident complications.

CMS recognizes that training needs are likely to change over time. Therefore, it is necessary for facilities to have the flexibility to determine training needs based on its facility assessment. Competencies and skill sets for all new and existing staff, individuals providing services under a contractual arrangement, and volunteers must be consistent with their expected roles. All facility staff needs to be trained to be able to interact in a manner that enhances the resident's quality of life and quality of care and that they can demonstrate competency in the topic areas of the training program. The facility is also expected to keep a record of these trainings. Training requirements should be met prior to staff and volunteers independently providing services to residents, annually, and as necessary based on the facility assessment. See §483.71*(a)* (2)(iv).

CMS does not propose a specific training mechanism to meet the Training Requirements regulation, and the regulation does not specify that a member of the facility must conduct the training activities. Facilities have the flexibility to work with outside entities to provide facilitated training, computer-based training, self-directed learning, mentoring and/or coaching. CMS encourages facilities to leverage community resources to assist with developing training programs, identifying qualified instructors, identifying training materials, and implementing facility training programs.

Based upon the outcome of a facility assessment, suggestions for additional training topics may include, but are not limited to, advance care planning, cultural competence, end-of-life care, geriatrics and gerontology (i.e., understanding of how human beings change as they grow older), substance abuse, working with young and middle-aged adults, grief and loss, interdisciplinary collaboration, person centered care, specialized rehabilitative therapy, trauma informed care, intellectual disability, mental disorder and quality of life and care.

There are various free online training tools and resources that facilities can use to assist them in complying with this requirement. For example, the Agency for Healthcare Research and Quality (AHRQ) released a set of training modules to help educate LTC facility staff on key patient safety concepts to improve the safety of LTC facility residents. (See http://www.ahrq.gov/professionals/systems/long-term-care/resources/facilities/ptsafety/).
Long Term Care Ombudsman can provide in-service trainings to facility staff on a variety of topics. In addition to the web based materials, instructor and student handbooks can be sent to facilities at no additional cost.

For the purposes of this training requirement, staff includes all facility staff, (direct and indirect care functions), contracted staff, and volunteers (training topics as appropriate to role).

**NOTE:** References to non-U. S. Department of Health and Human Services (HHS) sources or sites on the internet are provided as a service and do not constitute or imply endorsement of these organizations or their programs by CMS. CMS is not responsible

for the content of pages found at these sites. URL addresses were current as of the date of this publication.

Surveyors need to consider the facilities compliance for all training requirements at **§483.95**. F940 would be cited as a result of the facility's failure to implement trainings for multiple training topics included at **§483.95**.

## F943

***(Rev. 225; Issued: 08-08-24; Effective: 08-08-24; Implementation: 08-08-24)***

**§483.95(c) Abuse, neglect, and exploitation.**
**In addition to the freedom from abuse, neglect, and exploitation requirements in § 483.12, facilities must also provide training to their staff that at a minimum educates staff on—**

**§483.95(c)(1) Activities that constitute abuse, neglect, exploitation, and misappropriation of resident property as set forth at § 483.12.**

**§483.95(c)(2) Procedures for reporting incidents of abuse, neglect, exploitation, or the misappropriation of resident property.**

**§483.95(c)(3) Dementia management and resident abuse prevention.**

**DEFINITION §483.95(c)**
Staff includes for the purposes of the training guidance, all facility staff, (direct and indirect care and auxiliary functions) contractors, and volunteers.

**GUIDANCE §483.95(c)**
All facilities must develop, implement and permanently maintain an effective training program for all staff, which includes, at a minimum, training on abuse, neglect, exploitation, misappropriation of resident property, and dementia management, that is appropriate and effective, as determined by staff need and the facility assessment (as specified at §483.7*1*).

Changes to the facility's resident population, staff turnover, the facility's physical environment, and modifications to the facility assessment may necessitate ongoing revisions to the facility's training program.

There are a variety of methods that could be used to provide training. For example, staff training may be facilitated through any combination of in-person instruction, webinars and/or supervised practical training hours.

