
CMS Manual System

Pub. 100-07 State Operations Provider Certification

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

Transmittal 208

Date: October 21, 2022

SUBJECT: Revisions to State Operation Manual (SOM), Appendix PP Guidance to Surveyors for Long Term Care Facilities

I. SUMMARY OF CHANGES: Revisions are being made to entire Appendix PP. All FTag numbers are new and much content of the Appendix is also new.

NEW/REVISED MATERIAL - EFFECTIVE DATE: October 21, 2022

IMPLEMENTATION DATE: October 24, 2022

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

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual not updated.)

(R = REVISED, N = NEW, D = DELETED) – (Only One Per Row.)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	Chapter 5/5000/Management of Complaints and Incidents
R	Chapter 5/5010/General Intake Process
R	Chapter 5/5060 ASPEN Complaints/Incident Tracking System (ACTS)
R	Chapter 5/5060.1 Data Entry
R	Chapter 5/5060.2 Reports
R	Chapter 5/5070/Priority Assignment for Nursing Homes, Deemed and Non-Deemed Non-Long Term Care Providers/Suppliers, and EMTALA
R	Chapter 5/5075.1/Immediate Jeopardy (for Nursing Homes, Deemed and Non-Deemed Non-Long Term Care Providers/Suppliers, and EMTALA)
R	Chapter 5/5075.2/Non-Immediate Jeopardy-High Priority (for Nursing Homes and Deemed and Non-Deemed Non-Long Term Care Providers/Suppliers, and EMTALA)
R	Chapter 5/5075.3/Non-Immediate Jeopardy-Medium Priority (for Nursing Homes and Deemed and Non-Deemed Non-Long Term Care Providers/Suppliers)
R	Chapter 5/5075.4/Non-Immediate Jeopardy-Low Priority (for Nursing Homes Deemed and Non-Deemed Non-Long Term Care Provider/Suppliers)
R	Chapter 5/5075.6/Referral-Immediate (for Nursing Homes, Deemed and Non-Deemed Non-Long Term Care Providers/Suppliers, and EMTALA)

R	Chapter 5/5075.8/No Action Necessary (for Nursing Homes, Deemed and Non-Deemed Non-Long Term Care Providers/Suppliers, and EMTALA)
R	Chapter 5/5075.9/Maximum Time Frames Related to the Federal Onsite Investigation of Complaints/Incidents
R	Chapter 5/5080.1/Report to Complainant
R	Chapter 5/5300.5 – Task 7: Exit Conference
R	Chapter 5/5310/Action on Allegations of Resident Neglect and Abuse, and Misappropriation of Resident Property for Nursing Homes
R	Chapter 5/5320.1/Written Procedures
R	Chapter 5/5310.2/Review and Triage of Allegations
N	Chapter 5/5310.2A/Immediate Jeopardy Priority
R	Chapter 5/5330/Reporting Abuse to Law Enforcement and the Medicaid Fraud Control Unit for Nursing Homes
R	Chapter 9/Exhibit 23 – ACTS Required Fields
N	Chapter 9/Exhibit 358 – Sample Form for Facility Reported Incidents
N	Chapter 9/Exhibit 359 – Follow-up Investigation Report
R	Appendix PP/F557
R	Appendix PP/F561
R	Appendix PP/F563
R	Appendix PP/578
R	Appendix PP/582
R	Appendix PP/584
R	Appendix PP/F600
R	Appendix PP/F602
R	Appendix PP/F603
R	Appendix PP/F604
R	Appendix PP/F605
R	Appendix PP/F606
R	Appendix PP/F607
D	Appendix PP/F608
R	Appendix PP/F609
R	Appendix PP/F622
R	Appendix PP/F623
R	Appendix PP/F624
R	Appendix PP/F626
R	Appendix PP/F641
R	Appendix PP/F656
R	Appendix PP/F658
R	Appendix PP/F659
R	Appendix PP/F675
R	Appendix PP/F679
R	Appendix PP/F686

R	Appendix PP/F687
R	Appendix PP/F689
R	Appendix PP/F690
R	Appendix PP/F694
R	Appendix PP/F695
R	Appendix PP/F697
R	Appendix PP/F699
R	Appendix PP/F700
R	Appendix PP/F712
R	Appendix PP/F725
R	Appendix PP/F727
R	Appendix PP/F729
R	Appendix PP/F732
R	Appendix PP/F740
R	Appendix PP/F741
R	Appendix PP/F742
R	Appendix PP/F743
R	Appendix PP/F744
R	Appendix PP/F755
R	Appendix PP/F758
R	Appendix PP/F812
N	Appendix PP/F847
N	Appendix PP/F848
R	Appendix PP/F851
R	Appendix PP/F865
R	Appendix PP/F866
R	Appendix PP/F867
R	Appendix PP/F868
R	Appendix PP/F880
R	Appendix PP/F881
R	Appendix PP/F882
R	Appendix PP/F883
R	Appendix PP/F895
R	Appendix PP/F919
R	Appendix PP/F940
R	Appendix PP/F941
R	Appendix PP/F942
R	Appendix PP/F944
R	Appendix PP/F945
R	Appendix PP/F946
R	Appendix PP/F947
R	Appendix PP/F949

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

IV. ATTACHMENTS:

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

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

State Operations Manual

Chapter 5 - Complaint Procedures

Table of Contents (Rev. 208; 10-21-22)

Transmittals for Chapter 5

5060 - ASPEN Complaints/Incidents Tracking System (ACTS)

5060.1-Data Entry

5060.2-Reports

5310 - Action on *Allegations* of Resident Neglect and Abuse, and Misappropriation of Resident Property *for Nursing Homes*

5310.2 - Review *and Triage* of Allegation

5310.2 A-Immediate Jeopardy Priority

5330 - Reporting Abuse to Law Enforcement and the Medicaid Fraud Control Unit *for Nursing Homes*

5000 - Management of Complaints and Incidents

(Rev. 208; Issued:10-21-22; Effective: 10-21-22; Implementation:10-24-22)

NOTE: “CMS Regional Office (RO)” is used interchangeably with “CMS location” throughout this Chapter of the SOM.

5010 - General Intake Process

(Rev. 208; Issued:10-21-22; Effective: 10-21-22; Implementation:10-24-22)

A complaint is an allegation of noncompliance with Federal and/or State requirements. If the SA determines that the allegation(s) falls within the authority of the SA, the SA determines the severity and urgency of the allegations, so that appropriate and timely action can be pursued. Each SA is expected to have written policies and procedures to ensure that the appropriate response is taken for *all allegations and is consistent with Federal requirements as well as with procedures in the State Operations Manual*. This structure needs to include response timelines and a process to document actions taken by the SA in response to *allegations*. If a State’s time frames for the investigation of a complaint/incident are more stringent than the Federal time frames, the intake is prioritized using the State’s timeframes. The SA is expected to be able to share the logic and rationale that was utilized in prioritizing the complaint/*incident* for investigation. The SA response must be designed to protect the health and safety of all residents, patients, and clients.

Besides the SA, other public entities receive information and/or perform investigations. These entities include the office of the coroner or medical examiner, end-stage renal disease (ESRD) networks, quality improvement *networks (QINs)*, law enforcement, the ombudsman’s office, and protection and advocacy systems. At times, these public entities will forward information to the SA if there are concerns about the health and safety of residents, patients, and clients. The SAs are required to manage and investigate these referrals as complaints.

An allegation is an assertion of *noncompliance with Federal health and safety regulations*. The point of receipt of the allegation is a critical fact-finding and decision-making point. The SA ensures that its complaint telephone number is listed in local directories. Information regarding the care, treatment and services provided to beneficiaries can come from a variety of sources, including beneficiaries themselves, beneficiaries’ family members, health care providers, concerned citizens, public agencies, or media reports. Report sources may be verbal or written. In some instances, the complainant may request anonymity.

The SA and RO ensure the privacy and anonymity of every complainant. Generally, the SA follows the disclosure procedures under chapter 3, [§3308](#). The SA discloses the complainant’s identity only to those individuals with a need to know who are acting in an official capacity to investigate the complaint.

In addition to these Federal requirements, the SA abides by any State procedures not in direct conflict with CMS instructions. The SA notifies the RO if State regulations conflict directly with any part of these complaint procedures.

See also Section 5310.1 for information related to facility-reported incidents.

5060 – ASPEN Complaints/Incidents Tracking System (ACTS) ***(Rev. 208; Issued:10-21-22; Effective: 10-21-22; Implementation:10-24-22)***

The SA collects information related to complaints and facility-reported incidents and uses a system to track and monitor the receipt and disposition of complaint and incident intakes.

The ASPEN Complaints/Incidents Tracking System (ACTS) is designed to track, process, and report on complaints and incidents reported against health care providers and suppliers regulated by CMS. It is designed to manage all operations associated with complaint/incident processing, from initial intake and investigation through the final disposition.

The ACTS must be used for the intake of all allegations against Medicare/Medicaid-certified providers/suppliers and CLIA. The ACTS is a Federal system and data entered into ACTS is subject to Federal laws governing disclosure and the protection of an individual's right to privacy.

A complaint/incident record is created in ACTS based on how the allegation is received by the SA or RO. For example, if one person calls with ten allegations about one provider/supplier, this is counted as one complaint record. If six people call with the same allegation, this is counted as six telephone calls and is counted as six complaint records. If one letter is received with one or many allegations and is signed by 20 people, this is counted as one complaint record.

5060.1 - Data Entry

The SAs and ROs are required to enter into ACTS:

- All complaints gathered as part of Federal survey and certification responsibilities, regardless if an onsite survey is conducted *[i.e., complaints related to noncompliance with the Federal condition(s) of participation (COPs), condition(s) for coverage (CFCs), condition(s) for certification, requirement(s) for participation (RFPs), or EMTALA requirement(s)]*; **and**
- *For nursing homes, all self-reported incidents that are reported under Federal law and the requirements for participation [i.e., reporting to law enforcement of crimes occurring in LTC facilities – §1150B of the Social Security Act and §483.12(b)(5); alleged violations of abuse, neglect, exploitation or mistreatment,*

including injuries of unknown source and misappropriation of resident property – §483.12(c)(1) and (4)]. For non-long term care providers/suppliers, all self-reported incidents that require a Federal onsite survey.

The information recorded in ACTS reflects the allegation furnished by the complainant/*provider/supplier* at the time of the intake. At a minimum, if the intake information requires an onsite survey and the allegation may involve both Federal and State licensure requirements, a Federal onsite survey is completed and entered into ACTS.

If an investigation finds one or more violations of Federal requirements, the findings must be cited under the appropriate tags and entered into the Federal system even if the information is entered into a State licensure data system. Since this information is essential to the effective management of the survey and certification program, it is important that SAs complete the required fields in ACTS in a timely manner.

[Exhibit 23](#) defines the required fields in ACTS.

Tracking of Referrals in ACTS

The SAs are required to enter into ACTS all referrals from public entities that allege noncompliance with the Federal requirements. For reporting purposes, the SAs should enter these cases as complaints (i.e., Intake Type=Complaint, Intake Subtype=Federal COPs, CFCs, RFPs, EMTALA). In order to more quickly identify which of these cases stem from a referral, the SAs are expected to check the appropriate category under the “Source” field. For example, for referrals from the coroner’s office, states would check “Coroner” under the “Source” field for the intake.

Tracking of State Monitoring Visits (See Section [5077](#)) in ACTS

When a State Monitoring Visit results in a Federal deficiency, the SA will identify the survey in ASPEN as “complaint” and create an intake and survey record in ACTS. The data should be entered into ACTS as follows:

- Intake Type = Complaint;
- Intake Subtype = Federal COPs, CFCs, RFPs, EMTALA;
- Source = State SA;
- Priority = can vary; and
- Allegation Type = State Monitoring.

5060.2 - Reports

The ACTS produces a variety of reports that may be used for analysis and evaluation of provider/supplier performance. Complaint/incident reports are generated and displayed through menus that can be accessed in ACTS. Reports may be produced for one provider/supplier, or reports may be combined and present information for multiple

providers/suppliers. Report filtering criteria is available through the Report Customization window, which allows the user to select criteria for the report to meet the user's specifications. Refer to the ACTS Procedures Guide for a list and description of the reports available in ACTS.

NOTE:

FOR ADDITIONAL INFORMATION ON SPECIFIC POLICIES RELATED TO:

- **DEEMED PROVIDERS AND SUPPLIERS, EXCLUDING CLIA, SEE [SECTION 5100](#)**
- **NON-DEEMED PROVIDERS AND SUPPLIERS, SEE [SECTION 5200](#)**
- **NURSING HOMES, SEE [SECTION 5300](#)**
- **EMTALA, SEE [SECTION 5400](#)**
- **CLIA LABORATORIES, SEE [SECTION 5500](#)**
- **ESRD, SEE [SECTION 5160](#) AND [SECTION 5170](#)**

5070 - Priority Assignment for Nursing Homes, Deemed and Non-Deemed Non-Long Term Care Providers/Suppliers, and EMTALA
(Rev. 208; Issued:10-21-22; Effective: 10-21-22; Implementation:10-24-22)

This section does not apply to clinical laboratories subject to the Clinical Laboratory Improvement Amendments of 1988 (CLIA). See Sections 5500 – 5590 for CLIA information.

An assessment of each complaint or incident intake must be made by an individual who is professionally qualified to evaluate the nature of the problem based upon his/her knowledge of Federal requirements and his/her knowledge of current clinical standards of practice.

From a complainant's allegation(s) or an allegation from a facility-reported incident, the SA/CMS Location identifies potential concerns where the provider/supplier may not be in compliance with Federal requirements. The SA/CMS Location must review the allegation(s) for all requirements that apply and should be investigated. These requirements will be specific to each health care entity. The surveyor then investigates each of those areas of concern and health care entity type.

The role of the surveyor is not to validate whether the events contained in the allegation had occurred, but it is to determine whether the facility is in compliance with the Federal requirements for Medicare/Medicaid-certified providers/suppliers. If CMS or the SA

believes that the complaint or facility-reported incident should also be investigated under the jurisdiction of another entity, referrals should be made as appropriate (e.g., law enforcement for criminal activity, State licensing boards for health care practitioners, the Medicare Administrative Contractor (MAC) for billing issues).

In the case of nursing homes, in situations where a determination is made that immediate jeopardy may be present and ongoing, the SA must start the on-site investigation within three business days of receipt of the initial complaint or incident report. Receipt of the initial complaint or incident report means when the report is received by the SA, whether it is received by the SA directly, or another State agency under arrangement or contractor that is receiving the report on behalf of the SA from the complainant or facility. Also, if a complaint or facility-reported incident is received after business hours, then it is considered to be received on the next business day, for purposes of calculating the investigation timeframe. For example, if a complaint is received on Saturday and the SA office is closed during the weekend, then the following Monday will be used to calculate the investigation timeframe. For non-long term care providers/suppliers, in situations where a determination is made that immediate jeopardy may be present and ongoing, the SA is required to start the on-site investigation within two business days of receipt of the complaint or incident report, or, in the case of a deemed provider or supplier, within two business days of RO authorization for investigation. The same process applies to EMTALA complaints or a survey related to a report of a hospital or CAH Distinct Part Unit patient death associated with the use of restraint or seclusion. The SA's investigation must be initiated within two business days of RO authorization for investigation.

Generally, an alleged event occurring more than 12 months prior to the intake date would not require a complaint investigation. However, the SA is not precluded from conducting a Federal investigation (with appropriate RO authorization, where required) to determine current compliance status based on the concerns identified in the complaint.

For nursing homes, an onsite survey may not be required if there is sufficient evidence that the facility does not have continuing noncompliance and the alleged event occurred before the last standard survey.

For all intakes concerning deemed status providers or suppliers where the intake involves allegations of substantial noncompliance (in other words, the allegation would result in a condition-level deficiency citation if found to be true and uncorrected), the SA must submit a request for RO approval of a complaint validation survey (i.e., substantial allegation validation survey). The SA must obtain RO approval before conducting a substantial allegation validation survey. The RO will authorize the SA to conduct the survey by issuing electronically via ACTS a Form CMS-2802, which will indicate the specific conditions for which the SA must assess compliance. The RO must authorize assessment of compliance for a whole condition and not just for particular standards within a condition, unless the Form CMS-2802 for the applicable provider/supplier type permits selection of a specific standard, e.g., Life Safety Code.

All allegations of EMTALA violations related to a hospital (which also includes cancer, children's, long term care, psychiatric and rehabilitation hospitals) or CAH, regardless of whether the hospital or CAH is deemed, must be referred to the RO. The RO will determine whether the SA will conduct an EMTALA investigation.

In cases where the SA or RO has noted a pattern of similar complaints about a specific provider or supplier, each of which on its own merits would be triaged at a medium or low level, the SA or RO has the discretion to assign a higher triage level to a current intake based on the noted pattern, in order to ensure timely investigation of the provider's/supplier's compliance with the applicable requirements or Conditions.

CMS expects SAs to prioritize complaints at the appropriate level that is warranted. The timeframes in Section 5075 below represent maximum timeframes for investigation; the SA is not precluded from investigating complaints and facility-reported incidents within a shorter timeframe. In addition, the SA is not precluded from taking other factors into consideration in its triage decision. For example, the SA may identify a trend in allegations that indicates an increased risk of harm to residents or the SA may receive corroborating information from other complainants regarding the allegation. See also Section 5310.2 for requirements for nursing home facility-reported incidents.

5075 - Priority Definitions for Nursing Homes, Deemed and Non-Deemed Non-Long Term Care Providers/Suppliers, and EMTALA *(Rev. 208; Issued:10-21-22; Effective: 10-21-22; Implementation:10-24-22)*

5075.1 - Immediate Jeopardy (for Nursing Homes, Deemed and Non-Deemed Non-Long Term Care Providers/Suppliers, and EMTALA) *(Rev. 208; Issued:10-21-22; Effective: 10-21-22; Implementation:10-24-22)*

General Provisions

The regulations at [42 CFR 489.3](#) define immediate jeopardy as, "A situation in which the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident." [Appendix Q](#) contains the Guidelines for Determining Immediate Jeopardy. Intakes are assigned this priority if the alleged noncompliance indicates there was serious injury, harm, impairment or death of a patient or resident, or the likelihood for such, and there continues to be an immediate risk of serious injury, harm, impairment or death of a patient or resident unless immediate corrective action is taken. *In addition, for nursing homes, facility-reported incidents are assigned this priority if immediate jeopardy may have occurred, regardless of whether an immediate risk may continue to exist. Examples of intakes that are assigned this priority include, but are not limited to, the following:*

- *All intakes alleging abuse of a resident/patient/client and it is uncertain that they are adequately protected.*
- *For nursing homes, all intakes alleging eviction of a resident to an unsafe location.*
- Intakes alleging EMTALA noncompliance may also be assigned this priority.

- Any hospital self-reported incident of patient death associated with use of restraint or seclusion which the RO determines requires an on-site investigation is also assigned this priority.

When the SA or RO makes the determination that a complaint or incident report suggests an immediate jeopardy may be present, the investigation is to be initiated in accordance with Section [5075.9](#).

See also Section 5310.2A for additional guidance related to nursing home facility-reported incidents.

Fires Resulting in Serious Injury or Death

Fires resulting in serious injury or death are prioritized as “immediate jeopardy”. The following actions are taken when a report of a fire resulting in serious injury or death in a Medicare/Medicaid certified facility is received from any source:

The SA

- Enters the complaint or self-reported incident into ACTS (Priority = IJ, Allegation Category = Life Safety Code);
- Informs the appropriate RO of fire resulting in serious injury or death no later than one working day after receipt of the intake;
- Compiles information as needed to present a comprehensive picture of the situation surrounding the fire;
- Takes appropriate action necessary to assist the Medicare/Medicaid-certified provider/supplier to protect and/or relocate residents or patients from further harm; and
- Performs the Life Safety Code investigation.

The RO

- Informs CMS Central Office (CO) of the fire and planned actions, sending a copy of the alert to the Life Safety Code specialist;
- Consults with the CO to determine whether there is an indication for CO participation in the survey for program evaluation purposes;
- Reports any findings and actions taken by the SA to the CO at the end of the on-site survey; and
- At its discretion, may accompany the SA during the on-site survey.

The CO

- Consults with the RO to determine whether or not issues are present that indicate further investigation to determine the adequacy of current standards and their application; and
- In certain cases, CO staff may accompany regional and/or state personnel on the on-site survey.

5075.2 - Non-Immediate Jeopardy - High Priority (for Nursing Homes and Deemed and Non-Deemed Non-Long Term Care Providers/Suppliers, and EMTALA)

(Rev. 208; Issued:10-21-22; Effective: 10-21-22; Implementation:10-24-22)

Nursing Homes:

Intakes are assigned a “high” priority if the alleged noncompliance with one or more requirements may have caused harm that negatively impacts the individual’s mental, physical and/or psychosocial status and are of such consequence to the person’s well-being that a rapid response by the SA is indicated. Usually, specific rather than general information (such as: descriptive identifiers, individual names, date/time/location of occurrence, description of harm, etc.) factors into the assignment of this level of priority.

When the SA makes the determination that *the alleged noncompliance may have caused actual physical and/or psychosocial harm to the resident(s), the SA must initiate an onsite survey within an annual average of 15 business days of receipt of the initial report, not to exceed 18 business days.*

NOTE: Exhibit 22 provides additional guidance to distinguish between the priorities of “immediate jeopardy” and “non-immediate jeopardy - high” for nursing home complaints/incidents.

NOTE: Please refer to Tag F610 in Appendix PP of the State Operations Manual for information related to facility responses to alleged violations, including facility investigation, resident protection, and corrective actions.

Non-Long Term Care Providers/Suppliers

Intakes are assigned this priority if the alleged noncompliance with the applicable Conditions of Participation, Coverage or Certification, or EMTALA requirements, if found to be true and uncorrected, would not represent an IJ, but would result in a determination of substantial noncompliance, i.e., at least one condition-level deficiency.

Intakes assigned this priority require an onsite survey to be initiated within 45 calendar days after intake prioritization for non-deemed providers/suppliers, and within 45

calendar days after authorization of the investigation by the RO for deemed status providers/suppliers. The RO has the discretion to request the onsite survey be initiated in less than 45 calendar days.

5075.3 - Non-Immediate Jeopardy - Medium Priority (for Nursing Homes and Deemed and Non-Deemed Non-Long Term Care Providers/Suppliers)

(Rev. 208; Issued:10-21-22; Effective: 10-21-22; Implementation:10-24-22)

Nursing Homes:

Complaints are assigned a “medium” priority if the alleged noncompliance with one or more requirements caused no actual physical and/or psychosocial harm but there is the potential for more than minimal harm to the resident(s) (Severity Level 2). Facility-reported incidents are assigned a “medium” priority if the alleged noncompliance with one or more requirements caused no actual physical and/or psychosocial harm but there is the potential for more than minimal harm to the resident(s) (Severity Level 2) and the facility has not provided an adequate response to the allegation or it is not known whether the facility provided an adequate response. For complaints and facility-reported incidents that are assigned a “medium” priority, the SA must initiate an onsite survey within 45 calendar days of receipt of the initial report.

NOTE: Please refer to Tag F610 in Appendix PP of the State Operations Manual for surveyor guidance related to facility responses to alleged violations, including facility investigation, resident protection, and corrective actions.

Non-Long Term Care Providers/Suppliers

Intakes are assigned this priority if the alleged noncompliance with one or more standards within a Condition of Participation, Condition for Coverage or Condition for Certification is limited in manner and degree and/or caused, or may cause, harm that is of limited consequence and does not impair the individual’s mental, physical and/or psychosocial status or function. In other words, the incident or complaint, if found to be true and uncorrected, would not result in a determination of substantial non-compliance, i.e., there would not be any condition-level deficiency.

For non-deemed providers/suppliers, intakes assigned this priority are scheduled in accordance with section 5075.9 for investigation no later than when the next on-site survey occurs.

For deemed providers/suppliers, the SA (or RO, if the RO handled the intake) advises the complainant that the allegation does not meet the criteria for a Federal investigation and refers the complainant to the applicable accrediting organization(s)(AOs) in accordance with the provisions of section 5100.2.

5075.4 - Non-Immediate Jeopardy – Low Priority (for Nursing Homes and Deemed and Non-Deemed Non-Long Term Care Providers/Suppliers)

(Rev. 208; Issued:10-21-22; Effective: 10-21-22; Implementation:10-24-22)

Nursing Homes

Intakes are assigned a “low” priority if the alleged noncompliance with one or more requirements may have *no actual harm with a potential for minimal harm (Severity Level 1)*. The investigation is to be initiated in accordance with section [5075.9](#).

In addition, facility-reported incidents are assigned a “low” priority if the alleged noncompliance with one or more requirements may have caused no actual physical and/or psychosocial harm but there is the potential for more than minimal harm to the resident(s)(Severity Level 2) and the facility has provided a potentially adequate response to the allegation.

NOTE: Please refer to Tag F610 in Appendix PP of the State Operations Manual for information related to facility responses to alleged violations, including facility investigation, resident protection, and corrective actions.

The SA reviews these intakes for tracking of possible trends in order to determine if there are common themes that suggest areas for focused attention when the next on-site survey occurs. If the SA identifies a trend that suggests similar concerns, the SA either investigates the concerns during the next standard or complaint survey or initiates a complaint survey.

Non-Long Term Care Providers/Suppliers

Intakes are assigned this priority if the alleged noncompliance with one or more standards within a Condition of Participation, Coverage or Certification may have caused physical, mental and/or psychosocial discomfort that does not constitute injury or damage.

For non-deemed providers/suppliers, the SA reviews these intakes for tracking of possible trends in the nature of complaints in order to determine if there are common themes that suggest areas for focused attention when the next on-site survey occurs. Individual investigations of each intake are not required, although the SA has the discretion to conduct a complaint survey if trending suggests a number of similar problems that might warrant an on-site investigation.

For deemed providers/suppliers, the SA (or RO, if the RO handled the intake) advises the complainant that the allegation does not meet the criteria for a Federal investigation and refers the complainant to the applicable accreditation organization(s)(AOs) in accordance with the provisions of section 5100.2.

5075.6 - Referral – Immediate (for Nursing Homes, Deemed and Non-Deemed Non-Long Term Care Providers/Suppliers, and EMTALA)
(Rev. 208; Issued:10-21-22; Effective: 10-21-22; Implementation:10-24-22)

Intakes are assigned a “Referral – Immediate” priority if the nature and seriousness of a complaint/incident or State procedures requires the referral or reporting of this information for investigation to another agency, board, or ESRD network **without delay**.

For example, if a complaint has criminal implications and the complainant has not reported the incident to law enforcement, the SA must report the suspected crime to law enforcement immediately (NOTE: In such cases, the referral is recorded in the Contact/Refer tab under the ACTS intake). This priority may be assigned **in addition to** one of the priorities in sections 5075.1 through 5075.5.

When the SA refers the complaint/incident to another agency or entity (e.g., law enforcement, Ombudsman, licensure agency, etc.) for action, the SA must request a written report on the results of the investigation by the outside entity. Referral to an outside entity does not relieve the SA of the responsibility to assess compliance with Federal conditions or requirements, when applicable. The timeframes for investigation are not altered by the referral. (Expressed requests by law enforcement that the SA defer an onsite investigation should be discussed with the CMS RO, as appropriate.)

5075.8 - No Action Necessary (for Nursing Homes, Deemed and Non-Deemed Non-Long Term Care Providers/Suppliers, and EMTALA)
(Rev. 208; Issued:10-21-22; Effective: 10-21-22; Implementation:10-24-22)

Intakes are assigned a “No Action Necessary” priority if the SA or RO determines with certainty that no further investigation, analysis, or action is necessary.

For example, no action is necessary if the allegation is not related to any Federal COPs, CFCs, conditions for certification, RFPs, or EMTALA requirement(s); or situations in which a previous survey investigated the exact same event(s) and either did not find noncompliance, or noncompliance was previously identified and subsequently corrected by the provider/supplier.

This category would also be used for intakes concerning an event that occurred more than 12 months in the past, unless the SA (or the RO, in the case of a deemed status provider/supplier) determines that a complaint investigation is nevertheless warranted.

Nursing Homes

The following are examples of reports that require no further action or investigation by the SA/RO:

- 1) *Facility-reported incidents that are not reportable events under Federal law or regulations;*
- 2) *Facility-reported incidents involving injuries where the resident was able to explain or describe how he/she received the injury as long as there is no other indication of abuse or neglect;*
- 3) *Facility-reported incidents involving lost items, which are found and no theft is suspected; and*
- 4) *The alleged event occurred before the last standard survey and there is sufficient evidence that the facility does not have continuing noncompliance since the last standard survey.*

NOTE: Sufficient evidence that the facility does not have continuing noncompliance may be indicated by a recent survey that reviewed the concern, no additional complaints or facility reported incidents have been received regarding the same issue, and interview with the Long-term Care Ombudsman which reveal no concerns.

5075.9 - Maximum Time Frames Related to the Federal Onsite Investigation of Complaints/Incidents

(Rev. 208; Issued:10-21-22; Effective: 10-21-22; Implementation:10-24-22)

Provider Type	Intake Prioritization			
	Immediate Jeopardy (IJ)	Non-IJ High	Non-IJ Medium	Non-IJ Low
Nursing home <i>complaints</i>	SA must initiate an onsite survey within 3 business days of receipt of <i>the initial report.</i>	SA must initiate an onsite survey within <i>an annual average of 15 business days of receipt of the initial report, not to exceed 18 business days.</i>	<i>SA must initiate an onsite survey within 45 calendar days of receipt of the initial report.</i>	<i>SA must track/trend for potential focus areas during the next onsite survey, or initiate a new complaint survey.</i>
<i>Nursing home incidents</i>	<i>With inadequate resident protection, SA must initiate an onsite survey within 3 business days of receipt of the initial report.</i> <i>With potentially adequate resident protection, SA must initiate an onsite survey within 7 business days of receipt of the initial report.</i> <i>See Section 5310.2F.</i>	<i>SA must initiate an onsite survey within an annual average of 15 business days of receipt of the initial report, not to exceed 18 business days.</i>	<i>With an inadequate facility response, SA must initiate an onsite survey within 45 calendar days of receipt of the initial report.</i>	<i>With a potentially adequate facility response, SA must track/trend for potential focus areas during the next onsite survey, or initiate a new complaint survey.</i>
Non-deemed non-long term care providers/suppliers	SA must initiate an onsite survey within 2 business days of receipt.	SA must initiate an onsite survey within 45 calendar days of prioritization	SA must investigate no later than when the next onsite survey occurs	SA must track/trend for potential focus areas during the next onsite survey.
Deemed providers/suppliers	SA must initiate an onsite survey within 2 business days of receipt of RO authorization	SA must initiate an onsite survey within 45 calendar days of receipt of RO authorization.	Complainant is referred to the applicable accrediting organization(s)	Complainant is referred to the applicable accrediting organization(s)
EMTALA	SA must initiate an onsite survey within 2 business days of receipt of RO authorization.	SA must initiate an onsite survey within 45 calendar days of receipt of RO authorization	N/A	N/A
Death associated with restraint/seclusion-Hospitals	SA must initiate an onsite survey within 2 business days of receipt of RO authorization.	N/A	N/A	N/A
Fires resulting in serious injury or death	SA must initiate an onsite survey within 2 business days of receipt.	N/A	N/A	N/A

5080.1 - Report to the Complainant

(Rev. 208; Issued:10-21-22; Effective: 10-21-22; Implementation:10-24-22)

The SA/*CMS location* provides the complainant a written report of the investigation findings as a summary record of the investigation.

The following principles guide preparation of the report to the complainant:

- Acknowledge the complainant’s concern(s);
- Identify the SA’s regulatory authority to investigate the complaint/incident and any statutory or regulatory limits that may bear on the authority to conduct an investigation;
- Provide a summary of investigation methods (e.g., on-site visit, written correspondence, telephone inquiries, etc.);
- Provide date(s) of investigation;
- Provide an explanation of your SA’s decision-making process *(NOTE: CMS and the SA should avoid using terms such as “substantiated” and “unsubstantiated”)*;
- Provide *the complainant with information regarding whether or not noncompliance was identified during the complaint investigation.* *(NOTE: To the extent possible, the summary should not compromise the anonymity of individuals, or include specific situations that may be used to identify individuals, when anonymity has been requested or is appropriate in the judgment of the SA);*
- *Identify where the complainant may find the Statement of Deficiencies and Plan of Correction (e.g., posted at the nursing home, Nursing Home Care Compare, request the CMS-2567 from the SA);*
- *Describe how the complainant may request a copy of the investigation report, subject to Federal and State disclosure requirements (e.g., see 42 CFR §488.325 and FOIA requirements at 45 CFR Part 5); and*
- Identify appropriate referral information (i.e., other agencies that may be involved).

5300.5 - Task 7: Exit Conference

(Rev. 208; Issued:10-21-22; Effective: 10-21-22; Implementation:10-24-22)

Conduct an Exit Conference related to a complaint survey in accordance with the process described *in the Exit Conference section located in the Long-Term Care Survey Process*

(LTCSP) Procedure Guide (<https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Nursing-Homes.html>). Do not inform the nursing facility of confidential information unless the individual who provided the information specifically authorizes you to do so.

If a deficiency is not present now, but was present and has been corrected, notify the facility orally and in writing that the complaint was substantiated because deficiencies existed at the time that the complaint situation occurred. (See SOM [Chapter 7](#), Survey and Enforcement Process for Skilled Nursing Facilities and Nursing Facilities, for specific information about citing past noncompliance.)

If the complaint is unsubstantiated, (i.e., the surveyor(s) cannot determine that it occurred and there is no indication of deficient practice), notify the facility of this decision.

5310 - Action on *Allegations* of Resident Neglect and Abuse, and Misappropriation of Resident Property *for Nursing Homes* *(Rev. 208; Issued:10-21-22; Effective: 10-21-22; Implementation:10-24-22)*

5310.1 - Written Procedures

(Rev. 208; Issued:10-21-22; Effective: 10-21-22; Implementation:10-24-22)

The State must *develop and implement* written procedures for the timely review and investigation of allegations of resident abuse and neglect, and misappropriation of resident property, *including both complaints and facility-reported incidents. The State's policies and procedures must be consistent with Federal requirements as well as with procedures in the State Operations Manual.*

Nursing homes send the following types of incidents to the State Survey Agency:

- All alleged violations involving abuse, neglect, exploitation or mistreatment, including injuries of unknown source and misappropriation of resident property;*
- The results of all facility investigations involving alleged violations of abuse, neglect, exploitation or mistreatment, including injuries of unknown source and misappropriation of resident property; and*
- Reasonable suspicions of crimes against nursing home residents.*

NOTE: If the SA receives information that a suspected crime may have occurred in a facility and there is indication that it has not been reported or the SA cannot verify that a report was made to law enforcement, then the SA forwards the information from the initial report immediately to law enforcement. The SA must follow applicable laws and regulations related to information disclosures, privacy and confidentiality, as it makes referrals. The SA may also contact the CMS Location office for more information.

A. Initial Reporting of Facility-Reported Incidents

The information collected during intake is critical in determining what may be occurring in a facility and the effect(s) that it may have on residents. While States have discretion in how they collect information from facilities (e.g., through electronic submission), at a minimum, the State Survey Agency must provide instructions to the facility and collect sufficient information to determine how the incident should be prioritized. See also Exhibit XX for sample instructions with examples of information and Appendix PP, Tag F609. If the facility has not provided sufficient information, the SA should take this into consideration as it triages the incident.

1. Facility Reported Incidents – Initial Report

The facility must provide in its report sufficient information to describe the alleged violation and indicate how residents are being protected [See §483.12(c)(3)]. It is important that the facility provide as much information as possible, to the best of its knowledge at the time of submission of the report, so that state agencies can initiate action necessary to oversee the protection of nursing home residents. See Exhibit XX for a sample form for initial reporting with examples of information and see also Appendix PP, Tag F609.

B. Reporting of Investigation Findings for Facility-Reported Incidents

For alleged violations of abuse, neglect, exploitation or mistreatment, including injuries of unknown source and misappropriation of resident property, the facility is required to submit a report of the results of the investigation within 5 working days to the State Survey Agency (See 42 C.F.R. §483.12(c)(4), Tag F609 of Appendix PP of the State Operations Manual). While States have discretion in how they collect information from facilities (e.g., through electronic submission), at a minimum, the State Survey Agency must provide instructions to the facility and collect sufficient information to determine how the incident should be prioritized.

5-Day Final Report of Suspected Allegation

Within 5 working days of the incident, the facility must provide in its report sufficient information to describe the results of the investigation, and indicate any corrective actions taken, if the allegation was verified. It is important that the facility provide as much information as possible, to the best of its knowledge at the time of submission of the report, so that State agencies can initiate action necessary to oversee the protection of nursing home residents

[see §483.12(c)(4)]. See Exhibit XX for a sample form for the investigation report with examples of information, and see also Appendix PP, Tag F609.

5310.2 - Review *and* Triage of Allegations

(Rev. 208; Issued:10-21-22; Effective: 10-21-22; Implementation:10-24-22)

The State *reviews* all allegations of resident neglect and abuse and misappropriation of resident property regardless of the source.

5310.2A-Immediate Jeopardy Priority

(Rev. 208; Issued:10-21-22; Effective: 10-21-22; Implementation:10-24-22)

In cases where the initial report indicates the following, the SA must initiate an onsite survey within three business days of receipt of the initial report:

- 1) The alleged noncompliance may have caused, or may likely cause, serious injury, harm, impairment, or death to a resident, and*
- 2) The facility has not implemented adequate protection for all residents or the SA has not received sufficient evidence to conclude that residents are adequately protected.*

For these cases, the SA will enter into ACTS: Intake Type=Incident; Priority = IJ; and Investigate Within X Days = 3 Working Days.

In cases where the initial report indicates the following, the SA must initiate an onsite survey within seven business days of receipt of the initial report:

- 1) The alleged noncompliance may have caused, or may likely cause, serious injury, harm, impairment, or death to a resident, and*
- 2) The facility has potentially implemented adequate protection for all residents.*

For these cases, the SA will enter into ACTS: Intake Type=Incident; Priority = IJ; and Investigate Within X Days = 7 Working Days.

NOTE: See Appendix Q of the State Operations Manual for guidance related to immediate jeopardy situations.

Depending on the nature of the allegation, the facility would be expected to take immediate action(s) to ensure the protection of residents. Information provided by the facility may assist the SAs in determining whether there are potentially adequate protections provided to the resident. Examples of such information include, but are not limited to:

- Monitoring of the alleged victim and other identified residents who are at risk, such as conducting unannounced management visits at different times and shifts;*

- *Evaluation of whether the alleged victim feels safe and if he/she does not feel safe, taking immediate steps to alleviate the fear, such as a room relocation, increased supervision, etc.;*
- *Providing social services (e.g., emotional support and counseling) to the resident, as needed;*
- *Immediate assessment of the alleged victim and provision of medical treatment as necessary;*
- *Provision of goods and/or services that are necessary to avoid serious injury, harm, impairment, or death to a resident;*
- *Immediate notification of the alleged victim's physician and the resident representative, when there is injury or a change in condition or status;*
- *If the alleged perpetrator is staff- Removal of access by the alleged perpetrator to the alleged victim and other residents and assurance that ongoing safety and protection is provided for the alleged victim and other residents*
- *If the alleged perpetrator is a resident or visitor- Removal of access by the alleged perpetrator to the alleged victim and, as appropriate, other residents and assurance that ongoing safety and protection is provided for the alleged victim and other residents*
- *Notification of the alleged violation to other agencies or law enforcement authorities, within timeframes as specified under Federal or State law or regulations; and*
- *Whether administrative staff, including the administrator, were informed and involved as necessary in the investigation.*

Below are examples that indicate that a resident(s) may not be protected in the facility:

- *The alleged perpetrator continues to have access to the alleged victim and/or other residents;*
- *Retaliation occurs against a resident who reports an alleged violation;*
- *A resident who repeatedly fondles other residents is moved to another unit, where he/she continues to exhibit the same behaviors to other residents; and*
- *A resident with a history of striking a resident is left unsupervised with a resident who has been targeted in the past.*

The SA may contact the resident/representative to determine whether adequate protections are provided to the resident

5330 - Reporting Abuse to Law Enforcement and the Medicaid Fraud Control Unit *for Nursing Homes*

(Rev. 208; Issued:10-21-22; Effective: 10-21-22; Implementation:10-24-22)

If the SA receives information that a suspected crime may have occurred in a facility and there is indication that it has not been reported or the SA cannot verify that a report was made to law enforcement, the SA must report the suspected crime to law enforcement immediately.

Verifying that a complainant, facility, and/or covered individual(s) has made a report to law enforcement would include review and confirmation of the following information:

- Who submitted the report to law enforcement, including name and contact information;*
- Who did the reporter contact, including law enforcement entity, name, and contact information;*
- Date/Time that the report was filed;*
- Any copies of the report made to law enforcement, if available;*
- What information was conveyed to law enforcement; and*
- The police report number provided by law enforcement.*

When the SA or RO substantiates a finding of abuse, the SA or RO must report the substantiated findings to local law enforcement and, if appropriate, the Medicaid Fraud Control Unit.

NOTE: "Covered individual" is defined in section 1150B(a)(3) of the Act as anyone who is an owner, operator, employee, manager, agent or contractor of the facility (§483.12(b)(5)(i)).

Medicare State Operations Manual

Chapter 9 - Exhibits

Exhibits *(Rev.208;10-21-22)*

Exhibit	Description	Download
<i>23</i>	ACTS Required Fields	http://www.cms.gov/manuals/downloads/som107_exhibit_023.pdf
<i>358</i>	<i>Sample Form for Facility Reported Incidents</i>	http://www.cms.gov/manuals/downloads/som107_exhibit_358.pdf
<i>359</i>	<i>Follow-up Investigation Report</i>	http://www.cms.gov/manuals/downloads/som107_exhibit_359.pdf

State Operations Manual

Appendix PP - Guidance to Surveyors for Long Term Care Facilities

Table of Contents
(Rev. 208;10-21-22)

Transmittals for Appendix PP

INDEX

§483.5 Definitions

§483.10 Resident Rights

§483.12 Freedom from Abuse, Neglect, and Exploitation

§483.15 Admission Transfer and Discharge Rights

§483.20 Resident Assessment

§483.21 Comprehensive Person-Centered Care Plans

§483.24 Quality of Life

§483.25 Quality of Care

§483.30 Physician Services

§483.35 Nursing Services

§483.40 Behavioral health services

§483.45 Pharmacy Services

§483.50 Laboratory Radiology and Other Diagnostic Services

§483.55 Dental Services

§483.60 Food and Nutrition Services

§483.65 Specialized Rehabilitative Services

§483.70 Administration

§483.75 Quality Assurance and Performance Improvement

§483.80 Infection Control

§483.85 Compliance and Ethics Program

§483.90 Physical Environment

§483.95 Training Requirements

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.

F557

(Rev. 208; Issued:10-21-22; Effective: 10-21-22; Implementation:10-24-22)

§483.10(e) Respect and Dignity.

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

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

INTENT §483.10(e)(2)

All residents' possessions, regardless of their apparent value to others, must be treated with respect.

GUIDANCE §483.10(e)(2)

The right to retain and use personal possessions promotes a homelike environment and supports each resident in maintaining their independence.

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

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

PROCEDURES §483.10(e)(2)

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

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

- Residents, their representatives, or family members have been discouraged from bringing personal items to the facility.
- A decision to refuse to allow a resident to retain any personal belongings was not based on space limitations or on a determination that the rights, health or safety of other residents would be infringed.

- *Facility staff searching a resident's body or personal possessions without the resident's or, if applicable, the resident's representative's consent.*

It is important for facility staff to have knowledge of signs, symptoms, and triggers of possible illegal substance use; such as changes in resident behavior, increased unexplained drowsiness, lack of coordination, slurred speech, mood changes, and/or loss of consciousness, etc. This may include asking residents, who appear to have used an illegal substance (e.g., cocaine, hallucinogens, heroin), whether or not they possess or have used an illegal substance.

If the facility determines through observation that a resident may have access to illegal substances that they have brought into the facility or secured from an outside source, the facility should not act as an arm of law enforcement. Rather, in accordance with state laws, these cases may warrant a referral to local law enforcement. To protect the health and safety of residents, facilities may need to provide additional monitoring and supervision. If facility staff identify items or substances that pose risks to residents' health and safety and are in plain view, they may confiscate them. But, facility staff should not conduct searches of a resident or their personal belongings, unless the resident, or resident representative agrees to a voluntary search and understands the reason for the search. For concerns related to the identification of risk and the provision of supervision to prevent accidental overdose, investigate potential non-compliance at F689, §483.25(d) – Accidents.

For concerns related to the behavioral health services that are provided, investigate potential non-compliance at F740, §483.40 – Behavioral Health Services.

F561

(Rev. 208; Issued:10-21-22; Effective: 10-21-22; Implementation:10-24-22)

§483.10(f) Self-determination.

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

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

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

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

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

INTENT §483.10(f)(1)-(3) and (8)

The intent of this requirement is to ensure that each resident has the opportunity to exercise his or her autonomy regarding those things that are important in his or her life. This includes the residents' interests and preferences.

GUIDANCE §§483.10(f)(1)-(3), (8)

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

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

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

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

If a facility changes its policy to prohibit smoking (including electronic cigarettes), it should allow current residents who smoke to continue smoking in an area that maintains the quality of life for these residents and takes into account non-smoking residents. The smoking area may be an outside area provided that residents remain safe. Residents admitted after the facility changes its policy must be informed of this policy at admission. (See §483.10(g)(1) and §483.10(g)(16)) For further explanation of safety concerns, refer to §483.25(d), F689. For information on smoking policies, refer to §483.90(i)(5), F926.

PROCEDURES §483.10(f)(1)-(3) *and* (8)

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

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

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

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

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

POTENTIAL TAGS FOR ADDITIONAL CONSIDERATION

- If other concerns are identified regarding justice involved residents, see §483.10(a), F550, Resident Rights for further guidance.
- For issues regarding a resident's accommodation of needs, see §483.10(e)(3), F558.
- For issues related to resident visitation, see §483.10(f)(4)(ii)-(v), F563.
- If it is determined a resident's preferences is not honored due to possible concerns with insufficient numbers of staff or staff competencies, see §483.35(a), F725, Sufficient Nursing Staff.

F563

(Rev. 208; Issued:10-21-22; Effective: 10-21-22; Implementation:10-24-22)

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

(ii) The facility must provide immediate access to a resident by immediate family and other relatives of the resident, subject to the resident’s right to deny or withdraw consent at any time;

(iii) The facility must provide immediate access to a resident by others who are visiting with the consent of the resident, subject to reasonable clinical and safety restrictions and the resident’s right to deny or withdraw consent at any time;

(iv) The facility must provide reasonable access to a resident by any entity or individual that provides health, social, legal, or other services to the resident, subject to the resident’s right to deny or withdraw consent at any time; and

(v) The facility must have written policies and procedures regarding the visitation rights of residents, including those setting forth any clinically necessary or reasonable restriction or limitation or safety restriction or limitation, when such limitations may apply consistent with the requirements of this subpart, that the facility may need to place on such rights and the reasons for the clinical or safety restriction or limitation.