Supervised practical training means training in a setting in which instruction and oversight are provided by a person who has relevant education and/or experience specific to the subject of the training being provided.

All training should support current scope and standards of practice through curricula which detail learning objectives, performance standards and evaluation criteria, and addresses potential risks to residents, staff and volunteers if procedures are not followed. There should be a process in place to track staff participation in the required trainings.

The facility must provide staff orientation and training on the prohibition of all forms of abuse, neglect, and exploitation prohibition. The training must address forms of abuse, neglect, misappropriation of resident property, exploitation and dementia management. Such training would include, but is not limited to:

- Identifying how person-centered thinking, planning, and practice skills contribute to a facility culture of prevention and identification of abuse, neglect, and exploitation
- Identifying and preventing behavior constituting abuse (including injuries from an unknown source), neglect, exploitation, and misappropriation of resident property;
- Identifying physical or psychosocial indicators of abuse (including injuries from an unknown source), neglect, exploitation, and misappropriation of resident property from situations which include, but are not limited to:

    - Verbal, mental, sexual or physical abuse;
    - Taking or using photographs or recordings of residents in a demeaning or humiliating manner and sharing them in any manner, including through the use of technology or social media;
    - Theft of a resident's personal belongings;
    - Involuntary seclusion of a resident;
    - Exploitation of a resident; and
    - Neglect of a resident as demonstrated by a pattern of willfully failing to provide care to a resident(s).

- Facility procedures and Federal and State requirements for reporting abuse, neglect, exploitation, and misappropriation of resident property, including injuries of unknown sources, timeframes for reporting, and to whom staff and others must report their knowledge related to any alleged violation without fear of retaliation;
- Reporting reasonable suspicion of a crime against a resident;
- Educating staff on factors related to dementia care and abuse prevention, such as understanding that expressions or indications of distress of residents with dementia are often attempts to communicate an unmet need, discomfort or thoughts that they can no longer articulate with words. However, they may be perceived as challenging behaviors to staff and could increase the risk of resident abuse and neglect. Expressions or indications of distress can include, but are not limited to:

    - Aggressiveness;
    - Wandering or elopement;
    - Agitation;

    - Yelling out; or
    - Delusions.

- Conflict resolution and anger management skills, including resolving conflicts between staff and residents, visitor and resident, and resident-to-resident conflicts; and

- Identifying and addressing factors that may precipitate abuse/neglect/exploitation, including, but not limited to:

    - Signs of staff burnout, frustration, and stress;
    - Staff prejudices to age, culture, race, religion, and sexual orientation;
    - Gender differences; and
    - Negative attitudes toward working with individuals with disabilities.

While not required, sources of training materials that facilities may want to consider include:

- National Center on Elder Abuse. [On-Line]. Available: https://ncea.acl.gov
- University of Southern California. Training Resources on Elder Abuse. Available: http://trea.usc.edu/

References to non-CMS, non-governmental sources do not constitute or imply endorsement of these organizations or their programs by CMS or the U.S. Department of Health and Human Services and were current as of the date of this publication.

**PROBES §483.95(c)**

If there is a concern that a resident was abused, neglected, or exploited, interview staff and review training records to determine the following:

- Was staff observed working with residents in a manner that indicates a training need?
- Did interviews with residents and/or resident representatives indicate any areas where training was needed?
- What type of training do the staff report receiving about the concern identified by the surveyor?
- What process does the facility have to encourage staff to express concerns and request training in challenging situations? How does the facility respond to staff's concerns and requests?
- Review the training coursework to determine if the content meets professional standards/guidelines and covers relevant facility policy and procedures.
- How does the facility's abuse, neglect, and exploitation training program ensure staff are instructed to meet the requirements of §483.12(b) Develop/Implement Abuse/Neglect, etc. Policies, tag F607?

- How does the facility's policies reflect staff training is in compliance with §483.12 and §483.12(a)(1) Freedom from abuse, neglect, and exploitation, tag F600?
- Verify that the facility has a mandatory requirement that all facility staff participate in an abuse, neglect, and exploitation prevention and dementia management training program, with a process in place to track attendance.
- How does the facility determine when training content requires updating to be consistent with current professional standards and Federal and State regulations?
- How does the facility assess staff to determine if the training has been effective?