***GUIDANCE* §483.10(f)(4)(ii)-(v)**

“Reasonable clinical and safety restrictions” include a facility’s policies, procedures or practices that protect the health and security of all residents and staff. These may include, but are not be limited to:

- Restrictions placed to prevent community-associated infection or communicable disease transmission to *one or more* residents. A resident’s risk factors for infection (e.g., immunocompromised condition) or current health state (e.g., end-of-life care) should be considered when restricting visitors.
- In general, visitors with signs and symptoms of a transmissible infection (e.g., a visitor is febrile and exhibiting signs and symptoms of an influenza-like illness) should defer visitation until he or she is no longer potentially infectious (e.g., 24 hours after resolution of fever without antipyretic medication), *or according to CDC guidelines, and/or local health department recommendations.*
- Keeping the facility locked or secured at night with a system in place for allowing visitors approved by the resident;
- Denying access or providing limited and supervised access to an individual if that individual is suspected of abusing, exploiting, or coercing a resident until an investigation into the allegation has been completed or has been found to be abusing, exploiting, or coercing a resident;
- Denying access to individuals who have been found to have been committing criminal acts such as theft;

- Denying access to individuals who are inebriated or disruptive; *or*
- *Denying access or providing supervised visitation to individuals who have a history of bringing illegal substances into the facility which places residents' health and safety at risk.*

Visitation Considerations During a Communicable Disease Outbreak

Facilities may need to modify their visitation practices when there are infectious outbreaks or pandemics to align with current CMS guidance and CDC guidelines that enables maximum visitation, such as by:

- *Offering options for outdoor or virtual visitation, or indoor designated visitation areas*
- *Providing adequate signage with instructions for infection prevention, i.e. hand hygiene, cough etiquette, etc.*
- *Ensuring access to hand hygiene supplies*
- *Taking other actions that would allow visitation to continue to occur safely in spite of the presence of a contagious infection*
- *Contacting their local health authorities for guidance or direction on how to structure their visitation to reduce the risk of communicable disease transmission during an outbreak*

During an infectious disease outbreak, while not recommended, residents who are on transmission-based precautions (TBP) can still receive visitors. In these cases, before visiting residents who are on TBP, visitors should be made aware of the potential risk of visiting and precautions necessary in order to visit the resident. Visitors should adhere to principles of infection prevention.

For purposes of this regulation, immediate family is not restricted to individuals united by blood, adoptive, or marital ties, or a State's common law equivalent. It is important to understand that there are many types of families, each of which being equally viable as a supportive, caring unit. For example, it might also include a foster family where one or more adult serves as a temporary guardian for one or more children to whom they may or may not be biologically related.

Residents have the right to define their family. During the admissions process, facility staff should discuss this issue with the resident. If the resident is unable to express or communicate whom they identify as family, facility staff should discuss this with the resident's representative.

Resident's family members are not subject to visiting hour limitations or other restrictions **not imposed by the resident**, *with the exception of reasonable clinical and safety restrictions, consistent with §483.10(f)(4)(v), placed by the facility based on recommendations of CMS, CDC, or the local health department.* With the consent of the resident, facilities must provide 24-hour

access to other non-relative visitors, subject to reasonable clinical and safety restrictions.

Visitation should be person-centered, consider the residents' physical, mental, and psychosocial well-being, and support their quality of life.

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

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

Visitation and Illegal Substance Use

It is important for facility staff to have knowledge of signs, symptoms, and triggers of possible illegal substance use such as changes in resident behavior, particularly after interaction with visitors or leaves of absence, increased unexplained drowsiness, lack of coordination, slurred speech, mood changes, and/or loss of consciousness, etc. Following such occurrences, this may include asking residents, who appear to have used an illegal substance (e.g., cocaine, hallucinogens, heroin), whether or not they possess or have used an illegal substance.

If the facility determines illegal substances have been brought into the facility by a visitor, the facility should not act as an arm of law enforcement. Rather, in accordance with state laws, these cases may warrant a referral to local law enforcement. To protect the health and safety of residents, facilities may need to provide additional monitoring and supervision. Additionally, facility staff should not conduct searches of a resident or their personal belongings, unless the resident or resident representative agrees to a voluntary search and understands the reason for the search. For concerns related to the identification of risk and the provision of supervision to prevent accidental overdose, investigate potential non-compliance at F689, §483.25(d) – Accidents.

For concerns related to the behavioral health services that are provided, investigate potential non-compliance at F740, §483.40 – Behavioral Health Services.

PROCEDURES §483.10(f)(4)(ii)-(v)

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

- If a concern is identified, interview facility staff to determine how they ensure 24-hour or immediate access as permitted under these requirements.

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

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

F578

(Rev. 208; Issued:10-21-22; Effective: 10-21-22; Implementation:10-24-22)

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

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

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

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

(v) The facility is not relieved of its obligation to provide this information to the individual once he or she is able to receive such information. Follow-up procedures must be in place to provide the information to the individual directly at the appropriate time.

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

“Advance care planning” is a process of communication between individuals and their healthcare agents to understand, reflect on, discuss, and plan for future healthcare decisions for a time when individuals are not able to make their own healthcare decisions.

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

“Physician Orders for Life-Sustaining Treatment (or POLST) paradigm form” is a form designed to improve patient care by creating a portable medical order form that records patients’ treatment wishes so that emergency personnel know what treatments the patient wants in the event of a medical emergency, taking the patient’s current medical condition into consideration. A POLST paradigm form is not an advance directive.

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

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

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

GUIDANCE §483.10(c)(6), (c)(8), *and* (g)(12)

The resident has the right to request treatment; however, facility staff are not required to provide medical treatment or services if the requested treatment or services are medically unnecessary or inappropriate. While the resident also has the right to refuse any treatment or services, the resident’s refusal does not absolve facility staff from providing other care that allows him/her to attain or maintain his or her highest practicable physical, mental, and psychosocial well-being.

For example, facility staff would still be expected to provide appropriate measures for pressure injury prevention, even if a resident has refused food and fluids and is nearing death.

If a resident (directly or through an advance directive) declines treatment (such as refuses artificial nutrition or IV hydration, despite having lost considerable weight), the resident may not

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

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

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

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

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

- Determining on admission whether the resident has an advance directive and, if not, determining whether the resident wishes to formulate an advance directive;
- Providing information in a manner easily understood by the resident or resident representative about the right to refuse medical or surgical treatment and formulate an advanced directive. This includes a written description of the facility's policies to implement advance directives and applicable State law regarding advance directives.

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

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

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

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

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

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

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

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

KEY ELEMENTS OF NONCOMPLIANCE §483.10(c)(6), (c)(8), (g)(12):

To cite deficient practice at *F578*, the surveyor's investigation will generally show that the facility failed to do one or more of the following:

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

POTENTIAL TAGS FOR ADDITIONAL CONSIDERATION

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

- 42 CFR §483.10(a)(3)-(7), F551 o For concerns regarding designation of resident representative.

- 42 CFR §483.10(c)(2)-(3), F553, Right to Participate in Planning Care o For concerns regarding the resident’s right to participate in and be informed of his or her treatment.

F582

(Rev. 208; Issued:10-21-22; Effective: 10-21-22; Implementation:10-24-22)

§483.10(g)(17) The facility must—

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

§483.10(g)(18) The facility must inform each resident before, or at the time of admission, and periodically during the resident’s stay, of services available in the facility and of charges for those services, including any charges for services not covered under Medicare/ Medicaid or by the facility’s per diem rate.

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

DEFINITIONS §483.10(g)(17)-(18)

“Periodically” means whenever changes are being introduced that will affect the resident’s liability and whenever there are changes in services.

GUIDANCE §483.10(g)(17)-(18)

Residents must be told in advance when changes will occur in their bills. Providers must fully inform the resident of services and related changes.

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

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

Beneficiary Notices

1. Notice of Medicare Non-Coverage (NOMNC)

The NOMNC, Form CMS-10123, is given by the facility to all Medicare beneficiaries at least two days before the end of a Medicare covered Part A stay or when all of Part B therapies are ending. The NOMNC informs the beneficiaries of the right to an expedited review by a Quality Improvement Organization. See also 42 CFR 405.1200 and 422.624.

*The NOMNC is **not** given if:*

- The beneficiary exhausts the SNF benefits coverage (100 days), thus exhausting their Medicare Part A SNF benefit.*
- The beneficiary initiates the discharge from the SNF.*
- The beneficiary elects the hospice benefit or decides to revoke the hospice benefit and return to standard Medicare coverage.*

2. Skilled Nursing Facility Advanced Beneficiary Notice of Non-coverage (SNF ABN)

It is important to note that the SNF ABN, CMS-10055, is only issued if the beneficiary intends to continue services and the SNF believes the services may not be covered under Medicare. It is the facility's responsibility to inform the beneficiary about potential non-coverage and the option to continue services with the beneficiary accepting financial liability for those services.

Per Ch. 30, section 70.2 of the Medicare Claims Processing Manual (IOM Pub. 100-04), a SNFABN must be given to a beneficiary for the following triggering events:

- Initiation - In the situation in which a SNF believes Medicare will not pay for extended care items or services that a physician has ordered, the SNF must provide a SNFABN to*

the beneficiary before it furnishes those non-covered extended care items or services to the beneficiary.

- *Reduction - In the situation in which a SNF proposes to reduce a beneficiary's extended care items or services because it expects that Medicare will not pay for a subset of extended care items or services, or for any items or services at the current level and/or frequency of care that a physician has ordered, the SNF must provide a SNFABN to the beneficiary before it reduces items or services to the beneficiary.*
- *Termination - In the situation in which a SNF proposes to stop furnishing all extended care items or services to a beneficiary because it expects that Medicare will not continue to pay for the items or services that a physician has ordered and the beneficiary would like to continue receiving the care, the SNF must provide a SNF ABN to the beneficiary before it terminates such extended care items or services.*

The SNF ABN provides information to beneficiaries so that they can decide if they wish to continue receiving the skilled services that may not be paid for by Medicare and assume financial responsibility. If the SNF provides the beneficiary with *the* SNF ABN, the facility has met its obligation to inform the beneficiary of his or her potential *financial* liability and related standard claim appeal rights.

The SNF:

- *Files a claim when requested by the beneficiary (this claim is called a "demand bill"); and*
- *May not charge the beneficiary for Medicare covered Part A services during demand bill process.*

For detailed information refer to the Medicare Claims Processing Manual (IOM Pub. 100-04) at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c30.pdf>. SNFABN is addressed in Ch. 30, section 70 of the manual and NOMNC is addressed in section 260.

***NOTE:** A facility's requirement to notify and explain via the SNFABN that the individual is no longer receiving Medicare Part A services based on the SNF's belief that Medicare Part A will not pay for the resident's stay, is separate and unrelated to the admission and discharge requirements under 42 CFR §483.15, which outlines the notification and requirements under which an individual may be discharged from the facility or when the transfer or discharge is not initiated by the resident.*

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

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

- Notify each Medicaid- eligible resident in writing of the items and services which are/are not covered under Medicaid or by the facility's per diem rate, including the cost of those items and services:

- o At the time of admission, **or**
- o When the resident became eligible for Medicaid, **or**
- Inform each Medicaid-eligible resident when changes were made to the items and services covered by Medicaid; **or**
- Inform each resident of services available in the facility and the charges for those services not covered under Medicare/Medicaid or by the facility's per diem rate:
 - o Before admission or at the time of admission, and periodically during the resident's stay; **or**
 - o As soon as reasonably possible when a change in coverage occurs; **or**
 - o At least 60 days prior to implementation of changes made to charges for other items and services that the facility offers; **or**
- Refund the applicable funds to the resident, resident representative, or estate when a resident died, or was hospitalized, or was transferred and did not return to the facility; **or**
- Refund any and all funds due the resident:
 - o Within 30 days from the date of discharge; **or**
 - o To the resident or resident representative; **or**
- Included terms in the admission contract that conflicted with the requirements of these regulations.

F584

(Rev. 208; Issued:10-21-22; Effective: 10-21-22; Implementation:10-24-22)

§483.10(i) Safe Environment.

The resident has a right to a safe, clean, comfortable and homelike environment, including but not limited to receiving treatment and supports for daily living safely.

The facility must provide—

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

- (i) This includes ensuring that the resident can receive care and services safely and that the physical layout of the facility maximizes resident independence and does not pose a safety risk.**
- (ii) The facility shall exercise reasonable care for the protection of the resident's property from loss or theft.**

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

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

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

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

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

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

DEFINITIONS §483.10(i)

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

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

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

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

“Environment” refers to any environment in the facility that is frequented by residents, including (but not limited to) the residents’ rooms, bathrooms, hallways, dining areas, lobby, outdoor patios, therapy areas and activity areas.

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

“Orderly” is defined as an uncluttered physical environment that is neat and well-kept.

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

GUIDANCE §483.10(i)

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

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

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

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

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

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

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

Adequate lighting design has these features:

- Lighting with minimum glare in areas frequented by residents. Elimination of high levels of glare produced by shiny flooring and from unshielded window openings;
- Even light levels in common areas and hallways, avoiding patches of low light caused by too much space between light fixtures, within limits of building design constraints;
- Use of daylight as much as possible;

- Extra lighting, such as table and floor lamps to provide sufficient light to assist residents with tasks such as reading;
- Lighting for residents who need to find their way from bed to bathroom at night (for example, red colored night lights preserve night vision); and
- Dimming switches in resident rooms (where possible and when desired by the resident) so that staff can tend to a resident at night with limited disturbances to them or a roommate. If dimming is not feasible, another option may be for staff to use flashlights/pen lights when they provide night care.

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

PROCEDURES §483.10(i)

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

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

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

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

PROBES §483.10(i)

- Does the resident have any concerns with lighting, noise, temperature, or anything else that may affect their comfort?

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

POTENTIAL TAGS FOR ADDITIONAL CONSIDERATION

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

- For concerns regarding the resident’s right to have personal possessions, including furnishings, see §483.10(e)(2), F557;
- For concerns related to misappropriation of resident property, see §483.12, F602, Misappropriation of Resident Property;
- For issues of safety of the environment, presence of hazards and hazardous practices, see §483.25(d), F689, Accidents;
- For kitchen sanitation, see §483.60(i), F812, Food Safety Requirements;
- For facility-wide sanitary practices affecting the quality of care, see §483.80, F880, Infection Control.
- *For issues of fire danger, see guidance provided for §483.90(a) which states, “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).”; or*
- For issues of cleanliness of areas of the facility used by staff only (such as the break room, medication room, laundry, kitchen, etc.) or the public only (such as the parking lot), see §483.90(h), F921, Other Environmental Conditions.

F600

(Rev. 208; Issued:10-21-22; Effective: 10-21-22; Implementation:10-24-22)

§483.12 Freedom from Abuse, Neglect, and Exploitation

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

§483.12(a) The facility must—

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

INTENT §483.12(a)(1)

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

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

DEFINITIONS §483.12(a)(1)

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

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

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

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

GUIDANCE §483.12(a)(1)

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

ABUSE

Sections §§1819(c)(1)(A)(ii) and 1919(c)(1)(A)(ii) of the Social Security Act provide that each resident has the right to be free from, among other things, physical or mental abuse and corporal punishment. The facility must provide a safe resident environment and protect residents from abuse.

Staff to Resident Abuse of Any Type

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

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

Resident to Resident Abuse of Any Type

A resident to resident altercation should be reviewed as a potential situation of abuse. *The surveyor should not assume that every resident to resident altercation results in abuse. For example, infrequent arguments or disagreements that occur during the course of normal social interactions (e.g., dinner table discussions) would not constitute abuse. The surveyor must determine whether the incident would meet the definition of abuse.*

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

The facility may provide evidence that it completed a resident assessment and provided care planning interventions to address a resident's distressed behaviors such as physical, sexual or verbal aggression. However, based on the presence of resident to resident altercations, if the facility did not evaluate the effectiveness of the interventions and staff did not provide immediate interventions to assure the safety of residents, then the facility did not provide sufficient protection to prevent resident to resident abuse. For example, redirection alone is not a sufficiently protective response to a resident who will not be deterred from targeting other residents for abuse once he/she has been redirected.

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

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

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

Visitor to Resident Abuse of Any Type

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

In addition, the survey team must review whether the facility has developed and implemented policies and procedures related to visitor access. This would include safety restrictions, such as denying access or providing limited and supervised access to a visitor who has been found to be abusing, exploiting, or coercing a resident or who is suspected of abusing, exploiting, or coercing a resident until an investigation into the allegation has been completed. Any such restriction should be discussed with the resident or resident representative first. Also, the

resident maintains the right to deny visitation according to his/her preferences. See guidance at F563- Visitation Rights and F564- Resident Right to Visitors.

TYPES OF ABUSE

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

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

In addition, the risk for abuse may increase when a resident exhibits a behavior(s) that may provoke a reaction by staff, residents, or others, such as³:

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

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

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

- Fear of a person or place, of being left alone, of being in the dark, and/or disturbed sleep and nightmares;
- Extreme changes in behavior, including aggressive or disruptive behavior toward a specific person; and

- Running away, withdrawal, isolating self, feelings of guilt and shame, depression, crying, talk of suicide or attempts.

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

Physical Abuse

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

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

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

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

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

Deprivation of Goods and Services by Staff

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

Mental and Verbal Abuse

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

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

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

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

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

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

Sexual Abuse

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

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

Generally, sexual contact is nonconsensual if the resident either:

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

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

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

Non-Sexual Physical Contact with Residents

Nothing in this guidance is intended to limit a resident's ability to receive non-sexual contact, such as holding a resident's hand. It is not the intent of this guidance for facilities to foster "no contact of any type" policies/procedures/practices between staff and residents or residents and others, assuming such contact is consistent with the resident's preferences. It should also not be assumed that all physical contact involving a resident would constitute sexual abuse.

Capacity and Consent

Residents have the right to engage in consensual sexual activity. However, anytime the facility has reason to suspect that a resident may not have the capacity to consent to sexual activity, *the facility must take steps to ensure that the resident is protected from abuse. These steps should include evaluating whether the resident has the capacity to consent to sexual activity.*

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

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

When investigating an allegation of sexual abuse, the facility must conduct a thorough investigation to determine the facts specific to the case investigated, including whether the resident had the capacity to consent and whether the resident actually consented to the sexual activity. A resident's voluntary engagement in sexual activity may appear to mean consent to the activity; in these instances, if the facility has reason to suspect that the resident may not have the capacity to consent, the facility must protect the resident from potential sexual abuse while the investigation is in progress *[See §483.12(c)(3)]*.

Determinations of capacity to consent depend on the context of the issue and one determination does not necessarily apply to all decisions made by the resident. For example, the resident may not have the capacity to make decisions regarding medical treatment, but may have the capacity to make decisions on daily activities (e.g., when to wake up in the morning, what activities to engage in). Determinations of capacity in this context are complex and cannot necessarily be based on a resident's diagnosis alone. Capacity on its most basic level means that a resident has the ability to understand potential consequences and choose a course of action for a given situation. Decisions of capacity to consent to sexual activity must balance considerations of safety and resident autonomy, and capacity determinations must be consistent with State law, if applicable. The facility's policies, procedures and protocols, should identify when, how, and by whom determinations of capacity to consent to a sexual contact will be made and where this documentation will be recorded. See also 42 CFR §483.10(f) [F561] for concerns related to the resident's right to self-determination through support of resident choice, and 42 CFR §483.10(b)(3)-(7) [F551] for concerns related to the exercise of the resident's rights by the resident representative.

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

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

Residents with Designated or Legally Appointed Representatives

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

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

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

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

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

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

Indicators of Potential Sexual Abuse

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

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

Literature indicates that the most prevalent psychosocial outcomes of abuse are depression, anxiety, and posttraumatic disorder⁴. Other possible outcomes of sexual abuse^{5,6} may include SUDDEN OR UNEXPLAINED CHANGES in the following behaviors and/or activities such as fear or avoidance of a person or place, of being left alone, of the dark, nightmares, and/or disturbed sleep.

Allegations of Sexual Abuse

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

- Sexual abuse by a staff member;
- Resident to resident sexual abuse; and

- Sexual abuse by a spouse or visitor.

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

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

See Tags F609 [*See §§ 483.12(b)(5), 483.12(c)(1) and (c)(4)*], and F610 [*See §§ 483.12(c)(2), (c)(3), and (c)(4)*].

Allegations of Staff to Resident Sexual Abuse

Nursing home staff are entrusted with the responsibility to protect and care for the residents of that facility. Nursing home staff are expected to recognize that engaging in a sexual relationship with a resident, even an apparently willingly engaged and consensual relationship, is not consistent with the staff member's role as a caregiver and will be considered an abuse of power. Also, for some health care professionals, it is prohibited by licensure or certification requirements for professionals to have a relationship with a resident (or patient).

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

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

Allegations of Resident To Resident Sexual Abuse

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

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

Allegations of Visitor to Resident Sexual Abuse

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

Response to Alleged Violations of Sexual Abuse

If an allegation of sexual abuse has been reported, the facility must immediately protect the alleged victim(s) involved, report the alleged violations to the Administrator and appropriate State and local authorities, and begin an investigation of the allegation. See 42 CFR §483.12 (c)(1)-(4), F609-Reporting of Alleged Violations and F610-Response to Alleged Violations. As the facility conducts its investigation, the facility must not tamper with evidence. Tampering with evidence would impede completion of a thorough investigation by the facility and other investigating authorities. Examples of tampering include, but are not limited to: washing linens or clothing, destroying documentation, bathing or cleaning the resident until the resident has been examined (including a rape kit, if appropriate), or otherwise impeding a law enforcement investigation. If the surveyor identifies that the facility has tampered with evidence, the surveyor should investigate whether the facility is in compliance with F607 and F610.

Determination of Findings and Potential to Foresee Abuse

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

Determination of Past Non-Compliance

Past noncompliance occurs when noncompliance has occurred in the past, but the facility corrects the deficiency and is in substantial compliance at the time of the current survey.

Prior to citing a deficiency as past-noncompliance, surveyors should investigate each instance thoroughly to determine if the facility took all the appropriate actions to correct the noncompliance, and determine the date on which the facility had returned to substantial compliance.

More specifically, a deficiency citation at past noncompliance meets the following three criteria:

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

The surveyors must document the facility's corrective actions in the CMS-2567; the facility is not required to submit a plan of correction. Refer to SOM Section [7510.1](#) and [7510.2](#) for *additional guidance and* information on findings of past noncompliance.

NOTE: When a facility has identified abuse, the facility must take all appropriate steps to remediate the noncompliance and protect residents from additional abuse immediately. Facilities that take immediate action to correct any issues can reduce the risk of further harm continuing or occurring to other residents, thereby potentially preventing the scope and severity of the deficiency from increasing. Failure to take steps could result in findings of current noncompliance and increased enforcement action, including, but are not limited to, the following:

- *Taking steps to prevent further potential abuse [See F600, 483.12(a) and F610- § 483.12(c)(3)];*
- *Reporting the alleged violation and investigation within required timeframes [See F609- § 483.12(c)(1) and (c)(4)];*
- *Conducting a thorough investigation of the alleged violation [See F610 – § 483.12(c)(2)];*
- *Taking appropriate corrective action [See F610 –§ 483.12(c)(4)]; and*
- *The facility must revise the resident's care plan if the resident's medical, nursing, physical, mental, or psychosocial needs or preferences change as a result of an incident of abuse [See Tag F656- §483.21(b)].*

NEGLECT

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

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

Neglect at F600 should not automatically be cited in addition to the Resident's Rights/Quality of Care/Quality of Life tags. While the latter citations identify potential or actual negative outcomes in the areas of resident's rights, quality of care, and quality of life, neglect identifies the facility's failure to provide the required structures and processes in order to meet the needs of one or more residents. This may include, but is not necessarily limited to, the facility's failure to provide necessary staff, supplies, services, policies, training, or staff supervision and oversight to meet the resident's needs.

Noncompliance at tags such as F686 and F689, do not automatically indicate noncompliance at F600 for neglect. For example, a survey team identifies that a facility had failed to perform a skin assessment for a resident, resulting in failure to implement interventions to prevent the development of an avoidable Stage 2 pressure ulcer for a resident. Upon further investigation, the survey team finds that the facility identified the pressure ulcer and treated it with no further worsening. While the survey team would identify noncompliance at F686, the facility would not generally be cited at F600 as well. Another example is when a resident requires supervision when ambulating and a staff member fails to provide assistance to the resident, resulting in a fall. In this scenario, the survey team would identify noncompliance at F689; however, the facility would not be cited at F600 for neglect. In both of these examples, a citation for neglect would require additional evidence that identifies that the facility knew, or should have known, to provide the staff, supplies, services, policies, training, or staff supervision and oversight to meet the resident's needs, but continued to fail to take action necessary to avoid the potential for harm, or actual harm to the resident.

Identifying Neglect

"Neglect," is defined at §483.5 as "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." Neglect occurs when the facility is aware of, or should have been aware of, goods or services that a resident(s) requires but the facility fails to provide them to the resident(s), that has resulted in or may result in physical harm, pain, mental anguish, or emotional distress. Neglect includes cases where the facility's indifference or disregard for resident care, comfort or safety, resulted in or could have resulted in, physical harm, pain, mental anguish, or emotional distress. Neglect may be the result of a pattern of failures or may be the result of one or more failures involving one resident and one staff person.

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

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

Identification of Goods and Services Required by Residents

When a resident is admitted to a nursing home, the nursing home has determined that it has the capability and capacity to provide goods and services to meet the needs of the resident by its staff. *See, for example, requirements at §483.10-Resident Rights, §483.24-Quality of Life, and §483.25-Quality of Care.* In addition, other services as needed by the resident must be assessed and addressed by the nursing home. This does not mean that all services must be directly provided by the nursing home, but the nursing home must assist and/or make referrals for the resident to receive necessary services. Examples of structures and processes in the facility include but are not limited to, the following:

- Structures - The nursing home's capability and capacity to provide needed care and services such as:
 - A facility's assessment to determine what resources are necessary to care for its residents competently;
 - The provision of sufficient numbers of qualified, trained staff based upon the facility's assessment and as needed to meet resident needs;
 - An effective orientation, training, and evaluation program, which includes, but is not limited to, nursing home resident care policies specific to resident's identified

- care needs, resident care requirements based upon assignments and duties including types of services and treatments required for each resident, and other interventions necessary to meet a resident(s) needs;
- Oversight and monitoring of staff performance including conducting performance evaluations for direct care staff (nurse aides), and how weaknesses or training needs are addressed;
 - Oversight and monitoring of contracted services or services provided under arrangement;
 - Resident care policies and procedures to ensure that the facility provides care and services in accordance with current standards of practice, that address resident's diagnosis, and that provide clinical and technical direction to meet the needs of each resident admitted;
 - Sufficient amounts of food to meet dietary needs;
 - Availability of medications and supplies necessary to provide care;
 - Implementation of an infection control and prevention program that includes staff procedures for care including hand hygiene, standard and transmission based precautions, including use of PPE;
 - A safe and sanitary environment;
 - Provision of sufficient clean linens;
 - Adequate and appropriate equipment and devices and other available technology, including procedures for how to use, clean, maintain and store equipment; and
 - If admitted, the provision of specialized services for residents who require rehabilitation services, dialysis, respiratory therapy (mechanical ventilation or oxygen therapy), IV therapy, and hospice.
- Processes so that the needs of each resident are met, based upon:
 - Initial and ongoing assessments of the clinical needs of the resident including any acute changes in condition, such as cardio/respiratory failure, choking, hemorrhaging, poor glycemic control, onset of delirium, behavioral emergencies, or falls resulting in head injuries or fractures;
 - The provision and implementation of a resident-specific care plan including the ongoing evaluation and revision of the care plan as necessary; and
 - Ongoing monitoring and supervision of staff to assure the implementation of the care plan as written.

The cumulative effect of different individual failures in the provision of care and services by staff leads to an environment that promotes neglect. *Neglect occurs when the facility is aware of, or should have been aware of, goods or services that a resident(s) requires but the facility fails to provide them to the resident(s), resulting in, or may result in, physical harm, pain, mental anguish, or emotional distress.* Examples of individual failures include, but are not limited, to the following:

- Failure to provide sufficient, qualified, competent staff, to meet resident's needs;
- Failure to provide orientation and/or training to staff;

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

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

INVESTIGATIVE SUMMARY FOR ABUSE AND NEGLECT INVESTIGATION OF ALLEGATIONS OF ABUSE

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

Summary of Procedures

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

- Refer to the Neglect Critical Element Pathway (form CMS-20130) to investigate concerns about structures or processes leading to a resident(s) failing to receive required care and services.
- Refer also to the Investigative Protocol for *F607 – Policies and Procedures Related to Allegations of Retaliation by the Facility Against a Covered Individual, for an allegation of retaliation and F609-Reporting Reasonable Suspicion of a Crime*, if a covered individual did not report a reasonable suspicion of a crime.

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

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

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

For specific allegations of abuse, the surveyor should review:

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

- For allegations of visitor to resident abuse, whether there was any indication of risk to the resident(s) and whether adequate monitoring and supervision were provided as appropriate.

If Tag F600 is cited for abuse, the survey team includes the following language at the beginning of the Deficient Practice Statement on the Form CMS-2567: “Based on [observations/interviews/record review], the facility failed to protect the resident’s(s’) right to be free from [Type(s) of abuse: mental abuse/verbal abuse/physical abuse/sexual abuse/deprivation of goods and services] by [Perpetrator type: staff/a resident/a visitor]”

INVESTIGATION FOR ALLEGATIONS OF NEGLECT

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

Use

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

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

Summary of Procedures

Interview staff and review facility policies and procedures to determine:

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

If Tag F600 is cited for neglect, the survey team includes the following language at the beginning of the Deficient Practice Statement on the Form CMS-2567: “Based on [observations/interviews/record review], the facility failed to protect the resident’s(s’) right to be free from neglect....”

KEY ELEMENTS OF NONCOMPLIANCE FOR ABUSE AND NEGLECT §483.12(a)(1)

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

- Failed to protect a resident’s right to be free from any type of abuse, including corporal punishment, and neglect, that results in, or has the likelihood to result in physical harm, pain, or mental anguish; or

- Failed to ensure that a resident was free from neglect when it failed to provide the required structures and processes in order to meet the needs of one or more residents.

POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION

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

- 42 CFR §483.10(f)(4)(ii)-(v), F563 - Visitation Rights
 - Determine if the facility provided immediate access and visitation by family, designated representatives or other individuals, subject to reasonable restrictions and the resident's right to deny or withdraw consent.
- 42 CFR §483.10(f)(4)(vi), F564- Resident Right to Visitors
- 42 CFR §483.10(g)(1), F572 - Notice of Rights and Rules
- 42 CFR §483.10(h), F583- Personal Privacy/Confidentiality of Records
- 42 CFR §483.12(a)(3)-(4), F606 - Not Employ/Engage Staff with Adverse Actions
- 42 CFR §483.12(b)(1)-(4), §483.12(b)(5), F607 – Develop/Implement Abuse/Neglect, etc. Policies
- 42 CFR §483.12(c)(1), (4), §483.12(b)(5), F609 – Reporting of Alleged Violations
- 42 CFR §483.12(c)(2) - (4), F610 – Alleged Violations-Investigate/Prevent/Correct
- 42 CFR §483.24, F675 - Quality of Life
- 42 CFR §483.25(d), F689- Free of Accident Hazards/Supervision/Devices
 - Determine if the facility ensured that the resident environment remains as free from accident hazards as is possible and each resident receives adequate supervision to prevent accidents related to resident-to-resident altercations where the resident's action is not willful.
- 42 CFR §483.35, 483.35(a), and §483.35(c)- F725 and F726 – Sufficient and Competent Staff
- 42 CFR §483.35(a)(3) and (a)(4), §483.35(c), F726 – Competent Staff
- 42 CFR §483.40(b)-(b)(1), F742- Treatment/Svc for Mental/Psychosocial Concerns
- 42 CFR §483.75 (g)(2)(ii)- F867- QAA Activities
- 42 CFR §483.95(c), F942- Abuse, Neglect, and Exploitation Training
- 42 CFR §483.95(g), F946-Required In-Service Training for Nurse Aide

DEFICIENCY CATEGORIZATION §483.12(a)(1)

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

As the Psychosocial Outcome Severity Guide, located in the [Nursing Home Survey Resources Folder](#), describes, to apply the reasonable person concept, the survey team should determine the severity of the psychosocial outcome or potential outcome the deficiency may have had on a reasonable person in the resident's position (i.e., what degree of actual or potential harm would

one expect a reasonable person in the resident's similar situation to suffer as a result of the noncompliance). Generally, when applying the reasonable person concept, the survey team should consider the following as it determines the outcome to the resident, which include, but is not limited to:

- The resident may consider the facility to be their "home," where there is an expectation that he/she is safe, has privacy, and will be treated with respect and dignity.*
- The resident trusts and relies on facility staff to meet his/her needs.*
- The resident may be frail and vulnerable.*

Determining the severity of psychosocial outcomes for abuse can present unique challenges to surveyors. Given that the psychosocial outcome of abuse may not be apparent at the time of the survey, it is important for the survey team to apply the reasonable person concept in evaluating the severity of psychosocial outcomes. It is important for the surveyor to gather and document any information that identifies any psychosocial outcomes resulting from the noncompliance; for abuse, surveyors should also consider that the psychosocial outcome of abuse may not be apparent at the time of the survey. For example, a resident who was raped may demonstrate indifference to the incident at the time of the survey. In addition, residents may not be able to express themselves due to a medical condition and/or cognitive impairment (e.g., stroke, coma, Alzheimer's disease), not be able to recall what has occurred, or may not express outward signs of physical harm, pain, or mental anguish. However, when a nursing home resident is treated in any manner that does not uphold a resident's sense of self-worth and individuality, it dehumanizes the resident and creates an environment that perpetuates a disrespectful and/or potentially abusive situation for the resident(s).

There are situations that are likely to cause psychosocial harm which may sometimes take months or years to manifest and have long-term effects on the resident and his/her relationship with others. Therefore, during a survey, "Immediate Jeopardy" or "Actual Harm," may be supported when there is not an observed or documented negative psychosocial outcome, or a description of resident impact from the resident's representative or others who know the resident. Numerous situations involving abuse are likely to cause serious psychosocial harm (i.e. Immediate Jeopardy) to a resident who is a victim of these types of actions; these situations include, but are not limited to:

- Sexual assault (e.g., rape)*
- Unwanted sexual touching*
- Sexual harassment*
- Any staff to resident physical, sexual, or mental/verbal abuse [NOTE: Sexual abuse does not include the rare situation where a nursing home employee has a pre-existing and consensual sexual relationship with an individual (i.e., spouse or partner) who is then admitted to the nursing home unless there are concerns about the relationship not being consensual]*
- Staff posting or sharing demeaning or humiliating photographs or videos of nursing home residents*
- When facility staff, as punishment, threaten to take away the resident's rights, privileges, or preferred activities, or withhold care from the resident*

- *Any resident to resident physical abuse that is likely to result in fear or anxiety*

According to the Social Security Act [Sections §§1819(c)(1)(A)(ii) and 1919(c)(1)(A)(ii)], every resident has the right to be free from mental or physical abuse. A reasonable person would not expect that they would be harmed in his/her own “home” or a health care facility and would experience a negative psychosocial outcome (e.g. fear, anxiety, anger, humiliation, a decline from former social patterns). In incidents in which one resident abuses another resident, if a reasonable person would likely suffer actual harm as a result of the incident, the incident should not be cited below Severity Level 3 (Actual Harm).

NOTE: Surveyors should refer to the guidance related to physical, mental/verbal, and sexual abuse and deprivation of goods and services by staff.

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

- *The facility failed to protect a resident from sexual abuse when Resident 1 was found in Resident 2’s bedroom. Resident 1 was holding Resident 2, whose clothes had been partially removed and her breasts were exposed. Resident 2 was severely cognitively impaired. Resident 1 had a known history of sexually inappropriate behaviors, but there was no evidence that the facility had assessed and revised the care plan to identify the potential risks to other residents related to the behaviors; there was no evidence that Resident 2 could consent to sexual activity with other residents. Based on interview with Resident 2’s daughter, the daughter described her shock about the incident and how her mother would have been upset. Because this type of inappropriate, unwanted sexual contact would reasonably cause anyone to have psychosocial harm, it can be determined that the reasonable person in the resident’s position would have experienced severe psychosocial harm- dehumanization, and humiliation- as a result of the sexual abuse.*
- *The facility failed to ensure that a resident was free from physical abuse. A resident, who required 1:1 supervision due to physical aggression, was observed to have escalating behaviors, resulting in striking out at staff and residents in the vicinity. The staff failed to ensure that residents in the vicinity were safe, and the resident pushed another resident who was walking to his/her room while unsupervised by staff, as described by housekeeping staff who witnessed the incident. The victim fell to the floor with a resulting fracture to her arm that required treatment at the hospital, placement of a cast, and was in moderate pain due to the fracture. Even though there was no significant decline in mental or physical functioning, it can be determined that the reasonable person would have experienced severe psychosocial harm as a result of the physical abuse, since a reasonable person would not expect to be injured in this manner in his/her own home or a health care facility.*
- *The facility failed to ensure that a resident was free from mental abuse and corporal punishment. A resident who had a cognitive disability carried a doll around with her throughout the day. During an activity, the resident placed the doll in a chair next to*

her and refused to allow another resident to use the chair. The staff slapped the resident's hand and removed the doll so the other resident could sit down. The staff told the resident she could not attend any more activities with the doll, or he would get rid of it and the resident would never see it again. The resident began to scream, cry for her doll, and left the room. The resident will not leave her room to attend any activities for fear that the staff person will take her doll. The resident's behavior has declined and now cries and expresses fear when taken for bathing and meals without her doll. Based on the resident's behavior, it can be determined that the resident experienced severe psychosocial harm as a result of the mental abuse and corporal punishment.

- *The facility deprived residents of care related to the failure of staff to respond timely to residents' requests and treat residents with dignity and respect which resulted in ongoing embarrassment, humiliation, and the failure to provide incontinence care as needed to meet the needs of several residents. Based on family and resident group interviews, other residents and their family members complained that residents often waited a long time (up to an hour) before staff took them to the bathroom, resulting in residents urinating in their beds and lying in urine for long periods of time. Residents indicated that this is a problem, especially on the night shift. Residents were told by nurse aides to just urinate on their beds and staff would change the sheets in the morning. Two night-shift staff members confirmed that they had seen other staff disconnect call lights in residents' rooms so that they were not functioning. After investigation, it was determined that the nursing home failed to provide the necessary care. [NOTE: In this example, the surveyor had already identified noncompliance at dignity (F550) and urinary incontinence (F690)] It can be determined that the reasonable person in the residents' position would have experienced severe psychosocial harm (e.g., embarrassment, humiliation) as a result of the abuse.*
- *The facility deprived a resident of care by failing to provide access for resident communication and response to resident's requests for necessary care resulting in the resident's ongoing fear and anxiety. During a survey, the surveyor observed that a resident's call light was pinned to a privacy curtain that was out of reach of the resident. The resident stated that the staff removes the call light at night because the nursing staff said he used it too much and they did not have time to answer the light all the time. The resident began crying and expressed fear that something would happen and he would have no way of getting assistance as staff would not come if he called out for help. Based on the resident's behavior, it can be determined that the resident experienced severe psychosocial harm as a result of the deprivation of care.*
- The facility failed to protect a resident from sexual abuse resulting in serious psychosocial harm. A resident, with moderate confusion and who was dependent on staff for care, reported to staff that she was "touched down there" and identified the alleged perpetrator. However, staff, who thought the resident was confused, did not report her allegation to facility administration and failed to provide protection for the resident allowing ongoing access to the resident by the alleged perpetrator. The resident expressed recurring fear whenever the perpetrator approached the resident,

exhibited crying and agitation, and declined to leave her room. *Based on the resident's behavior, it can be determined that the resident experienced severe psychosocial harm as a result of the sexual abuse.*

- The facility failed to protect two residents from mental abuse and extreme humiliation perpetuated by two staff who posted videos and photographs on social media, of the residents during bathing, using the bathroom, and grooming, which included nude photos and photos of genitalia. In addition, on the videos, the two staff verbally taunted and made cruel remarks to the residents including making fun of the way the resident looked and acted. One resident who was cognitively impaired was shown on the video to be crying in response to the remarks made to her by the staff. One resident, who was cognitively intact, told surveyors that he was extremely humiliated and angry when he found out that these items were posted. *Based on the resident's behavior, it can be determined that the resident experienced severe psychosocial harm as a result of the mental abuse.*
- The facility failed to ensure that a resident was free from neglect when it did not have the structures to provide necessary goods and services to residents. During facility tour, the surveyor noted a strong urine odor. Residents were observed to be in bed with soiled clothes and linens. Residents told the surveyor that they did not get out of bed or dressed since there were not enough nurse aides to assist them. During interviews with nurse aides, it was reported that the facility lacked supplies, such as incontinence briefs, laundry/housekeeping supplies, gloves and food. Interview with the Director of Nurses revealed that the medical supply vendor was suspended and no longer providing supplies to the facility due to non-payment. Multiple staff also reported not receiving their last paychecks. During interviews with residents, residents reported mice in their rooms. During observation of the kitchen and interview with the dietary manager, there was evidence of rodent infestation, including staff seeing rodents eating and finding torn bags and crumbs on the floor. The administrator reported that the pest control company had visited the facility recently, but there was no record of the visit or proposal for remediation. Also, there was no sanitizer for the dishwasher and no alternative method for sanitizing dishes. *It can be determined that the reasonable person in the residents' position would have experienced severe psychosocial harm (e.g., embarrassment, humiliation, anxiety) as a result of neglect.*

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

- *The facility failed to protect a resident from physical abuse when Resident 1 slapped Resident 2 in the face. Based on resident and staff interviews, Resident 1 had previously exhibited an aggressive tone towards other residents. Based on the interview with the nurse aide, Resident 2 was talking loudly to Resident 1 in the hallway. Resident 1 shouted profanity to Resident 2, followed by: "If you say one more word, you're going to be sorry." The nurse aide was the only staff present in the area and was transferring another resident; the nurse aide could not intervene and did not call for assistance from other staff. Resident 2 continued to talk loudly. Resident 1*

then reached out, slapped Resident 2 on the left side of his face, and backed his wheelchair away from Resident 2. Based on the assessment of Resident 2, his left cheek exhibited some redness in the area that was slapped, but there were no other physical injuries. Based on the survey team's interview with Resident 1, Resident 1 was also able to recall the incident and said, "He [Resident 2] just won't stop talking...I don't know what came over me." Resident 2 was moderately cognitively impaired and when interviewed, could not recall the incident. The survey team interviewed Resident 2's son, who said that his father would have been mad after an incident like this. Therefore, by using the reasonable person concept, the survey team would conclude that Resident 2 would have experienced psychosocial harm (e.g. anger directed at the action or at a person) as a result of the physical abuse since there is an expectation that the resident would not be slapped in the face in the facility.

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

Examples of Severity Level 2 Considerations 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 protect Resident 2 from verbal abuse. During the interview with Resident 2, she mentioned that she does not get along with Resident 1. Based on an interview with staff, Resident 1 previously demanded Resident 2 to sit up at the table and that there was something wrong with her. However, staff would re-direct the residents to separate tables to prevent any situation from escalating. According to interviews with other residents, one weekend, residents recall that temporary staff had placed Resident 1 and 2 at the same table for a group activity. Resident 1 yelled to Resident 2 to sit up straight a few times. However, staff in the room would not intervene. Resident 1 called Resident 2 a derogatory name. Upon review of Resident 1 and 2's records, there was no documentation related to altercations. Even though Resident 2 did not have a reaction, it can be determined that the reasonable person would experience no actual harm with the potential for more than minimal psychosocial harm as a result of the verbal abuse.*

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

The failure of the facility to prevent abuse or neglect is more than minimal harm. Therefore,

Severity Level 1 does not apply for this regulatory requirement.

¹ World Health Organization. 2016. Adapted from *Elder Abuse Fact Sheet*. September. Accessed March 21, 2017. <https://www.who.int/mediacentre/factsheets/fs357/en>.

² CDC. 2016. *Elder Abuse: Risk and Protective Factors*. June. Accessed March 21, 2017. <http://www.cdc.gov/violenceprevention/elderabuse/riskprotectivefactors.html>.

³ Adapted from Lachs, Mark S, Tony Rosen, Jeanne A Teresi, Joseph P Eimicke, Mildred Ramirez, Stephanie Silver, and Karl Pillemer. 2013. "Verbal and physical aggression directed at nursing home staff by residents." *Journal of General Internal Medicine* 660-667.

⁴ Dong, XinQi, RuiJia Chen, E-Shien Chang, and Melissa Simon. 2013. "Elder Abuse and Psychological Well-Being: A Systematic Review and Implications for Research and Policy--A Mini Review." *Gerontology* 132-142.

⁵ Adapted from Burgess, Ann W, Elizabeth B Dowdell, and Robert A Prentky. 2000. "Sexual Abuse of Nursing Home Residents." *Journal of Psychosocial Nursing & Mental Health Services* 10-18.

⁶ Adapted from Burgess, Ann W, and Paul T Clements. 2006. "Information Processing of Sexual Abuse in Elders." *Journal of Forensic Nursing* 113-120.

F602

(Rev. 208; Issued:10-21-22; Effective: 10-21-22; Implementation:10-24-22)

§483.12

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

INTENT §483.12

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

NOTE: Refer to F609 for requirements related to reporting of a reasonable suspicion of a crime.

DEFINITIONS §483.12

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

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

GUIDANCE §483.12

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

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

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

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

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

INVESTIGATIVE PROTOCOL FOR MISAPPROPRIATION OF RESIDENT PROPERTY AND EXPLOITATION §483.12

OBJECTIVES

To determine:

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

USE

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

PROCEDURES §483.12

OFFSITE SURVEY PREPARATION

Information related to an alleged violation may be obtained from:

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

ONSITE SURVEY ACTIVITIES

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

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

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

OBSERVATION

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

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

Interview:

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

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

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

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

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

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

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

Staff Interview

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

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

Alleged Perpetrator Interview:

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

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

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

- How the facility investigated the allegation of misappropriation or exploitation;
- If the facility did not know if the resident had the property prior to the alleged loss, and how the facility protects the resident's property from loss or theft;

- Whether local law enforcement or other outside agencies were notified, and if so, any response that they are aware of; and
- What findings and resolutions have occurred.

Record Review

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

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

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

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

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

For an alleged theft of monies if the resident's funds are managed or held by the facility, review the accounting records for the resident's funds, including receipts for expenditures from the resident's funds. Attempt to reconcile whether the items are in the resident's possession.

Review interdisciplinary notes that relates to the alleged exploitation or misappropriation of property for documentation of the following:

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

- Panic attacks; and
- Changes in sleeping patterns.

Reports from Other Investigatory Agencies

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

Interview with Person Responsible for Quality Assurance

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

Administrator Interview

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

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

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

Additional Investigatory Activities Related to Allegations of Drug Diversion

For allegations of drug diversion, the surveyor determines:

- If there is evidence and/or potential outcomes such as unrelieved pain. For example, there may be evidence that on a particular shift, or when a particular staff member is working, a resident's pain symptoms are not relieved to the extent possible, but the pain symptoms are relieved on other shifts, based upon validated evidence (see also tag F697 for concerns related to pain management);
- Whether pharmacy policies at a minimum, address safeguarding and access, monitoring, administration, documentation, reconciliation and destruction of controlled substances (see also tag F755 for concerns related to facility procedures for pharmacy services);
- Whether the pharmacist has established a system of records of receipt and disposition of all controlled drugs in sufficient detail to enable accurate reconciliation and that the drug records are in order and that an account of all controlled drugs is maintained and periodically reconciled (see also tag F755 for concerns related to responsibilities of the licensed pharmacist); and
- Determine whether the resident's clinical record provides accurate documentation of the administration of a controlled medication and resident outcomes related to the medication administration (see also tag F755 for concerns related to procedures for administration and documentation of controlled substances).