**POTENTIAL ADDITIONAL TAGS FOR INVESTIGATION**

For concerns related to the development and implementation of written policies and procedures, that includes training related to abuse, neglect, exploitation, and misappropriation of resident property, see 42 CFR §483.12(b)(3) Develop/Implement Abuse/Neglect, etc. Policies, tag F607.

For concerns related to the reporting of a crime, see 42 CFR §483.12(b)(5), Reporting of Reasonable Suspicion of a Crime, tag F609.

## F947

***(Rev. 225; Issued: 08-08-24; Effective: 08-08-24; Implementation: 08-08-24)***

**§483.95 Training Requirements.**
**Training topics must include but are not limited to—**

**§483.95(g) Required in-service training for nurse aides.**
**In-service training must—**

**§483.95(g)(1) Be sufficient to ensure the continuing competence of nurse aides, but must be no less than 12 hours per year.**

**§483.95(g)(2) Include dementia management training and resident abuse prevention training.**

**§483.95(g)(3) Address areas of weakness as determined in nurse aides' performance reviews and facility assessment at §483.7*1* and may address the special needs of residents as determined by the facility staff.**

**§483.95(g)(4) For nurse aides providing services to individuals with cognitive impairments, also address the care of the cognitively impaired.**

**DEFINITIONS**

A “nurse aide” is defined in §483.5 as 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.

Private duty nurse aides who are not employed or utilized by the facility on a contract, per diem, leased, or other basis, do not come under the nurse aide training provision and therefore are not required to take the training.

Performance Reviews: The process used to evaluate the performance of staff on a periodic basis, which may be annually.

NOTE: See Tag F730-§483.35(d)(7) related to the conduct of performance reviews for every nurse aide at least once every 12 months.

**GUIDANCE §483.95(g)**

All facilities must develop, implement and permanently maintain an in-service training program for nurse aides that is appropriate and effective, as determined by nurse aide performance reviews [see §483.35(d)(7)] and the facility assessment as specified at §483.7*1*. Changes to the facility’s resident population, the facility’s physical environment, staff turnover, and modifications to the facility assessment may necessitate ongoing revisions to the facility’s training program.

There are a variety of methods that could be used to provide training. For example, nurse aide training may be facilitated through any combination of in-person instruction, webinars (though, should not be webinars alone) and/or supervised practical training hours and should be reflective of nurse aides’ performance reviews in order to address identified weaknesses. When able, each nurse aide should be evaluated based on individual performance, and the facility should develop training that can be utilized and beneficial to all nurse aide staff when applicable.

Supervised practical training means training in a setting in which instruction and oversight are provided by a person who has relevant education and/or experience specific to the subject of the training being provided.

All training should support current scope and standards of practice through curricula which detail learning objectives, performance standards and evaluation criteria, and addresses potential risks to residents, staff and volunteers if procedures are not followed. There should be a process in place to track nurse aide participation in the required trainings.

The adequacy of the in-service education program may be measured not only by documentation of hours of completed in-service education, but also by demonstrated

competencies of nurse aide staff through written exam and/or in consistently applying the interventions necessary to meet residents' needs as identified in the facility assessment. Observations of nurse aides that indicate deficiencies in their nurse aide skills may be the result of an inadequate training program and/or inadequate performance review.

A minimum of 12 hours of nurse aide training per year is required under §483.95(g)(1). The training must be sufficient to ensure the continuing competence of the nurse aides, which may require more than 12 hours of training per year to meet identified staff or resident needs.

The survey team does not need to find a negative outcome to cite a deficiency at F947.