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

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

KEY ELEMENTS OF NONCOMPLIANCE §483.12

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

POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION

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

- 42 CFR §483.10(e)(2), F557- Right to Have Personal Property
- 42 CFR §483.10(f)(10)(i)-(ii), F567-Protection/Management of Personal Funds
- 42 CFR §483.10(i), F584 – Safe Environment
- 42 CFR §483.10(j), F585- Grievances
- 42 CFR §483.12(a)(3)-(4), F606 - Not Employ/Engage Staff with Adverse Actions
- 42 CFR §483.12(b)(1)-(5), F607 – Develop/Implement Abuse/Neglect, etc. Policies
- 42 CFR §483.12(b)(5), (c)(1), and (c)(4), F609 – Reporting of Alleged Violations
- 42 CFR §483.12(c)(2) - (4), F610 – Alleged Violations-Investigate/Prevent/Correct
- 42 CFR §483.25(k), F697- Pain Management - Determine if there is evidence and/or potential outcomes such as unrelieved pain. For example, evidence that on a particular shift, or when a particular staff member is working, a resident’s pain symptoms are not relieved to the extent possible, but the pain symptoms are relieved on other shifts, based upon validated evidence.
- 42 CFR §483.45, §483.45(a)-(b), F755- Pharmacy Svcs/Procedures/Pharmacist/Records and 42 CFR §483.45(g)-(h), F761- Label/Store Drugs & Biologicals - Determine whether pharmacy policies at a minimum, address safeguarding and access, monitoring, administration, documentation, reconciliation and destruction of controlled substances; Determine whether the pharmacist has established a system of records of receipt and disposition of all controlled drugs in sufficient detail to enable accurate reconciliation and that the drug records are in order and that an account of all controlled drugs is maintained and periodically reconciled.
- 42 CFR §483.75 (g)(2)(ii)- F867- QAA Activities
- 42 CFR §483.95(c), F942- Abuse, Neglect, and Exploitation Training
- 42 CFR §483.95(g), F946-Required In-Service Training for Nurse Aide

DEFICIENCY CATEGORIZATION §483.12

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

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

- The facility had failed to protect residents from misappropriation of resident property, had failed to immediately report and investigate alleged violations, and had failed to implement policies and procedures for reporting the possible crime to law enforcement. A resident reported to staff that she was missing a gold necklace. She had last seen the necklace in a nightstand drawer next to her bed. The resident was tearful, since she had received the necklace from her children who had purchased it for her 80th birthday. The resident was worried that she had carelessly lost the necklace and did not want her children to be angry at her. The resident discontinued attending activities, since she did not want to leave her room so that she could protect her belongings. During the facility's investigation, during an interview, CNA #1 stated that she had noticed that CNA #2 had a new necklace that looked familiar. CNA #1 said that CNA#2 quickly evaded questions as to how she had acquired the necklace, until she said that a new boyfriend had given it to her. CNA #1 stated that she did not want to cause any trouble and did not report anything about the necklace until a week later, when it was brought to the Director of Nursing's attention that a resident's necklace was missing. Also, during the investigation, the facility received more reports from staff of stolen jewelry from five other residents, but no staff reported any of the incidents to law enforcement or the State survey agency.

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

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

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

The failure of the facility to prevent misappropriation of resident property and exploitation is more than minimal harm. Therefore, Severity Level 1 does not apply for this regulatory requirement.

F603

(Rev. 208; Issued:10-21-22; Effective: 10-21-22; Implementation:10-24-22)

§483.12(a)(1) 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.

Not use verbal, mental, sexual, or physical abuse, corporal punishment, or involuntary seclusion;

INTENT §483.12(a)(1)

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

DEFINITIONS §483.12(a)(1)

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

GUIDANCE §483.12(a)(1)

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

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

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

- A resident displays disruptive behaviors, such as yelling, screaming, distracting others (such as standing and obstructing others viewing abilities for the TV or programs) and staff remove and seclude the resident in a separate location such as in an office area or his/her room, leaving and closing the door and without providing interventions to address the behavioral symptoms;
- In an attempt to isolate a resident in order to prevent him/her from leaving an area, the resident(s) is involuntarily confined to an area by staff placing furniture, carts, chairs in front of doorways or areas of egress;

- Staff hold a door shut, from the opposite side of the door, in order to prevent egress;
- Staff place a resident in a darkened room, office, or area secluded from other staff and residents for convenience or as punishment;
- A resident is physically placed in an area without access to call lights, and/or other methods of communication creating an environment of seclusion and isolation for the resident; and
- A resident placed in a secured area of the facility, but does not meet the criteria for the unit and is not provided with access codes or other information for independent egress.

Considerations Involving Secured/Locked Areas

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

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

- The facility has identified the clinical criteria for placing a resident in the secured/locked area;

Placement in a secured/locked area is not:

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

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

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

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

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

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

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

Transmission Based Precautions

When used appropriately, transmission-based precautions (i.e., isolation due to infection) is not to be considered involuntary seclusion. The facility's policies must identify the type and duration of the transmission-based precautions required, depending upon the infectious agent or organism involved; and the precautions should be the least restrictive possible for the resident based on his/her clinical situation. Furthermore, the resident's record must contain the rationale for the selected transmission-based precautions. However, once the resident is no longer a risk for transmitting the infection, the removal of transmission-based precautions is required in order to avoid unnecessary involuntary seclusion. See also 42 CFR §483.65 – Infection Control (Tag F880).

INVESTIGATIVE PROTOCOL FOR INVOLUNTARY SECLUSION USE §483.12(a)(1)

Use this protocol for investigating:

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

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

Review of Facility Policies and Procedures

Obtain and review the facility's policies and procedures related to the allegation under investigation.

Observations

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

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

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

Interview:

Alleged Victim/Resident Representative and Witness Interviews

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

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

Interview the alleged victim/resident representative and witnesses to determine:

- What happened, when, where, and how often;

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

Staff Interview

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

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

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

Alleged Perpetrator Interview:

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

- What position he/she holds and how long the alleged perpetrator has worked in the facility;

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

Other Health Care Professionals Interview

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

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

Record Review-Resident

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

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

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

Determine if the record reflects:

- The date/time of the allegation and/or the date/time when the allegation was first discovered and reported; and

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

Record Review-Alleged Perpetrator's Personnel File Review, if Staff

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

The allegation being investigated or history of other allegations;

- Adverse personnel actions taken;
- Screening that occurred prior to and during employment; and
- Training and orientation related to abuse and neglect prevention.

Additional Activities for Investigating Possible Involuntary Seclusion for Residents in Secured/Locked Areas

If a resident lives in an area that restricts free movement throughout the facility, the survey team must determine the following:

- Whether the facility has developed and implemented policies and procedures related to secured/locked areas, including criteria for placement and ongoing assessment to assure that the resident meets the criteria;
- Whether the facility attempted alternatives prior to placement in a secured/locked area; if so, what alternatives, and what the resident's response was to the alternative interventions;
- Why the resident is placed in the secured/locked area;
- Whether the resident/resident representative was involved in the placement decision; whether the resident/resident representative agreed with the decision or not; if not, how did the facility address this; and
- Whether the secured/locked area is accessible to other residents in the facility and visitors, and if so, how.

Facility Investigator Interview

If the facility has investigated the alleged involuntary seclusion, identify the staff member responsible for the initial reporting and the overall investigation of the alleged involuntary seclusion. This may be the administrator in some facilities. Obtain a copy of the investigation report, if any.

NOTE: Refer to F609 for further investigation if the facility does not have a copy of the investigation report available.

Interview the facility investigator to determine:

- When he/she was notified of the allegation and by whom;

- When and what actions were taken to protect the alleged victim(s) while the investigation was in process;
- Steps taken to investigate the allegation and a timeline of events that occurred;
- What happened as a result of the investigation;
- When and who received the results of the investigation; and
- Whether there is any related information regarding the allegation that may not be included in the investigation report.

Administrator Interview

The administrator is responsible for the overall implementation of the facility policies/procedures, including to prohibit involuntary seclusion. This includes the obligation to report, investigate, protect the alleged victim, and take corrective actions, as necessary, based upon the outcome of the investigation. Note that some of this information may have already been obtained from the facility investigator.

Interview the administrator to determine:

- When he/she was notified of the alleged involuntary seclusion, and when the initial report was made to the required agencies;
- Who was/is responsible for the investigation, whether it has been completed and the outcome, or whether the investigation is ongoing;
- When the results of the investigation were reported to the administrator and to the required agencies;
- How the alleged victim and other residents at risk were protected during the investigation;
- If the alleged violation is verified, what corrective actions are being taken;
- Whether any changes were necessary to the facility's policies and procedures;
- Whether the alleged perpetrator had previous warnings or incidents at the facility; and
- What information has been provided to staff and residents related to involuntary seclusion, including reporting requirements.

Interview with Person Responsible for Quality Assurance

Interview the person responsible for quality assurance activities. Determine how the committee is providing monitoring and oversight of potential and/or actual reported allegations of involuntary seclusion. Evaluate whether the committee has made recommendations such as policy revision and/or training to prohibit involuntary seclusion.

KEY ELEMENTS OF NONCOMPLIANCE §483.12(a)(1)

To cite deficient practice at F603, the surveyor's investigation will generally show that the facility separated or secluded a resident against the resident's will or the resident representative's will without clinical justification.

POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION

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

- 42 CFR §483.10, §483.10(a)(1)-(2), §483.10(b)(1)-(2), F550- Resident Rights and Dignity
- 42 CFR §483.10(c)(1),(4),(5), F552- Right to be Informed/Make Treatment Decisions
- 42 CFR §483.10(c)(2)-(3), F553 - Right to Participate Planning Care
- 42 CFR §483.10(g)(14), F580-Notify of Changes (Injury/Decline/Room,Etc)
- 42 CFR §483.10(j), F585- Grievances
- 42 CFR §483.12(a)(3)-(4), F606 - Not Employ/Engage Staff with Adverse Actions
- 42 CFR §483.12(b)(1)-(5), F607 – Develop/Implement Abuse/Neglect, etc. Policies
- 42 CFR §483.12(b)(5), (c)(1), (4), F609 – Reporting of Alleged Violations
- 42 CFR §483.12(c)(2) - (4), F610 – Alleged Violations-Investigate/Prevent/Correct
- 42 CFR §483.20(b)(1)-(2)(i),(2)(iii), F636-Comprehensive Assessments & Timing
- 42 CFR §483.20(b)(2)(ii), F637-Comprehensive Assess After Significant Change
- 42 CFR §483.21(b)(1), F656- Develop/Implement Comprehensive Care Plan
- 42 CFR §483.21(b)(2), F657- Care Plan Development and Revision
- 42 CFR §483.24, F675 - Quality of Life
- 42 CFR §483.95(c), F942- Abuse, Neglect, and Exploitation Training
- 42 CFR §483.95(g), F946-Required In-Service Training for Nurse Aide
- Life safety code requirements
 - If there are concerns with life safety code requirements, the survey team should notify its SA supervisor that a life safety code concern has been identified and may require a life safety code survey.

DEFICIENCY CATEGORIZATION §483.12(a)(1)

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 is not limited to:

- The facility failed to assure that a resident was free from involuntary seclusion. The resident with a history of suicidal ideation and displaying behavioral symptoms which included episodic periods of yelling and screaming, especially towards the end of the day and during the night. According to the resident's record, after dinner last evening, the resident was placed by staff in her recliner with a tray attached by the nurse's station. It was documented and corroborated by staff interviews that they heard the resident yell and scream loudly, pounding on her tray. Several residents began complaining about the noise. A nurse aide transferred the resident to a wheelchair, and placed the resident, who was at risk for suicidal ideation, in a housekeeping supply room, which was used for storage of chemicals. The nurse aide closed the door and went back to the floor. The

resident began crying loudly, banging on the doors and yelling for help. Another staff person thought that she heard a resident yelling, but was busy completing tasks for another resident. Afterwards, she heard the yelling continue, found the resident, and removed the resident from the room, the resident was sweating profusely, her face was reddened, and was shaking and sobbing incoherently. Upon interview, the nurse aide who had secluded the resident stated that she did not have the time to deal with the yelling, and she had to get other residents to bed. She moved the resident to the supply room to quiet her down.

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

- The facility failed to assure that a resident was free from involuntary seclusion. A resident was admitted to a secured area at the request of his representative. After admission, the resident requested the security codes in order to go in and out of the area, but staff refused to provide the codes. The resident then requested to be transferred, but staff refused his request. The staff then contacted the resident's attending physician, who made the determination that was not any clinical reason for the resident to be located in the secured area; once the physician made this determination, he notified the facility, which immediately transferred the resident to a room not located in the secured area. During interview with the resident, he stated that he was still angry that he had been placed in the secured area against his will for his first day in the facility, and felt afraid to leave his room except for meals or else staff would place him again in the secured area, even though staff attempted to regain his trust.

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

- The facility failed to assure that a resident was free from involuntary seclusion. Based on resident and staff interviews, it was stated that a nurse aide was transporting him to an activity. The resident, who was dependent on staff for mobility in his wheelchair, said that he was annoyed that he was late to the activity. He began to insult the nurse aide. The nurse aide transported the resident in his wheelchair to an unused shower room, instead of to the activity room and the nurse aide told the resident that when he stopped insulting her, she would take him to the activity. The nurse aide stood outside the door to supervise the resident and when the resident became quiet, she took the resident back to the activity. Afterwards, the resident reported what had happened to the activity director and said that he did not want the aide working with him anymore. During interview, the resident stated that this was the only time something like this happened.

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

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

F604

(Rev. 208; Issued:10-21-22; Effective: 10-21-22; Implementation:10-24-22)

§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 body¹.

“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(h), F841-Responsibilities of Medical Director
- 42 CFR §483.75 (g)(2)(ii)- F867- QAA Activities

DEFICIENCY CATEGORIZATION

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

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§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(h), F841-Responsibilities of Medical Director
- 42 CFR §483.75 (g)(2)(ii)- F867- QAA Activities

DEFICIENCY CATEGORIZATION

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

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

- The facility administered a medication to a resident for staff convenience without a medical symptom identified. The resident was admitted to a secured area of the facility two months prior to the survey. During observations the resident was observed lying in a reclining chair, sleeping and staff had difficulty arousing the resident for meals. The staff had to provide one to one assistance to assist the resident to eat. The resident was unable to hold the utensils, and was being fed a pureed meal. The resident required a two-person assist to transfer from bed to chair and required total assistance for activities of daily living. The resident's record revealed that on admission, the resident was independent in mobility and ambulation and did not require assistance to eat. Staff interviewed stated that they had difficulty monitoring the resident as they were taking care of other residents. They stated that there were no identified interventions or activities to address these behaviors. As a result, staff requested a medication from the physician for the wandering behavior. The physician was interviewed and stated that the medication was being administered for wandering, but that he was not aware that the resident was sedated and the resident's decline in walking and activities of daily living. There was no other evidence in the resident's record or from interviews with staff and the physician that indicate a medical reason for the decline and sedating effect.
- The facility failed to assure that a medication it administered to a resident was being used to treat a medical symptom and not for staff convenience. The resident was admitted for post-surgical rehabilitation of a fractured hip. During an interview, the resident's representative stated that prior to admission, the resident had been alert, was able to recognize her family members, was used to sitting with the family after the evening meal at home, and, although pleasantly confused, enjoyed a warm bath prior to bedtime and slept through the night. However, after admission, there had been a significant change in the resident's status. The resident's record reflected that the resident, after admission, was immediately put to bed after the evening meal every day; subsequently, the resident began yelling out for help, wanted to get out of bed, and disrupted other residents' sleep. During an interview with the practitioner, staff had contacted him and requested an antipsychotic medication to keep the resident quiet during the night hours as she was disruptive and agitated. The practitioner ordered an antipsychotic medication twice a day, but did not provide documentation of a medical symptom being treated with the medication. Observations throughout the survey revealed the resident seated in a wheelchair, subdued or sleeping, sucking on her hand, mumbling to self, and not aware of surroundings or visitors. Staff interviewed corroborated that there had been a decline in the resident's condition since the administration of the medication. Due to the significant change in the resident's status related to the initiation and use of a chemical restraint, serious harm occurred to the resident.

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

- The facility administered a medication that was not being used to treat medical symptoms, the facility did not attempt any less restrictive interventions, and the medication was used for the convenience of staff. As a result of this noncompliance, the resident was sedated into the morning hours. The resident was unable to be aroused

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

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

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

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

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

F606

(Rev. 208; Issued:10-21-22; Effective: 10-21-22; Implementation:10-24-22)

§483.12(a) The facility must—

§483.12(a)(3) Not employ or otherwise engage individuals who—

- (i) **Have been found guilty of abuse, neglect, exploitation, misappropriation of property, or mistreatment by a court of law;**

- (ii) **Have had a finding entered into the State nurse aide registry concerning abuse, neglect, exploitation, mistreatment of residents or misappropriation of their property; or**
- (iii) **Have a disciplinary action in effect against his or her professional license by a state licensure body as a result of a finding of abuse, neglect, exploitation, mistreatment of residents or misappropriation of resident property.**

§483.12(a) (4) Report to the State nurse aide registry or licensing authorities any knowledge it has of actions by a court of law against an employee, which would indicate unfitness for service as a nurse aide or other facility staff.

INTENT

The facility must not hire an employee or engage an individual who was found guilty of abuse, neglect, exploitation, or mistreatment or misappropriation of property by a court of law; or who has a finding in the State nurse aide registry concerning abuse, neglect, exploitation, mistreatment of residents or misappropriation of resident property, or has a disciplinary action in effect taken against his/her professional license. The facility must report knowledge of actions by a court of law against an employee that indicates the employee is unfit for duty.

DEFINITIONS

“Found guilty ... by a court of law” applies to situations where the defendant pleads guilty, is found guilty, or pleads no contest to charges of abuse, neglect, exploitation, misappropriation of property, or mistreatment.

“Finding” is defined as a determination made by the State that validates allegations of abuse, neglect, exploitation, mistreatment of residents, or misappropriation of their property.

“Mistreatment,” as defined at §483.5, means “inappropriate treatment or exploitation of a resident.”

GUIDANCE

Employment

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

Facilities must be thorough in their investigations of the histories of prospective staff. In addition to inquiry of the State nurse aide registry or licensing authorities, the facility should check information from previous and/or current employers and make reasonable efforts to uncover information about any past criminal prosecutions. It has been reported that former nurse aides with a finding of abuse, neglect, misappropriation of resident property, exploitation, or mistreatment may seek employment in other departments of a facility, such as maintenance or laundry services/department, or at another nursing home in a non-nursing capacity.

Some States may have additional requirements for criminal background checks and State law may prohibit persons convicted of certain crimes from working in a long-term care facility. The State Survey Agency may use its own authority for assuring facility compliance such as the use of the National Background Check Program or specific State licensure requirements that may address criminal background checks. In addition, some facilities may have more stringent hiring restrictions than what is required by State or Federal law.

If a facility has not developed and/or implemented policies and procedures related to screening procedures prior to employment, a finding of noncompliance should be considered at F607, not F606. If it is determined that the facility employed or engaged an individual, either directly or under contract, who was found guilty by a court of law of abuse, neglect, misappropriation of property, exploitation or mistreatment, or had a finding entered into the State nurse aide registry or has a disciplinary action in effect against his/her professional license concerning abuse, neglect, mistreatment of residents or misappropriation of resident property, a finding of noncompliance *is* cited at F606.

Reporting to the State Nurse Aide Registry or Licensing Authorities

A nurse aide found guilty of neglect, abuse, mistreatment, misappropriation of property, or exploitation by a court of law, must have his/her name entered into the State nurse aide registry [*See 483.12(a)(4)*]. A licensed staff member found guilty of the above must be reported to his/her licensing board. Further, if a facility determines that actions by a court of law against an employee are such that they indicate that the individual is unsuited to work in a nursing home, then the facility must report that individual to the State nurse aide registry (if a nurse aide) or to the State licensing authorities (if a licensed staff member). Examples of convictions that may indicate unfitness to work in a nursing home include, but are not limited to, child abuse, sexual assault, theft, and assault with a deadly weapon.

NOTE: In addition, according to 42 CFR 483.156(c)(1)(iv)(A) to (c)(1)(iv)(D), Registry of Nurse Aides, the State must include the following information on any finding of abuse, neglect, or misappropriation of property by the individual:

- Documentation of the State's investigation, including the nature of the allegation and the evidence that led the State to conclude that the allegation was valid;
- The date of the hearing, if the individual chose to have one, and its outcome; and
- A statement by the individual disputing the allegation, if he or she chooses to make one.

This information must be included in the registry within 10 working days of the finding and must remain in the registry permanently, unless the finding was made in error, the individual was found not guilty in a court of law, or the State is notified of the individual's death.

Refer to the CE Pathways for Abuse (Form CMS-20059) and Neglect (Form CMS-20130) and the Investigative Protocols for tags F602 and F603.

KEY ELEMENTS OF NONCOMPLIANCE

To cite deficient practice at F606, the surveyor's investigation will generally show that the facility did **any** one or more of the following:

- Hire or engage an individual who, unless the individual in question has appealed their disqualification from employment in a nursing home and that appeal has been successful under State or federal law:
 - Has been found guilty of abuse, neglect, exploitation, misappropriation of property, or mistreatment by a court of law; **or**
 - Has had a finding entered into the State nurse aide registry concerning abuse, neglect, exploitation, mistreatment of residents, or misappropriation of their property; **or**
 - Has had a disciplinary action in effect against his/her professional license by a state professional licensure body as a result of a finding of abuse, neglect, exploitation, mistreatment of residents, or misappropriation of resident property; **or**
- Failed to report to the State nurse aide registry or licensing authorities any knowledge of actions taken by a court of law that would indicate unfitness as a staff member of a nursing home.

F607

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§483.12(b) The facility must develop and implement written policies and procedures that:

§483.12(b)(1) Prohibit and prevent abuse, neglect, and exploitation of residents and misappropriation of resident property,

§483.12(b)(2) Establish policies and procedures to investigate any such allegations, and

§483.12(b)(3) Include training as required at paragraph §483.95,

§483.12(b)(4) Establish coordination with the QAPI program required under §483.75.

§483.12(b)(5) Ensure reporting of crimes occurring in federally-funded long-term care facilities in accordance with section 1150B of the Act. The policies and procedures must include but are not limited to the following elements.

§483.12(b)(5)(ii) Posting a conspicuous notice of employee rights, as defined at section 1150B(d)(3) of the Act.

§483.12(b)(5)(iii) Prohibiting and preventing retaliation, as defined at section 1150B(d)(1) and (2) of the Act.

INTENT

This regulation was written to provide protections for the health, welfare and rights of each resident residing in the facility. In order to provide these protections, the facility must develop

written policies and procedures to prohibit and prevent abuse, neglect, exploitation of residents, and misappropriation of resident property. These written policies must include, but are not limited to, the following components:

- Screening [*See §§483.12(a)(3) and 483.12(b)(1)*];
- Training [*See §483.12(b)(3)*];
- Prevention [*See §483.12(b)(1)*];
- Identification [*See §483.12(b)(2)*];
- Investigation [*See §483.12(b)(2)*];
- Protection [*See §§483.12(b)(2) and 483.12(c)(3)*]; and
- Reporting/response [*See §§483.12(b)(2), 483.12(b)(4), 483.12(b)(5), 483.12(c)(1) and (4)*].

In order to ensure that the facility is doing all that is within its control to prevent such occurrences, these policies must be implemented (i.e., carried out), otherwise, the policies and procedures would not be effective. The facility is expected to provide oversight and monitoring to ensure that its staff, who are agents of the facility, implement these policies during the provision of care and services to each resident residing in the facility. A facility cannot disown the acts of its staff, since the facility relies on them to meet the Medicare and Medicaid requirements for participation by providing care in a safe environment.

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

DEFINITIONS

“Covered individual” is anyone who is an owner, operator, employee, manager, agent or contractor of the facility (see section 1150B(a)(3) of the Act).

“Crime”: Section 1150B(b)(1) of the Act provides that a “crime” is defined by law of the applicable political subdivision where the facility is located. A political subdivision would be a city, county, township or village, or any local unit of government created by or pursuant to State law.

“Law enforcement,” as defined in section 2011(13) of the Act, is the full range of potential responders to elder abuse, neglect, and exploitation including: police, sheriffs, detectives, public safety officers; corrections personnel; prosecutors; medical examiners; investigators; and coroners.

“Serious bodily injury” means an injury involving extreme physical pain; involving substantial risk of death; involving protracted loss or impairment of the function of a bodily member, organ, or mental faculty; requiring medical intervention such as surgery, hospitalization, or physical rehabilitation; or an injury resulting from criminal sexual abuse (see sections 2011(19)(A) and (B) of the Act).

“Criminal sexual abuse”: *In the case of “criminal sexual abuse” which is defined in section 2011(19)(B) of the Act, serious bodily injury/harm shall be considered to have occurred if the conduct causing the injury is conduct described in section 2241 (relating to aggravated sexual abuse) or section 2242 (relating to sexual abuse) of Title 18, United States Code, or any similar offense under State law. In other words, serious bodily injury includes sexual intercourse with a resident by force or incapacitation or through threats of harm to the resident or others or any sexual act involving a child. Serious bodily injury also includes sexual intercourse with a resident who is incapable of declining to participate in the sexual act or lacks the ability to understand the nature of the sexual act.*

GUIDANCE

The facility must develop and implement policies and procedures that include the following seven components:

I. Screening:

The facility must have written procedures for screening potential employees for a history of abuse, neglect, exploitation, or misappropriation of resident property in order to prohibit abuse, neglect, and exploitation of resident property, and consistent with the applicable requirements at §483.12(a)(3). This includes attempting to obtain information from previous employers and/or current employers, and checking with the appropriate licensing boards and registries. See F729 for requirements related to registry verification and multi-State registry verification.

Additionally, a facility’s services may be furnished under arrangement, with a registry, contracted, or temporary agency staff, or students from affiliated academic institutions. The facility’s policies must also address how pre-screening occurs for prospective consultants, contractors, volunteers, caregivers and students in its nurse aide training program and students from affiliated academic institutions, including therapy, social, and activity programs. The facility should require these individuals be subject to the same scrutiny prior to placement in the facility, whether screened by the facility itself, the third-party agency, or academic institution. The facility should maintain documentation of the screening that has occurred.

The facility must have written procedures for screening that may include, but are not limited to:

- For prospective employees, reviewing:
 - The employment history (e.g., dates of employment position or title), particularly where there is a pattern of inconsistency;
 - Information from former employers, whether favorable or unfavorable; and/or
 - Documentation of status and any disciplinary actions from licensing or registration boards and other registries.

NOTE: If a facility has not developed and/or implemented policies and procedures related to screening procedures prior to employment, a finding of noncompliance should be considered at F607, not F606. If it is determined that the facility employed or engaged an individual, either

directly or under contract, who was found guilty by a court of law of abuse, neglect, misappropriation of property, exploitation or mistreatment, or had a finding entered into the State nurse aide registry or has a disciplinary action in effect against his/her professional license concerning abuse, neglect, mistreatment of residents or misappropriation of resident property, a finding of noncompliance must be cited at F606.

In addition, a facility must develop and implement policies and procedures to prohibit and prevent both abuse and neglect. This would include screening prospective residents to determine whether the facility has the capability and capacity to provide the necessary care and services for each resident admitted to the facility. The facility's written procedures may include, but are not limited to:

- For prospective residents, reviewing:
 - An assessment of the individual's functional and mood/behavioral status;
 - Medical acuity; and
 - Special needs (e.g., mechanical ventilation care, dialysis, hospice).

The facility can then determine whether – in consideration of current staffing patterns, staff qualifications, competency and knowledge, clinical resources, physical environment, and equipment- it can safely and competently provide the necessary care to meet the resident's needs. For example, a resident may have a prior history of distressed behaviors such as unsafe wandering, physically aggressive behaviors including sexually aggressive behaviors, or mental/psychiatric illnesses. In order to provide protections and a safe environment for the resident and other residents, the facility must determine whether it has sufficient competent and qualified staff in order to meet the needs of the resident. If the individual is admitted, pre-admission screening information may provide information that may be used as part of the initial assessment and care planning data.

II. Training:

The facility must have written policies and procedures that include training new and existing nursing home staff and in-service training for nurse aides in the following topics which include:

- Prohibiting and preventing all forms of abuse, neglect, misappropriation of resident property, and exploitation;
- Identifying what constitutes abuse, neglect, exploitation, and misappropriation of resident property;
- Recognizing signs of abuse, neglect, exploitation and misappropriation of resident property, such as physical or psychosocial indicators;
- Reporting abuse, neglect, exploitation, and misappropriation of resident property, including injuries of unknown sources, and to whom and when staff and others must report their knowledge related to any alleged violation without fear of reprisal; and • Understanding behavioral symptoms of residents that may increase the risk of abuse and neglect and how to respond. These symptoms, include, but are not limited to, the following:
 - Aggressive and/or catastrophic reactions of residents;
 - Wandering or elopement-type behaviors;

- Resistance to care;
- Outbursts or yelling out; and
- Difficulty in adjusting to new routines or staff.

NOTE: The provision of training on abuse prohibition alone does not relieve the nursing home of its responsibility to assure that the resident is free from abuse. Ongoing oversight and supervision of staff assures that its policies and procedures are implemented as written.

NOTE: Federal regulations at 42 CFR §483.95(c) and §483.95(g) specify that a facility must develop, implement, and maintain a training program that includes staff training related to abuse, neglect, and exploitation. If the facility fails to develop and implement policies and procedures that include training as required at 42 CFR §483.95(c) and (g)(2), then F607 would be cited. Refer to tag F943 if there are concerns related to the development, implementation and maintenance of an effective training program for all new and existing staff, which includes training on activities that constitute abuse, neglect, exploitation, and misappropriation of resident property; procedures for reporting incidents; and dementia management. Refer to tag F947 for concerns related to the provision of in-service training, which must include dementia management training and resident abuse prevention training.

III. Prevention:

The facility must have and implement written policies and procedures to prevent and prohibit all types of abuse, neglect, misappropriation of resident property, and exploitation that achieves (but is not limited to):

- Establishing a safe environment that supports, to the extent possible, a resident's consensual sexual relationship and by establishing policies and protocols for preventing sexual abuse, such as the identify when, how, and by whom determinations of capacity to consent to a sexual contact will be made and where this documentation will be recorded; and the resident's right to establish a relationship with another individual, which may include the development of or the presence of an ongoing sexually intimate relationship;
- Identifying, correcting and intervening in situations in which abuse, neglect, exploitation, and/or misappropriation of resident property is more likely to occur. This includes the implementation of policies that address the deployment of trained and qualified, registered, licensed, and certified staff on each shift in sufficient numbers to meet the needs of the residents, and assure that the staff assigned have knowledge of the individual residents' care needs and behavioral symptoms, if any (see also F727 related to proficiency of nurse aides);
- Assuring that residents are free from neglect by having the structures and processes to provide needed care and services to all residents, which includes, but is not limited to, the provision of a facility assessment to determine what resources are necessary to care for its residents competently;

- The identification, ongoing assessment, care planning for appropriate interventions, and monitoring of residents with needs and behaviors which might lead to conflict or neglect, such as:
 - Verbally aggressive behavior, such as screaming, cursing, bossing around/demanding, insulting to race or ethnic group, intimidating;
 - Physically aggressive behavior, such as hitting, kicking, grabbing, scratching, pushing/shoving, biting, spitting, threatening gestures, throwing objects;
 - Sexually aggressive behavior such as saying sexual things, inappropriate touching/grabbing;
 - Taking, touching, or rummaging through other's property;
 - Wandering into other's rooms/space;
 - Residents with a history of self-injurious behaviors;
 - Residents with communication disorders or who speak a different language; and
 - Residents that require extensive nursing care and/or are totally dependent on staff for the provision of care.

- Ensuring the health and safety of each resident with regard to visitors such as family members or resident representatives, friends, or other individuals subject to the resident's right to deny or withdraw consent at any time and to reasonable clinical and safety restrictions;

- Providing residents and representatives, information on how and to whom they may report concerns, incidents and grievances without the fear of retribution; and providing feedback regarding the concerns that have been expressed. (See F585 for further information regarding grievances).

The facility may also develop and implement policies and procedures, which achieve the following:

- Identifying, correcting and intervening in situations in which abuse, neglect, exploitation, and/or misappropriation of resident property is more likely to occur. This includes an analysis of and implementation of policies that address at a minimum:
 - Features of the physical environment that may make abuse, neglect, exploitation, and misappropriation of resident property more likely to occur, such as secluded areas of the facility; and
 - The identification of who is responsible for the supervision of staff on all shifts and how supervision will occur in order to identify inappropriate staff behaviors, such as using derogatory language, rough handling, ignoring residents while giving care, and directing residents who need assistance with the bathroom to urinate or defecate in their beds.

- Providing staff information on how and to whom they may report concerns, such as insufficient staffing or a shortage in supplies, without the fear of retribution; and providing feedback regarding the concerns that have been expressed.

IV. Identification:

The facility must have written procedures to assist staff in identifying abuse, neglect, and exploitation of residents, and misappropriation of resident property. This would include identifying the different types of abuse- mental/verbal abuse, sexual abuse, physical abuse, and the deprivation by an individual of goods and services.

Because some cases of abuse are not directly observed, understanding resident outcomes of abuse could assist in identifying whether abuse is occurring or has occurred. Possible indicators of abuse include, but are not limited to:

- An injury that is suspicious because the source of the injury is not observed or the extent or location of the injury is unusual, or because of the number of injuries either at a single point in time or over time; and
- Sudden or unexplained changes in the following behaviors and/or activities such as fear of a person or place, or feelings of guilt or shame.

V. Investigation:

The facility must have written procedures for investigating abuse, neglect, misappropriation, and exploitation that include:

NOTE: See also Section VI regarding protection of the alleged victim.

- Identifying staff responsible for the investigation;
- Exercising caution in handling evidence that could be used in a criminal investigation (e.g., not tampering or destroying evidence);
- Investigating different types of alleged violations;
- Identifying and interviewing all involved persons, including the alleged victim, alleged perpetrator, witnesses, and others who might have knowledge of the allegations;
- Focusing the investigation on determining if abuse, neglect, exploitation, and/or mistreatment has occurred, the extent, and cause; and
- Providing complete and thorough documentation of the investigation.

VI. Protection:

The facility must have written procedures that ensure that all residents are protected from physical and psychosocial harm during and after the investigation. This must include:

- Responding immediately to protect the alleged victim and integrity of the investigation;
- Examining the alleged victim for any sign of injury, including a physical examination or psychosocial assessment if needed;
- Increased supervision of the alleged victim and residents;
- Room or staffing changes, if necessary, to protect the resident(s) from the alleged perpetrator;

- Protection from retaliation; and
- Providing emotional support and counseling to the resident during and after the investigation, as needed.

VII. Reporting/Response:

The facility must have written procedures that must include:

- Immediately reporting all alleged violations to the Administrator, state agency, adult protective services and to all other required agencies (e.g., law enforcement when applicable) within specified timeframes;
- Assuring that reporters are free from retaliation or reprisal;
- *Post a conspicuous notice of employee rights, including the right to file a complaint with the State Survey Agency if they believe the facility has retaliated against an employee or individual who reported a suspected crime and how to file such a complaint;*
- Reporting to the State nurse aide registry or licensing authorities any knowledge it has of any actions by a court of law which would indicate an employee is unfit for service;
- Taking all necessary actions as a result of the investigation, which may include, but are not limited to, the following:
 -
 - Analyzing the occurrence(s) to determine why abuse, neglect, misappropriation of resident property or exploitation occurred, and what changes are needed to prevent further occurrences;
 - Defining how care provision will be changed and/or improved to protect residents receiving services;
 - Training of staff on changes made and demonstration of staff competency after training is implemented;
 - Identification of staff responsible for implementation of corrective actions;
 - The expected date for implementation; and
 - Identification of staff responsible for monitoring the implementation of the plan.

To encourage reporting of reasonable suspicions of a crime, facilities should develop and implement policies and procedures that promote a culture of safety and open communication in the work environment. This may be accomplished through prohibiting retaliation against an employee who reports a suspicion of a crime. Actions that constitute retaliation against staff include:

- *When a facility discharges, demotes, suspends, threatens, harasses, or denies a promotion or other employment-related benefit to an employee, or in any other manner discriminates against an employee in the terms and conditions of employment because of lawful acts done by the employee.*
- *When a facility files a complaint or a report against a nurse or other employee with the state professional licensing agency because of lawful acts done by the nurse or employee for reporting a reasonable suspicion of a crime to law enforcement.*

An example of retaliation would be if a staff member, on behalf of or as an agent of the facility, harasses an employee who had reported a reasonable suspicion of a crime.

In addition to developing policies prohibiting retaliation for reporting suspicions of a crime, the facility must develop and implement policies and procedures for posting notice in a conspicuous location informing covered individuals of their rights under section 1150B of the Act, including the right to file a complaint with the State Survey Agency if they believe the facility has retaliated against an employee or individual who reported a suspected crime and how to file such a complaint.

The sign may be posted in an area that is visible to employees, such as the same area where the facility posts other employee signs, such as labor management posters. Size and type requirements for the sign should be no less than the minimum required for any other required employment-related signs.

VIII. Coordination with QAPI:

The facility must develop written policies and procedures that define how staff will communicate and coordinate situations of abuse, neglect, misappropriation of resident property, and exploitation with the QAPI program under §483.75.

Cases of physical or sexual abuse, for example by facility staff or other residents, always require corrective action and tracking by the QAA Committee, at §483.75(g)(2).

This coordinated effort would allow the QAA Committee to determine:

- *If a thorough investigation is conducted;*
- *Whether the resident is protected;*
- *Whether an analysis was conducted as to why the situation occurred;*
- *Risk factors that contributed to the abuse (e.g., history of aggressive behaviors, environmental factors); and*
- *Whether there is further need for systemic action such as:*
 - *Insight on needed revisions to the policies and procedures that prohibit and prevent abuse/neglect/misappropriation/exploitation,*
 - *Increased training on specific components of identifying and reporting that staff may not be aware of or are confused about,*
 - *Efforts to educate residents and their families about how to report any alleged violations without fear of repercussions,*
 - *Measures to verify the implementation of corrective actions and timeframes, and*
 - *Tracking patterns of similar occurrences.*

NOTE: *For failures related to the development and implementation of policies and procedures to communicate and coordinate with the QAPI program situations of abuse, neglect, misappropriation of resident property, and exploitation, cite tag F607. For failures related to the QAA Committee's identification of quality deficiencies or its development and implementation of action plans to correct identified quality deficiencies, cite tag F867.*

Refer also to the CE Pathways for Abuse (Form CMS-20059) and Neglect (Form CMS-20130) and the Investigative Protocols for tags F602 and F603.

***INVESTIGATIVE PROTOCOL
FOR POLICIES AND PROCEDURES RELATED TO ALLEGATIONS OF RETALIATION BY
THE FACILITY AGAINST A COVERED INDIVIDUAL***

USE

Use this protocol during any survey, if, based on a complaint or an investigation of abuse, neglect, misappropriation of resident property, or exploitation, an allegation of retaliation by the facility against a covered individual was received. Refer to the CE Pathways for Abuse (Form CMS-20059) and Neglect (Form CMS-20130) and the Investigative Protocols for tags F602, and F603, which gathers information about what information was or was not reported by covered individuals and whether retaliation may have occurred.

The protocol below investigates whether the facility developed and implemented policies and procedures related to:

- *Posting notification of employee rights, and*
- *Prohibiting and preventing retaliation.*

PROCEDURES

Facility Policies and Procedures

Obtain and review the facility's policies and procedures to determine whether the facility is:

- *Posting notification of employee rights, and*
- *Prohibiting and preventing retaliation against covered individuals who make reports of a reasonable suspicion of a crime.*

Observations

Observe whether the facility has posted notification of employee rights and whether the notification includes all of the required components. Note the location of the notification, in relation to whether it is likely to be noticed by all employees.

Interview of State Professional Licensing Authorities

If there is an allegation of facility retaliation against an employee, the surveyor should contact the appropriate State licensing board to determine whether the facility had filed a complaint or report against the employee, and if so, what information was provided in the complaint or report.

Interview Staff

For an allegation of retaliation, interview staff about what occurred, how the facility allegedly retaliated against staff, and when.

Interview – Administrator

Interview the Administrator to determine the following:

- *How the Administrator oversees the implementation of policies and procedures for reporting of suspected crimes;*
- *For an allegation of retaliation:*
 - *Whether any actions were taken against an employee, and if so, what actions and why;*
 - *Whether the facility had submitted a report to the State professional licensing agency against the employee(s), and if so, why.*

Review of Employee Personnel Records

If there is an allegation of retaliation against an employee or other covered individual, obtain a copy of the employee's personnel records, and records for other covered individuals as applicable, to determine if the facility may have taken any action against the individual which may be related to the report of a suspected crime.

NOTE: If the surveyor discovers a reasonable suspicion of a crime committed against a resident of or an individual receiving services from the facility and it has not been reported by a covered individual, the surveyor reminds the facility of the covered individuals' obligation to report suspected crimes pursuant to section 1150B of the Act within the required timeframes. "Covered individual" is anyone who is an owner, operator, employee, manager, agent or contractor of the facility as defined in section 1150B(a)(3) of the Act. If a covered individual reports the suspected crime to local law enforcement, the surveyor must verify that the report was made (e.g., obtain time/date of report, name of person who received report, case number, etc.). If the covered individual refuses to report, or the surveyor cannot verify that a report was done, the surveyor must consult with his/her supervisor immediately, and the State Agency must report the potential criminal incident to law enforcement immediately.

KEY ELEMENTS OF NONCOMPLIANCE

To cite deficient practice at F607, the surveyor's investigation will generally show that the facility has failed to do one or more of the following:

- Develop and implement written policies and procedures that prohibit and prevent abuse, neglect and exploitation of residents and misappropriation of resident property and includes the screening of prospective employees and residents; **or**
- Develop and implement written policies and procedures for the investigation of allegations of abuse, neglect and exploitation of residents and misappropriation of resident property and includes the staff identification of abuse, neglect, exploitation, and misappropriation of resident property, protection of residents during investigations, and the reporting of allegations and investigative findings and taking corrective actions; **or**
- Develop and implement written policies and procedures that include training as required at §483.95; *or*
- *Develop and implement written policies and procedures that establish coordination with the QAPI program required under §483.75; or*
- *Develop and implement written policies and procedures related to posting conspicuous signage of employee rights related to retaliation against the employee for reporting a suspected crime; and prohibiting and preventing retaliation.*

F609

(Rev. 208; Issued:10-21-22; Effective: 10-21-22; Implementation:10-24-22)

§483.12(b) The facility must develop and implement written policies and procedures that:

§483.12(b)(5) Ensure reporting of crimes occurring in federally-funded long-term care facilities in accordance with section 1150B of the Act. The policies and procedures must include but are not limited to the following elements.

- (i) Annually notifying covered individuals, as defined at section 1150B(a)(3) of the Act, of that individual's obligation to comply with the following reporting requirements.*
 - (A) Each covered individual shall report to the State Agency and one or more law enforcement entities for the political subdivision in which the facility is located any reasonable suspicion of a crime against any individual who is a resident of, or is receiving care from, the facility.*
 - (B) Each covered individual shall report immediately, but not later than 2 hours after forming the suspicion, if the events that cause the suspicion result in serious bodily injury, or not later than 24 hours if the events that cause the suspicion do not result in serious bodily injury.*

§483.12(c) In response to allegations of abuse, neglect, exploitation, or mistreatment, the facility must:

§483.12(c)(1) Ensure that all alleged violations involving abuse, neglect, exploitation or mistreatment, including injuries of unknown source and misappropriation of resident property, are reported immediately, but not later than 2 hours after the allegation is made, if the events that cause the allegation involve abuse or result in serious bodily injury, or not later than 24 hours if the events that cause the allegation do not involve abuse and do not result in serious bodily injury, to the administrator of the facility and to other officials (including to the State Survey Agency and adult protective services where state law provides for jurisdiction in long-term care facilities) in accordance with State law through established procedures.

§483.12(c)(4) Report the results of all investigations to the administrator or his or her designated representative and to other officials in accordance with State law, including to the State Survey Agency, within 5 working days of the incident, and if the alleged violation is verified appropriate corrective action must be taken.

INTENT

The intent is for the facility to develop and implement policies and procedures that:

- Provide annual notification to each covered individual of their obligation to comply with the reporting requirements under section 1150B(b) of the Act;*
- Ensure reporting reasonable suspicion of crimes against a resident or individual receiving care from the facility within prescribed timeframes to the appropriate entities, consistent with Section 1150B of the Act; and*

- *Ensure that all covered individuals, i.e., the owner, operator, employee, manager, agent or contractor, report reasonable suspicion of crimes, as required by Section 1150B of the Act.*

The facility should provide oversight and monitoring to ensure that implement the required policies and procedures, per 42 CFR §483.12(b).

In addition, the facility must report alleged violations related to mistreatment, exploitation, neglect, or abuse, including injuries of unknown source and misappropriation of resident property and report the results of all investigations to the proper authorities within prescribed timeframes.

DEFINITIONS

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

“**Alleged violation**” is a situation or occurrence that is observed or reported by staff, resident, relative, visitor, *another health care provider*, or others but has not yet been investigated and, if verified, could be noncompliance with the Federal requirements related to mistreatment, exploitation, neglect, or abuse, including injuries of unknown source, and misappropriation of resident property.

“Covered individual” is anyone who is an owner, operator, employee, manager, agent or contractor of the facility (see section 1150B(a)(3) of the Act).

“Crime”: Section 1150B(b)(1) of the Act provides that a “crime” is defined by law of the applicable political subdivision where the facility is located. A political subdivision would be a city, county, township or village, or any local unit of government created by or pursuant to State law.

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

“**Injuries of unknown source**” – An injury should be classified as an “injury of unknown source” when *all* of the following criteria are met:

- *The source of the injury was not observed by any person; and*
- The source of the injury could not be explained by the resident; **and**
- The injury is suspicious because of the extent of the injury or the location of the injury (e.g., the injury is located in an area not generally vulnerable to trauma) or the number of injuries observed at one particular point in time or the incidence of injuries over time.

“Law enforcement,” as defined in section 2011(13) of the Act, is the full range of potential responders to elder abuse, neglect, and exploitation including: police, sheriffs, detectives, public safety officers; corrections personnel; prosecutors; medical examiners; investigators; and coroners.

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

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

“Serious bodily injury” is defined in section 2011(19) of the Act and means an injury involving extreme physical pain, substantial risk of death, protracted loss or impairment of the function of a bodily member, organ, or mental faculty, or requiring medical intervention such as surgery, hospitalization, or physical rehabilitation (see section 2011(19)(A) of the Act). Serious bodily injury is considered to have occurred when an injury results from criminal sexual abuse (see section 2011(19)(B) of the Act).

“Criminal sexual abuse”: In the case of “criminal sexual abuse” which is defined in section 2011(19)(B) of the Act, serious bodily injury/harm shall be considered to have occurred if the conduct causing the injury is conduct described in section 2241 (relating to aggravated sexual abuse) or section 2242 (relating to sexual abuse) of Title 18, United States Code, or any similar offense under State law. In other words, serious bodily injury includes sexual intercourse with a resident by force or incapacitation or through threats of harm to the resident or others or any sexual act involving a child. Serious bodily injury also includes sexual intercourse with a resident who is incapable of declining to participate in the sexual act or lacks the ability to understand the nature of the sexual act.

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

“Willful,” is defined at §483.5 in the definition of “abuse,” and “means the individual must have acted deliberately, not that the individual must have intended to inflict injury or harm.”