**PROCEDURES AND PROBES §483.95(g)**

If there have been deficient care practices identified during the survey, review as appropriate training received by nurse aides in that corresponding subject area. If there is a concern about required in-service training for nurse aides, interview staff and review training records to determine the following:

- Were nurse aides observed working with residents in a manner that indicates a training need?
- Did interviews with residents and/or resident representatives indicate any areas where training was needed?
- What type of training do the nurse aides report receiving about the concern identified by the surveyor?
- Verify the mandatory nurse aide in-service program is no less than 12 hours per year.
- Review facility training records which supports mandatory nurse aide attendance.
- How has in-service education addressed any areas of weakness identified in performance reviews, and any special resident needs, or needs of residents with cognitive impairments?
- How does the facility evaluate nurse aide performance to determine what topics must be included in in-service training to address areas of weakness?
- How does the facility determine when training content must be updated (e.g., in order to remain consistent with current professional standards and guidelines)?
- What process does the facility have to encourage nurse aides to express concerns and request training in challenging situations? How does the facility respond to nurse aide's concerns and requests?
- Does the facility's training address nurse aide training needs to ensure residents attain or maintain the highest practicable physical, mental, and psychosocial well-being as determined by resident assessments and individual plans of care?
- How does the facility assess nurse aides to determine if the training has been effective?

**POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION**

For concerns related to nurse aides not demonstrating competent care of a resident that is independent of or related to the training program, see 42 CFR §483.35(c) Proficiency of Nurse Aides tag F726 for guidance.

## F949

***(Rev. 225; Issued: 08-08-24; Effective: 08-08-24; Implementation: 08-08-24)***

**§483.95 Training Requirements.**

**Training topics must include but are not limited to—**

**§483.95(i) Behavioral health.**
**A facility must provide behavioral health training consistent with the requirements at §483.40 and as determined by the facility assessment at §483.7*1*.**

**GUIDANCE §483.95(i)**
All facilities must develop, implement, and maintain an effective training program for all staff, which includes, at a minimum, training on behavioral health care and services (consistent with §483.40) that is appropriate and effective, as determined by staff need and the facility assessment (as specified at §483.7*1*). For the purposes of this training requirement, staff includes all facility staff, (direct and indirect care functions), contracted staff, and volunteers (training topics as appropriate to role).

Changes to the facility's resident population, staff turnover, the facility's physical environment, and modifications to the facility assessment may require ongoing revisions to the facility's training program.

There are a variety of available methods to provide training, including in-person instruction, webinars, and/or supervised practical training.

Supervised practical training means training in a setting in which instruction and oversight are provided by a person who has relevant education and/or experience specific to the subject of the training being provided.

All training should support current scope and standards of practice through curricula which detail learning objectives, performance standards, and evaluation criteria. There should be a process in place to track staff participation in the required trainings.

A behavioral health training course as determined by the facility assessment should include, at a minimum, the competencies and skills necessary to provide the following:

- Person-centered care and services that reflect the resident's goals for care;
- Interpersonal communication that promotes mental and psychosocial well-being;
- Meaningful activities which promote engagement and positive meaningful relationships;

- An environment and atmosphere that is conducive to mental and psychosocial well-being;
- Individualized, non-pharmacological approaches to care;
- Care specific to the individual needs of residents that are diagnosed with a mental, psychosocial, or substance use disorder, a history of trauma and/or post-traumatic stress disorder, or other behavioral health condition; and
- Care specific to the individual needs of residents that are diagnosed with dementia (CMS Hand in Hand: A Training Series for Nursing Homes is an example of training that addresses this area).

**PROBES §483.95(i)**

If there is a concern that the behavioral health needs of residents are not being met, utilize observations, interviews and review of training records to determine the following:

- Does staff demonstrate the skills needed to promote the highest practicable level of functioning for residents with identified behavioral health care needs?
- Can staff explain concepts learned in training?
- How does the facility assure that all staff interacting with residents are trained as required? This may include nursing, therapy, activity, housekeeping, dietary staff, and others, as needed.
- How does the facility assure that all facility staff, contractors, and volunteers are trained to interact with those residents with specific behavioral health care needs?
- Is the training program designed to address the residents' specific behavioral health care needs?
- How does the facility keep track of staff participation in required training?
- How does the facility monitor the effectiveness of the training program?
- How are changes implemented to the training program if desired outcomes are not achieved?
- Is the training curriculum based on the results of the facility assessment required at 483.7*1*