GUIDANCE REPORTING

It is the responsibility of the facility to ensure that all staff are aware of reporting requirements and to support an environment in which *covered individuals report a reasonable suspicion of a crime, and* staff and others report all alleged violations of mistreatment, exploitation, neglect, or abuse, including injuries of unknown source, and misappropriation of resident property. Protection of residents can be compromised or impeded if individuals are fearful of reporting, especially if the alleged abuse has been carried out by a staff member *[See §483.12(b)(5)(i)].*

During investigations, some staff have stated that he/she was aware, or had knowledge, that the incident had occurred, but did not report because he/she did not think it met the definition of abuse, neglect, mistreatment, exploitation, or misappropriation of resident property *or a reasonable suspicion of a crime*. Anecdotal reports have indicated that failure to report an alleged violation may be due to, but not limited to, the following:

- An individual’s allegation is not believed due to a history of reporting false allegations;
- Staff fear of retaliation, or fear losing his/her job;
- Sympathy for co-workers, for example, not wanting to cause trouble for the co-worker;
- Communication, cultural, or language issues; or
- Residents/resident representatives may fear retaliation.

NOTE: Once an individual suspects that a crime has been committed, facility staff should exercise caution when handling materials that may be used for evidence or for a criminal investigation. Facilities should reference applicable State and local laws regarding preserving evidence. It has been reported that some investigations were impeded due to washing linens or clothing, destroying documentation, bathing or cleaning the resident before the resident has been examined, or failure to transfer a resident to the emergency room for examination including obtaining a rape kit, if appropriate.

The following table describes the different reporting requirements that are addressed under 42 CFR 483.12:

	<i>42 CFR 483.12(b)(5) and Section 1150B of the Act</i>	<i>42 CFR 483.12(c)</i>
<i>What is to be reported</i>	<i>Any reasonable suspicion of a crime against a resident or an individual receiving care from the facility</i>	<i>1) All alleged violations of abuse, neglect, exploitation or mistreatment, including injuries of unknown source and misappropriation of resident property 2) The results of all investigations of alleged violations</i>
<i>Who is required to report</i>	<i>Any covered individual, which means the owner, operator, employee, manager, agent or contractor of the facility</i>	<i>The facility</i>
<i>To whom</i>	<i>State Survey Agency (SA) and one or more law enforcement entities for the political subdivision in which the facility is located (i.e., the full range of potential responders to elder abuse, neglect, and exploitation including police, sheriffs, detectives, public safety</i>	<i>The facility administrator and to other officials in accordance with State law, including to the SA and the adult protective services where state law provides for jurisdiction in long-term care facilities</i>

	42 CFR 483.12(b)(5) and Section 1150B of the Act	42 CFR 483.12(c)
	<i>officers; corrections personnel; prosecutors; medical examiners; investigators; and coroners)</i>	
When	<p><i>Serious bodily injury- Immediately but not later than 2 hours* after forming the suspicion</i></p> <p><i>No serious bodily injury- not later than 24 hours*</i></p>	<p><i>All alleged violations-</i></p> <ol style="list-style-type: none"> <i>1) Immediately but not later than 2 hours*- if the alleged violation involves abuse <u>or</u> results in serious bodily injury</i> <i>2) Not later than 24 hours*- if the alleged violation involves neglect, exploitation, mistreatment, or misappropriation of resident property; <u>and</u> does not result in serious bodily injury</i> <p><i>Results of all investigations of alleged violations- within 5 working days of the incident</i></p>

** - Reporting requirements under this regulation are based on real (clock) time, not business hours*

ENSURING THE REPORTING OF A REASONABLE SUSPICION OF A CRIME

A facility's policies and procedures for reporting under 42 CFR 483.12(b)(5) should specify the following components, which include, but are not limited to:

- Identification of who in the facility is considered a covered individual;*
- Identification of crimes that must be reported;*

NOTE: *Each State and local jurisdiction may vary in what is considered to be a crime and may have different definitions for each type of crime. Facilities should consult with local law enforcement to determine what is considered a crime.*

- Identification of what constitutes "serious bodily injury;"*
- The timeframe for which the reports must be made; and*
- Which entities must be contacted, for example, the State Survey Agency and local law enforcement.*

There are instances where an alleged violation of abuse, neglect, misappropriation of resident property and exploitation would be considered to be reasonable suspicion of a crime. In these cases, the facility is obligated to report to the administrator, to the state survey agency, and to other officials in accordance with State law (see F609). Regardless, covered individuals still have the obligation to report the reasonable suspicion of a crime to the State Survey Agency and local law enforcement.

Some facilities may have policies and procedures where the administrator could coordinate timely reporting to the State Survey Agency and law enforcement on behalf of covered individuals who choose to report to the administrator. Risks to the covered individual for reporting to the administrator could be mitigated if an individual has clear assurance that the administrator is reporting it and submitting a collective report would not cause delays in reporting according to specified timeframes. Reports should be documented and the administrator should keep a record of the documentation. It remains the responsibility of each covered individual to ensure that his/her individual reporting responsibility is fulfilled, so it is advisable for any multiple-person report to include identification of all individuals making the report. In addition, a facility cannot prohibit or circumscribe a covered individual from reporting directly to law enforcement even if it has a coordinated internal system.

Surveyors must review whether the facility has included in its policies and procedures examples of crimes that would be reported. Examples of situations that would likely be considered crimes in all subdivisions would include but are not limited to:

- *Murder;*
- *Manslaughter;*
- *Rape;*
- *Assault and battery;*
- *Sexual abuse;*
- *Theft/Robbery;*
- *Drug diversion for personal use or gain;*
- *Identity theft; and*
- *Fraud and forgery.*

There are political subdivisions that have other examples for which instances of elder mistreatment are considered to be crimes. Because all reasonable suspicions of crimes must be reported, regardless of whether it is perpetrated by facility staff, residents, or visitors, it would be especially beneficial for the facility to work with local law enforcement in determining what would not be reported (e.g., all cases of resident to resident conflict may not rise to the level of abuse and may not be appropriate to report to local law enforcement).

Even in the presence of a policy and procedure, failure to report a reasonable suspicion of a crime may be indicative of failure to implement the facility's policies and procedures. Surveyors should investigate further and document the failure to develop and/or implement policies and procedures for reporting suspected crimes (e.g., how the facility may not have provided notification to its employees, how covered individuals are fearful of reporting or do not want to get others in trouble, etc.). Facilities must ensure the reporting of a reasonable suspicion of a crime by implementing proper policies and procedures addressing the following actions, which should include, but are not limited to:

- *Orienting new and temporary/agency/contractor staff to the reporting requirements;*
- *Assuring that covered individuals are annually notified of their responsibilities in a language that they understand;*

- *Identifying barriers to reporting such as fear of retaliation or causing trouble for someone, and implementing interventions to remove barriers and promote a culture of transparency and reporting;*
- *Identifying which cases of abuse, neglect, and exploitation may rise to the level of a reasonable suspicion of crime and recognizing the physical and psychosocial indicators of abuse/neglect/exploitation;*
- *Working with law enforcement annually to determine which crimes are reported;*
- *Assuring that covered individuals can identify what is reportable as a reasonable suspicion of a crime, with competency testing or knowledge checks;*
- *Providing in-service training when covered individuals indicate that they do not understand their reporting responsibilities; and*
- *Providing periodic drills across all levels of staff across all shifts to assure that covered individuals understand the reporting requirements.*

Annual Notification of Reporting Obligations to Covered Individuals

The facility must develop and implement written procedures that include, but are not limited to, notifying covered individuals annually of their obligations to report reasonable suspicion of crimes in the facility [See §483.12(b)(5)(i)]. Policies and procedures should include, but are not limited to, the following:

- *Identification of who are the covered individuals in the facility;*
- *How covered individuals are notified of the reporting requirements. Notification must include the following:*
 - *Each covered individual's independent obligation to report the suspicion of a crime against a resident or individual receiving care and services from the facility directly to local law enforcement and the State Survey Agency;*
 - *The timeframe requirements for reporting reasonable suspicion of crimes:*
 - *If the events that cause the reasonable suspicion result in serious bodily injury to a resident, the covered individual must report the suspicion immediately, but not later than 2 hours after forming the suspicion;*
 - *If the events that cause the reasonable suspicion do not result in serious bodily injury to a resident, the covered individual shall report the suspicion not later than 24 hours after forming the suspicion.*
- *Penalties associated with failure to report:*
 - *If a covered individual fails to report within mandated timeframes, the covered individual will be subject to a civil money penalty of not more than \$200,000, as adjusted annually under 45 CFR part 102; and the covered individual may be excluded from participation in any Federal health care program (as defined in section 1128B(f) of the Act).*
 - *If a covered individual fails to report within mandated timeframes and the violation exacerbates the harm to the victim of the crime or results in harm to another individual, the covered individual will be subject to a civil money penalty of not more than \$300,000, as adjusted annually under 45 CFR part 102; and the Secretary may make a determination in the same proceeding to exclude the covered individual from*

participation in any Federal health care program (as defined in section 1128B(f) of the Act).

- *The mechanism for documenting that all covered individuals have been notified annually of their reporting obligations. Documentation may include a copy of a notice or letter sent to covered individuals with confirmation that it was received or a completed training/orientation attendance sheet documenting the individual completed training on reporting obligations.*

REPORTING ALLEGED VIOLATIONS

An alleged violation can be observed or reported by staff, resident, relative, visitor, another health care provider, or others. For example, a receiving hospital may report to the facility suspicious bruising of the resident near the inner thighs and groin area, which were identified during a medical exam in the emergency department. An individual (e.g., a resident, visitor, facility staff) who reports an alleged violation to facility staff does not have to explicitly characterize the situation as “abuse,” “neglect,” “mistreatment,” or “exploitation” in order to trigger the Federal requirements at §483.12(c). Rather, if facility staff could reasonably conclude that the potential exists for noncompliance with the Federal requirements related to mistreatment, exploitation, neglect, or abuse, including injuries of unknown source, and misappropriation of resident property, then it would be considered to be reportable and require action under §483.12(c). For example, if a resident is abused but does not allege abuse, the resident’s failure or inability to provide information about the occurrence is immaterial when the abuse may be substantiated by other supporting evidence. Another example is when a nurse aide witnesses an act of abuse but fails to report the alleged violation; the failure to report does not support a conclusion that the abuse did not occur and the facility would not meet the reporting requirements.

All alleged violations, whether oral or in writing, must be reported to the administrator of the facility and to other officials in accordance with State law through established procedures (including to the State survey and certification agency and adult protective services where State law provides for jurisdiction in long-term care facilities). Conformance with this provision requires that each State Agency has a means to collect reports, even during off-duty hours (e.g., answering machine, voice mail, fax, electronic transmission, etc.). The facility must have documentation of the report, including what was reported and the date and time the report was made to the SA. *The facility must submit reports that are accurate, to the best of its knowledge at the time of submission of the report. It is important that facilities not make reports that are misleading, such as reports that deliberately omit facts, or reports that are designed to make the incident appear less serious than it was, or reports that misrepresent the facility’s response. Deliberate misrepresentations or omissions could result in a deficiency at F609 or may give rise to other deficiencies.*

Initial Report- *For alleged violations of abuse or if there is resulting serious bodily injury, the facility must report the allegation immediately, but no later than 2 hours after the allegation is made. For alleged violations of neglect, exploitation, misappropriation of resident property, or mistreatment that do not result in serious bodily injury, the facility must report the allegation no later than 24 hours. The facility must provide in its report sufficient information to describe the*

alleged violation and indicate how residents are being protected [see §483.12(c)(3)]. It is important that the facility provide as much information as possible, to the best of its knowledge at the time of submission of the report, so that State agencies can initiate action necessary to oversee the protection of nursing home residents. Please see [Exhibit 358](#) for a sample form for initial reporting, with examples of information.

Follow-up Investigation Report- *Within 5 working days of the incident, the facility must provide in its report sufficient information to describe the results of the investigation, and indicate any corrective actions taken, if the allegation was verified. It is important that the facility provide as much information as possible, to the best of its knowledge at the time of submission of the report, so that State agencies can initiate action necessary to oversee the protection of nursing home residents [see §483.12(c)(4)]. The facility should include any updates to information provided in the initial report. Please see [Exhibit 359](#) for a sample form for investigation report, with examples of information.*

In the absence of a shorter State time frame requirement, all alleged violations involving abuse or resulting in serious bodily injury are reported immediately, but not later than 2 hours after the allegation is made. If the alleged allegation involves neglect, misappropriation of resident property, or exploitation and does not result in serious bodily injury, the facility must report not later than 24 hours after the allegation is made. The facility is not prohibited from fulfilling its reporting obligations earlier than the timeframes provided in the regulations, so that immediate actions can be taken to protect the resident(s).

If an alleged violation has been identified and reported to the administrator/designee, the facility must report it and provide protection for the identified resident(s) prior to conducting the investigation of the alleged violation. In some situations, the facility may initially evaluate an occurrence to determine whether it meets the definition of an “alleged violation.” For example, upon discovery of an injury, the facility must take steps to evaluate whether the injury meets the definition of an “injury of unknown source.” Similarly, if a resident states that his or her belongings are *stolen*, the facility may make an initial determination whether the item has been misplaced in the resident’s room, in the laundry, or elsewhere before reporting misappropriation of property. However, if the alleged violation meets the definition of abuse, neglect, exploitation or mistreatment, the facility should not make an initial determination whether the allegation is credible before reporting the allegation.

NOTE: At the conclusion of the investigation, and no later than 5 working days of the incident, the facility must report the results of the investigation and if the alleged violation is verified, take corrective action, in accordance with §483.12(c)(4).

The phrase “**in accordance with State law**” modifies the word “officials” only. State law may stipulate that alleged violations and the results of the investigations be reported to additional State officials beyond those specified in Federal regulations. This phrase does not modify what **types** of alleged violations must be reported or the timeframes in which the reports are to be made. States may not eliminate the obligation for any of the alleged violations (i.e., mistreatment, neglect, abuse, injuries of unknown source, exploitation, and misappropriation of resident property) to be reported, nor can the State establish longer time frames for reporting than

mandated in the regulations at §§483.12(c)(1) and (4). No State can override the obligation of the nursing home to fulfill the requirements under §483.12(c), as long as the Medicare/Medicaid certification is in place.

Some States may have different reporting requirements that could go beyond the Federal requirements or are more specific than the Federal requirements. For example, some States require that all falls be reported to the SA. The SA should continue to manage and investigate these cases under its state licensure authority. If the State determines that these occurrences do meet the definition of abuse, neglect, mistreatment, or injuries of unknown source, as outlined in this guidance, the SA must assess whether the nursing home has met the requirements for reporting and investigating these cases in accordance with 42 C.F.R. §483.12(c).

If the surveyor discovers a reasonable suspicion of a crime committed against a resident of or an individual receiving services from the facility and it has not been reported by a covered individual, the surveyor reminds the facility of the covered individuals' obligation to report suspected crimes pursuant to section 1150B of the Act within the required timeframes. "Covered individual" is anyone who is an owner, operator, employee, manager, agent or contractor of the facility as defined in section 1150B(a)(3) of the Act. If a covered individual reports the suspected crime to local law enforcement, the surveyor must verify that the report was made (e.g., obtain time/date of report, name of person who received report, case number, etc.). If the covered individual refuses to report, or the surveyor cannot verify that a report was done, the surveyor must consult with his/her supervisor immediately, and the State Agency must report the potential criminal incident to law enforcement immediately. (See F609)

IDENTIFICATION OF ALLEGED VIOLATIONS

The following addresses facility responsibilities for reporting allegations/occurrences involving staff-to-resident abuse; resident-to-resident altercations; injuries of unknown source; misappropriation of resident property/exploitation; and mistreatment. A report of an alleged violation does not automatically indicate that a citation at F600, F602, or F603 is warranted; the survey team must conduct a thorough investigation of the allegation. If the collected evidence supports that abuse, neglect, or misappropriation of resident property/exploitation has occurred, it is appropriate for the survey team to cite the current or past noncompliance at the appropriate tag (e.g., F600-Free from Abuse and Neglect).

Section I. Staff to Resident Abuse

All allegations/occurrences of all types of staff-to-resident abuse must be reported to the administrator and to other officials, including the State Survey Agency and adult protective services, where state law provides for jurisdiction in nursing homes [see § 483.12(c)].

This includes, but is not limited to:

- *All allegations/occurrences of physical, sexual, mental, and verbal abuse, including deprivation of goods and services by staff, and involuntary seclusion perpetrated by staff (See F600 and F603 for examples of types of abuse);*
- *Staff taking or distributing demeaning or humiliating photographs or recordings of residents through social media or multimedia messaging; and*

- All reports from residents of abuse perpetrated by staff; allegations must not be dismissed on the basis of a resident’s cognitive impairment(s).

Section II. Resident to Resident Altercations

Resident-to-resident altercations that must be reported in accordance with the regulations include any willful action that results in physical injury, mental anguish, or pain, as defined at §483.5. The tables below includes examples of resident to resident altercations and whether they are required to be reported.

NOTE: This is not an exhaustive list of all reportable types of resident to resident altercations. There may be other incidents that are also reportable.

Examples of Mental/Verbal Conflict

Required to Report	Not Required to Report (Unless it rises to the level of what’s described in the first column)
<ul style="list-style-type: none"> • Intimidation • Bullying- Aggressive behavior in which someone intentionally* and repeatedly causes another resident mental anguish or discomfort** (adapted from the American Psychological Association¹) • Communication that is motivated by an actual or perceived characteristic, such as race, color, religion, sex, disability, or sexual orientation that results in mental anguish or social withdrawal** • Threats of violence • Inappropriate sexual comments that are used in a deliberately* threatening manner • Inappropriate sexual comments that offend, humiliate, or demean a resident**; • Taking and/or distributing demeaning or humiliating photographs or recordings of residents through social media or multimedia messaging 	<ul style="list-style-type: none"> • Non-targeted outbursts • Residents with certain conditions (e.g., Huntington’s/Tourette’s) who exhibit verbalizations • Arguments or disagreements, which do not include any behavior or communication identified in the “Required to Report” column

NOTE:

* Having a mental disorder or cognitive impairment does not automatically preclude a resident from engaging in deliberate or non-accidental actions.

** There may be some situations in which the psychosocial outcome to the resident may be difficult to determine or incongruent with what would be expected. In these situations, it is appropriate to consider how a reasonable person in the resident’s circumstances would be impacted by the incident.

Examples of Sexual Contact

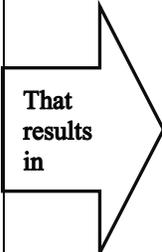
NOTE: See also guidance at F600 related to Sexual Abuse and Capacity and Consent.

Required to Report	Not Required to Report (Unless it rises to the level of what's described in the first column)
<ul style="list-style-type: none"> • <i>Unwanted touching of the breasts or perineal area</i> • <i>A resident who fondles or touches a person's sexual organs and the resident being touched indicates the touching is unwanted through verbal or non-verbal cues</i> • <i>Sexual activities where one resident indicates that the activity is unwanted through verbal or non-verbal cues</i> • <i>Sexual activity or fondling where one of the resident's capacity to consent to sexual activity is unknown</i> • <i>Sexual assault or battery (ex. rape, sodomy, coerced nudity)</i> • <i>Instances where the alleged victim is transferred to a hospital for examination and/or treatment of injuries resulting from possible sexual abuse</i> • <i>Forced observation of masturbation, or pornography</i> • <i>Forced, coerced or extorted sexual activity</i> • <i>Other unwanted actions for the purpose of sexual arousal or sexual gratification resulting in degradation or humiliation of another resident</i> 	<ul style="list-style-type: none"> • <i>Consensual sexual contact between residents who have the capacity to consent to sexual activity</i> • <i>Affectionate contact such as hand holding or hugging or kissing a resident who indicates that he/she consents to the action through verbal or non-verbal cues</i> • <i>Sexual activity between residents in a relationship, married couples or partners, unless one of the residents indicates that the activity is unwanted through verbal or non-verbal cues.</i>

Examples of Physical Altercations

Resident-to-resident physical altercations that must be reported include, any willful action that results in physical injury, mental anguish, or pain. Examples include, but are not limited to, the following:

WILLFUL ACTION*
<p><i>Willful actions include, but are not limited to, the following:</i></p> <ul style="list-style-type: none"> • <i>Hitting</i> • <i>Slapping</i> • <i>Punching</i> • <i>Choking</i> • <i>Pinching</i> • <i>Biting</i> • <i>Kicking</i> • <i>Throwing objects</i> • <i>Grabbing</i> • <i>Shoving</i> <p>*The action itself was deliberate or non-accidental, not that the individual intended to inflict injury or harm</p>



PHYSICAL INJURY
<p><i>A physical injury resulting from the willful action including, but not limited to, the following:</i></p> <ul style="list-style-type: none"> • <i>Death</i> • <i>Injury requiring medical attention beyond first aid (such as a cut requiring suturing or an injury requiring transfer to a hospital for examination and/or treatment)</i> • <i>Fracture(s), subdural hematoma, concussion</i> • <i>Bruises</i> • <i>Facial injury(ies), such as broken or missing teeth, facial fractures, black eye(s), bruising, bleeding or swelling of the mouth or cheeks</i>
MENTAL ANGUISH*
<p><i>Psychosocial outcomes resulting from the willful action including, but not limited to, the following:</i></p> <ul style="list-style-type: none"> • <i>Fear of a person or place or of being left alone or of being in the dark, disturbed sleep, nightmares</i> • <i>Changes in behavior, including aggressive or disruptive behavior toward a specific person</i> • <i>Running away, withdrawal, isolating self, feelings of guilt and shame, depression, crying, talk of suicide or attempts</i> <p><i>* There may be some situations in which the psychosocial outcome to the resident may be difficult to determine or incongruent with what would be expected. In these situations, it is appropriate to consider how a reasonable person in the resident's circumstances would be impacted by the incident.</i></p>
PAIN
<p><i>Pain resulting from the willful action including, but not limited to, the following:</i></p> <ul style="list-style-type: none"> • <i>Complaints of pain related to the altercation</i> • <i>Onset of pain evidenced by nonverbal indicators, such as</i> <ul style="list-style-type: none"> ○ <i>Groaning, crying, screaming</i> ○ <i>Grimacing, clenching of the jaw</i> ○ <i>Resistance to being touched</i> ○ <i>Rubbing/guarding body part</i>

NOTE:

** Having a mental disorder or cognitive impairment does not automatically preclude a resident from engaging in deliberate or non-accidental actions.*

The general examples of physical altercations below illustrate possible cases that would likely **NOT** need to be reported, as long as it is not a willful action that results in physical injury, mental anguish, or pain. Every case is fact specific and all facts, circumstances and conditions involving the event/occurrence would need to be examined.

- A resident lightly taps another resident to stop an irritating behavior or get attention, with no resulting physical injury, mental anguish, or pain.
- A resident who is slow, impedes the pathway of another resident, such as in the dining room, the other resident nudges the resident out of the way to get to his/her table faster, but there is no harm to the victim.
- A resident who swats at another resident who is trying to take some food off his/her plate, and no physical injury, mental anguish, or pain has occurred.

NOTE: Even if a physical altercation is not required to be reported, the facility should take into consideration that physical altercations can increase the risk for abuse to occur to residents involved in the altercation, and possibly other residents in the facility. The facility must meet requirements related to appropriate assessment (see § 483.20 – Resident Assessment), care planning by the interdisciplinary team (see § 483.21-Comprehensive Person-Centered Care Planning), and provide care and services according to acceptable standards of practice [see §483.21(b)(3)(i)- Tag F658] to prevent harm as a result of resident to resident altercations, as well as the development and implementation of policies and procedures to prevent abuse of residents [see § 483.12(b)(1)- Tag F607]].

Through these actions, the facility can determine areas of needed improvement in care/service provision, staff training or staff deployment.

Section III. Reporting Suspicious Injuries of Unknown Source

“Injuries of unknown source” – An injury should be classified as an “injury of unknown source” when ALL of the following criteria are met:

- The source of the injury was not observed by any person; and
- The source of the injury could not be explained by the resident; and
- The injury is suspicious because of:
 - a. The extent of the injury, or
 - b. The location of the injury (e.g., the injury is located in an area not generally vulnerable to trauma), or
 - c. The number of injuries observed at one particular point in time, or
 - d. The incidence of injuries over time.

Examples of Injuries of Unknown Source

Required to Report	Not Required to Report (Unless it rises to the level of what’s described in the first column)
<ul style="list-style-type: none"> • Unobserved/Unexplained fractures, sprains or dislocations 	<ul style="list-style-type: none"> • Bruising in an area where the resident has had recent medical tests/lab draws and there is no indication of abuse or neglect

Required to Report	Not Required to Report (Unless it rises to the level of what's described in the first column)
<ul style="list-style-type: none"> • Unobserved/Unexplained injuries that could have resulted from a burn, including blisters or scalds • Unobserved/Unexplained bite marks • Unobserved/Unexplained scratches and bruises found in suspicious locations such as the head, neck, upper chest or back • Unobserved/Unexplained swelling that is not linked to a medical condition • Unobserved/Unexplained lacerations with or without bleeding • Unobserved/Unexplained skin tears in sites found in suspicious locations (e.g., in sites other than the arms or legs) • Unobserved/Unexplained skin tears in patterns (e.g., bilateral, symmetrical skin tears on both arms) • Unobserved/Unexplained patterned bruises that suggest hand marks or finger marks, or bruising pattern caused by an object • Unobserved/Unexplained bilateral bruising to arms, bilateral bruising of the inner thighs, “wrap around” bruises that encircle the legs, arms or torso, and multicolored bruises which would indicate that several injuries were acquired over time. • Unobserved/Unexplained facial injuries, including facial fractures, black eye(s), bruising, or bleeding or swelling of the mouth or cheeks with or without broken or missing teeth • Unobserved/Unexplained bruising or other injuries in the genital area, inner thighs, or breasts • Unobserved/unexplained injury requiring transfer to a hospital for examination and/or treatment <p>NOTE: Any injury that is explained and appears to be a result of abuse must be reported.</p>	<ul style="list-style-type: none"> • Injuries where the resident was able to explain or describe how he/she received the injury as long as there is no other indication of abuse or neglect • Injuries that were witnessed by staff, where there is no indication of abuse or neglect <p>NOTE: Even if the injury is not one that requires a report, the facility should adequately assess and monitor the resident, notify the physician/resident representative as appropriate, and document the injury and investigation as a part of the resident's medical record.</p>

NOTE: If there is a reasonable suspicion of a crime having occurred related to the injury, covered individuals must report to the State Survey Agency and law enforcement under required timeframes (See Tag F609).

Section IV. Reportable Events Related to Potential Neglect

“Neglect,” means “the failure of the facility, its employees or service providers to provide goods and services to a resident that are necessary to avoid physical harm, pain, mental anguish or emotional distress.” (See §483.5) In other words, neglect occurs when the facility is aware, or should have been aware of, goods or services that a resident(s) requires but the facility fails to provide them to the resident(s), resulting in physical harm, pain, mental anguish or emotional distress. Alleged violations of neglect include cases where the facility demonstrates indifference or disregard for resident care, comfort or safety, resulting in physical harm, pain, mental anguish or emotional distress. There may be some situations in which the psychosocial outcome to the resident may be difficult to determine or incongruent with what would be expected. In these situations, it is appropriate to consider how a reasonable person in the resident’s position would be impacted by the incident.

Examples of events to be reported include, but are not limited to, the following:

- 1. Failure to meet payroll or pay supplier bills resulting in residents not receiving goods or services, such as
 - *Insufficient staff (including the night shift and weekends) resulting in the lack of provision for resident’s care needs (e.g., residents who need continuous skilled nursing care or supervision, residents with cognitive deficits requiring continuous supervision); or*
 - *Lack of essential supplies or equipment such as incontinence supplies, wound care supplies, or oxygen equipment or adaptive equipment according to the needs of the resident(s); or*
 - *Lack of sufficient amounts of food to meet the residents’ nutritional needs.**
- 2. Staff repeatedly ignoring residents’ needs for assistance with activities of daily living, resulting in residents remaining in bed when they want to be up and repeatedly missing activities; or residents being left in fecal material or urine.*
- 3. Failure to oversee the management of pain for a resident resulting in a resident not receiving required medications or treatments, leading to prolonged excruciating pain.*
- 4. Failure to implement and monitor care planned interventions, resulting in repeated failures to provide necessary care and services to prevent the development a new avoidable pressure ulcer that develops into a Stage 3 or 4 pressure ulcer.*

NOTE: Noncompliance at the Resident’s Rights/Quality of Care/Quality of Life tag alone does not automatically indicate noncompliance at F600, or F609. The survey team would need additional evidence that identifies that the facility knew, or should have known, to provide necessary staff, supplies, services, policies, training, or staff supervision and oversight to meet the resident’s needs, but failed to take action, resulting in harm to the resident. For example, a survey team identifies that a facility had failed to perform a skin assessment for a resident, resulting in failure to implement interventions to prevent the development of an avoidable Stage

2 pressure ulcer for a resident. Upon further investigation, the survey team finds that the facility identified the pressure ulcer and treated it with no further worsening. While the survey team would identify noncompliance at F686, the facility would not be cited at F600 and the facility would not be expected to report this as an alleged violation of neglect.

Section V. Reportable Allegations of Misappropriation of Resident Property and Exploitation

The facility must exercise reasonable care for the protection of the resident's property from loss or theft. See tag F584, 42 CFR §483.10(i)(1)(ii). The facility is expected to be responsive to a resident's concerns about lost items.

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

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

Examples of allegations of misappropriation of resident property and exploitation that must be reported include, but are not limited to:

- Theft of personal property, including but not limited to jewelry, computer, phone, and other valuable items such as eyeglasses and hearing aids;*
- Unauthorized/coerced use by staff of resident's personal property;*
- Theft of money from bank accounts;*
- Unauthorized or coerced purchases on a resident's credit card;*
- Unauthorized or coerced purchases from resident's funds;*
- Staff who accept money from a resident for any reason including when staff have made the resident believe that staff was in a financial crisis or the resident believes that he/she is in a relationship with the staff person;*
- A resident who provides a gift to staff in order to receive ongoing care, based on staff's persuasion; and*
- Missing prescription medications or diversion of a resident's medication(s), including, but not limited to, controlled substances for staff use or personal gain.*

Examples of allegations that would not be reported are:

- Theft of nominal items with little to no monetary or sentimental value;*
- Lost items that are not listed under “must be reported.”*

Section VI. Reportable Allegations of Mistreatment

“Mistreatment,” as defined at §483.5, is “inappropriate treatment or exploitation of a resident.”

Allegations of mistreatment should be reported only if they meet the criteria for reporting alleged violations of abuse and/or exploitation, which are described under the Sections above.

Refer to the CE Pathways for Abuse (Form CMS-20059) and Neglect (Form CMS-20130) and the Investigative Protocols for tags F602 and F603.

INVESTIGATIVE PROTOCOL FOR POLICIES AND PROCEDURES RELATED TO REPORTING OF REASONABLE SUSPICION OF A CRIME

USE

Use this protocol during any survey, if, based on a complaint or an investigation of abuse, neglect, misappropriation of resident property, or exploitation, a covered individual did not report a reasonable suspicion of a crime. Refer to the CE Pathways for Abuse (Form CMS-20059) and Neglect (Form CMS-20130) and the Investigative Protocols for tags F602, and F603, which gathers information about what information was or was not reported by covered individuals and whether retaliation may have occurred.

The protocol below investigates whether the facility developed and implemented policies and procedures related to:

- *Ensuring the reporting reasonable suspicion of crimes, and*
- *Notifying covered individuals of their reporting responsibilities.*

PROCEDURES

If the surveyor discovers a reasonable suspicion of a crime being committed against a resident of or an individual receiving services from the facility and it has not been reported by a covered individual, the surveyor reminds the facility of the covered individuals' obligation to report suspected crimes pursuant to section 1150B of the Act within the required timeframes.

“Covered individual” is anyone who is an owner, operator, employee, manager, agent or contractor of the facility as defined in section 1150B(a)(3) of the Act. If a covered individual reports the suspected crime to local law enforcement, the surveyor must verify that the report was made (e.g., obtain time/date of report, name of person who received report, case number, etc.). If the covered individual refuses to report, or the surveyor cannot verify that a report was done, the surveyor must consult with his/her supervisor immediately, and the State Agency must report the potential criminal incident to law enforcement immediately.

Facility Policies and Procedures

Obtain and review the facility's policies and procedures to determine whether the facility is:

- *Notifying covered individuals of their reporting responsibilities, and*
- *Ensuring the reporting of reasonable suspicions of crimes.*

Interview Staff

Interview staff who may have knowledge of the alleged incident to determine how did staff follow facility policies and procedures, such as:

- *What is his/her responsibility in reporting a reasonable suspicion of a crime,*
- *What is the facility's policies and procedures for reporting,*
- *What actions were taken when there was a suspected crime,*
- *When he/she may have last received orientation, training, in-service, and/or notification regarding the reporting of suspected crimes, and*

- *Whether there are any barriers to reporting.*

Additional interviews with other staff across all levels and different shifts may also be conducted.

Interview – Administrator

Interview the Administrator to determine how the Administrator oversees the implementation of policies and procedures for reporting of suspected crimes.

Review of In-service Training/Orientation Records

Obtain and review documentation of training to determine whether covered individuals were notified annually of their responsibility in a language that the individual would understand to report allegations of suspected crimes against residents and individuals receiving care from the facility.

Key Elements of Noncompliance

To cite deficient practice at F609, the surveyor’s investigation will generally show that the facility failed to do any one or more of the following:

- *Develop policies and procedures related to ensuring the reporting of suspected crimes, within mandated timeframes (i.e., immediately but not later than two hours if the suspected crime resulted in serious bodily injury, within 24 hours for all other cases) and notifying covered individuals annually of their reporting obligations;*
- Identify a situation as an alleged violation involving abuse, neglect, exploitation or mistreatment, including injuries of unknown source and misappropriation of resident property;
- Report an alleged violation involving abuse or resulting in serious bodily injury immediately, but not later than two hours after the allegation is made, to the administrator of the facility and to other officials, including to the State survey and certification agency and adult protective services in accordance with State law;
- Report an alleged violation involving neglect, misappropriation of resident property, exploitation, or mistreatment, and does not result in serious bodily injury not later than 24 hours to the administrator of the facility and to other officials, including to the State survey and certification agency and adult protective services in accordance with State law; or
- Report the results of all investigations within 5 working days to the administrator or his/her designated representative and to other officials in accordance with State law (including to the State survey and certification agency.

If Tag F609 is cited for failure to develop and/or implement policies and procedures for ensuring the reporting of a reasonable suspicion of a crime, the survey team includes the following language at the beginning of the Deficient Practice Statement on the Form CMS-2567: “Based on [observations/interviews/record review], the facility failed to develop and/or implement policies and procedures for ensuring the reporting of a reasonable suspicion of a crime in accordance with section 1150B of the Act...”

DEFICIENCY CATEGORIZATION - ENSURING REPORTING OF A REASONABLE SUSPICION OF A CRIME

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

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

- The facility failed to implement policies and procedures for covered individuals to identify and report a suspected crime to local law enforcement and the SA, resulting in failure to protect a resident from further potential criminal activity by an alleged perpetrator. *In addition, the facility had failed to report the alleged violation of abuse to the Administrator, as well as the State Survey Agency.* A resident, with a cognitive impairment who was dependent on staff for care, reported to family members that she was “touched down there” and identified the alleged perpetrator. Family members reported this to the licensed staff person on duty; however, the staff told the family that the resident was confused. Staff did not report the family’s allegation to anyone and failed to provide protection for the resident allowing ongoing access to the resident by the alleged perpetrator. The resident had emotional changes including crying and agitation and cowered with fear whenever the alleged perpetrator approached the resident. The resident subsequently developed a sexually transmitted disease (STD). Based on interviews with various staff members, these covered individuals were not aware of their reporting responsibilities for a suspected crime, *even though they had participated in abuse prevention training and had received their annual notification of their reporting obligations.* *Each staff member* assumed that this did not need to be reported because the resident was confused; therefore, the facility had failed to ensure reporting.

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

- The facility failed to implement policies and procedures for covered individuals to report to local law enforcement, the suspicion of a crime related to drug diversion. A resident was prescribed opioid pain medication to manage severe pain following recent surgery for a fractured hip. A resident had requested that staff review his pain medication as it was not effective over the weekend. The resident informed staff that he was unable to attend weekend daytime activities due to discomfort and lack of sleep from having pain at night. The resident stated that he received a different colored pill during the weekend, but it did not seem to work like the medication that was given during the weekdays. The facility’s investigation revealed that the same staff nurse worked on each of the weekend night shifts when the resident was identified to have unrelieved pain. This staff nurse had access to the controlled medications for residents on that unit. During interview with the nurse aide who worked on the same shift as the nurse, the nurse aide stated that she saw the nurse coming out of the resident’s room with the medication cup, and the nurse had told her that the resident was sleeping and she would give the medication later. The nurse aide reported that she then saw the nurse take the medication herself. She stated that she was afraid to report what she had seen since she did not want to jump into any conclusions or cause any trouble for the nurse. Interviews with other staff revealed they were not aware of facility policies or of their obligations to report a suspected crime including possible drug diversion.

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

The facility failed to provide annual notification to staff on their obligations to report suspected crimes and to post signage of employee rights related to retaliation against the employee for reporting a suspected crime. During the investigation, the surveyors did not see any signage related to employee rights related to retaliation. Based on interviews with five staff members, they had not received their annual notification from the facility regarding their obligations to report suspected crimes to law enforcement and to the State Survey Agency, without fear of retaliation. However, the staff members were knowledgeable about their obligations. *Additionally, two other staff members who were recently hired within the last 30 days, were not knowledgeable of their reporting obligations or rights to report a suspected crime without retaliation.*

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

- The failure of the facility to meet the requirements under this Federal requirement is more than minimal harm. Therefore, Severity Level 1 does not apply for this regulatory requirement.

¹ American Psychological Association . n.d. *Bullying*. Accessed April 15, 2019.
<https://www.apa.org/topics/bullying>.

F622

(Rev. 208; Issued:10-21-22; Effective: 10-21-22; Implementation:10-24-22)

§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 §483.70(e) (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 payer (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(j) for additional information).

NOTE: It may not be possible to convey all care plan information prior to urgent transfers, however, this information must be conveyed as close as possible to the actual time of transfer.

For residents being discharged (return not expected), the facility must convey all of the information listed above, along with *a copy of the* required information found at §483.21(c)(2) Discharge Summary, 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. 208; Issued:10-21-22; Effective: 10-21-22; Implementation:10-24-22)

§483.15(c)(3) Notice before transfer.

Before a facility transfers or discharges a resident, the facility must—

- Notify the resident and the resident's representative(s) of the transfer or discharge and the reasons for the move in writing and in a language and manner they understand. The facility must send a copy of the notice to a representative of the Office of the State Long-Term Care Ombudsman.**
- Record the reasons for the transfer or discharge in the resident's medical record in accordance with paragraph (c)(2) of this section; and**
- Include in the notice the items described in paragraph (c)(5) of this section.**

§483.15(c)(4) Timing of the notice.

- 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.**
- Notice must be made as soon as practicable before transfer or discharge when—**
 - The safety of individuals in the facility would be endangered under paragraph (c)(1)(i)(C) of this section;**
 - The health of individuals in the facility would be endangered, under paragraph (c)(1)(i)(D) of this section;**
 - The resident's health improves sufficiently to allow a more immediate transfer or discharge, under paragraph (c)(1)(i)(B) of this section;**
 - An immediate transfer or discharge is required by the resident's urgent medical needs, under paragraph (c)(1)(i)(A) of this section; or**
 - A resident has not resided in the facility for 30 days.**

§483.15(c)(5) Contents of the notice. The written notice specified in paragraph (c)(3) of this section must include the following:

- (i) The reason for transfer or discharge;**
- (ii) The effective date of transfer or discharge;**
- (iii) The location to which the resident is transferred or discharged;**
- (iv) A statement of the resident’s appeal rights, including the name, address (mailing and email), and telephone number of the entity which receives such requests; and information on how to obtain an appeal form and assistance in completing the form and submitting the appeal hearing request;**
- (v) The name, address (mailing and email) and telephone number of the Office of the State Long-Term Care Ombudsman;**
- (vi) For nursing facility residents with intellectual and developmental disabilities or related disabilities, the mailing and email address and telephone number of the agency responsible for the protection and advocacy of individuals with developmental disabilities established under Part C of the Developmental Disabilities Assistance and Bill of Rights Act of 2000 (Pub. L. 106-402, codified at 42 U.S.C. 15001 et seq.); and**
- (vii) For nursing facility residents with a mental disorder or related disabilities, the mailing and email address and telephone number of the agency responsible for the protection and advocacy of individuals with a mental disorder established under the Protection and Advocacy for Mentally Ill Individuals Act.**

§483.15(c)(6) Changes to the notice.

If the information in the notice changes prior to effecting the transfer or discharge, the facility must update the recipients of the notice as soon as practicable once the updated information becomes available.

§483.15(c)(8) Notice in advance of facility closure

In the case of facility closure, the individual who is the administrator of the facility must provide written notification prior to the impending closure to the State Survey Agency, the Office of the State Long-Term Care Ombudsman, residents of the facility, and the resident representatives, as well as the plan for the transfer and adequate relocation of the residents, as required at § 483.70(l).

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

F624

(Rev. 208; Issued:10-21-22; Effective: 10-21-22; Implementation:10-24-22)

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

A facility must provide and document sufficient preparation and orientation to residents to ensure safe and orderly transfer or discharge from the facility. This orientation must be provided in a form and manner that the resident can understand.

DEFINITIONS

“Transfer and Discharge”: Includes movement of a resident to a bed outside of the certified facility whether that bed is in the same physical plant or not. Transfer and discharge does not refer to movement of a resident to a bed within the same certified facility. *(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 guidance at this tag addresses the immediate orientation and preparation necessary for a *facility-initiated* transfer, such as to a hospital emergency room or therapeutic leave where discharge planning is not required because the resident will return, or for an emergent or immediate *facility-initiated* discharge where a complete discharge planning process is not practicable. For concerns related to how the facility planned for a discharge that meets a resident’s health and safety needs, as well as their preferences and goals in circumstances which permit a complete discharge planning process, please refer to F660, Discharge Planning.

Sufficient preparation and orientation means the facility informs the resident where he or she is going, and takes steps under its control to minimize anxiety. Examples of preparation and orientation may include explaining to a resident why they are going to the emergency room or other location or leaving the facility; working with family or resident’s representative to assure that the resident’s possessions (as needed or requested by the resident) are not left behind or lost; and ensuring that staff handle transfers and discharges in a manner that minimizes anxiety or depression and recognizes characteristic resident reactions identified by the resident’s assessment and care plan.

The facility must orient and prepare the resident regarding his or her transfer or discharge in a form and manner that the resident can understand. The form and manner of this orientation and preparation must take into consideration factors that may affect the resident’s ability to understand, such as educational level, language and/or communication barriers, and physical and mental impairments. The facility must also document this orientation in the medical record, including the resident’s understanding of the transfer or discharge.

Other tags for consideration would be:

- F622, Transfer and Discharge Requirements, specifically the clinical information that must be conveyed to the receiving provider, if the transfer or discharge is to another healthcare setting; and
- F843, Transfer Agreement, for concerns related to timely transfer to the acute care facility.

PROCEDURES

- Review nursing notes and any other relevant documentation to see if appropriate orientation and preparation of the resident prior to transfer and discharge has occurred.

- Through record review and interviews, determine if the resident received sufficient preparation prior to transfer or discharge, and if they understood the information provided to them.
- Were the resident's needed/requested possessions transferred with the resident to the new location?

Ask resident or his or her representative if they understand why the transfer or discharge occurred.

F626

(Rev. 208; Issued:10-21-22; Effective: 10-21-22; Implementation:10-24-22)

§483.15(e)(1) Permitting residents to return to facility.

A facility must establish and follow a written policy on permitting residents to return to the facility after they are hospitalized or placed on therapeutic leave. The policy must provide for the following.

- (i) A resident, whose hospitalization or therapeutic leave exceeds the bed-hold period under the State plan, returns to the facility to their previous room if available or immediately upon the first availability of a bed in a semi-private room if the resident—**
 - (A) Requires the services provided by the facility; and**
 - (B) Is eligible for Medicare skilled nursing facility services or Medicaid nursing facility services.**
- (ii) If the facility that determines that a resident who was transferred with an expectation of returning to the facility, cannot return to the facility, the facility must comply with the requirements of paragraph (c) as they apply to discharges.**

§483.15(e)(2) Readmission to a composite distinct part. When the facility to which a resident returns is a composite distinct part (as defined in § 483.5), the resident must be permitted to return to an available bed in the particular location of the composite distinct part in which he or she resided previously. If a bed is not available in that location at the time of return, the resident must be given the option to return to that location upon the first availability of a bed there.

INTENT

To ensure that facilities develop **and implement** policies that address *permitting residents to return to the facility after a hospitalization or therapeutic leave*. Specifically, residents who are hospitalized or on therapeutic leave are allowed to return *to the facility* for skilled nursing or nursing facility care or services. *When a facility does not allow the resident to return, the facility has initiated a discharge, and* the facility must comply with Transfer and Discharge Requirements at §483.15(c). The resident must be permitted to return and resume residence in the facility while an appeal *of the discharge* is pending.

DEFINITIONS

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

“Composite Distinct Part”: A composite distinct part is a distinct part consisting of two or more noncontiguous components that are not located within the same campus, as that term is defined in §413.65(a)(2). *The definition and* additional requirements specific to SNF/NF composite distinct parts are found at §483.5.

“Campus”: Campus is defined in §413.65(a)(2) and means the physical area immediately adjacent to the provider’s main buildings, other areas and structures that are not strictly contiguous to the main buildings but are located within 250 yards of the main buildings, and any other areas determined on an individual case basis, by the CMS regional office, to be part of the provider’s campus.

“Distinct Part”: A distinct part SNF or NF is physically distinguishable from the larger institution or institutional complex that houses it, meets the requirements of paragraph (2) *of this definition at §483.5*, and meets the applicable statutory requirements for SNFs or NFs in sections 1819 or 1919 of the Act, respectively. A distinct part SNF or NF may be comprised of one or more buildings or designated parts of buildings (that is, wings, wards, or floors) that are: In the same physical area immediately adjacent to the institution's main buildings; other areas and structures that are not strictly contiguous to the main buildings but are located within close proximity of the main buildings; and any other areas that CMS determines on an individual basis, to be part of the institution's campus. A distinct part must include all of the beds within the designated area, and cannot consist of a random collection of individual rooms or beds that are scattered throughout the physical plant. The term “distinct part” also includes a composite distinct part that meets the additional requirements *specified in the definition of “composite distinct part” of §483.5 described above*. Requirements specific to *distinct part SNFs or NFs* are found at §483.5.

“Therapeutic Leave”: *Resident* absences for purposes other than required hospitalization.

GUIDANCE §483.15(e)

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

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

The policies must also provide that if the facility determines that a resident cannot return, the facility must comply with the requirements of paragraph at 42 CFR 483.15(c) as they apply to facility-initiated discharges.

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

Not Permitting Residents to Return

Not permitting a resident to return following hospitalization or therapeutic leave *constitutes a facility-initiated discharge and* requires a facility to meet the requirements as outlined in §483.15(c)(1)(ii). A facility must not discharge a resident unless:

1. The discharge or transfer is necessary for the resident's welfare and the facility cannot meet the resident's needs.
2. The resident's health has improved sufficiently so that the resident no longer needs the services of the facility.
3. The resident's clinical or behavioral status endangers the safety of individuals in the facility.
4. The resident's clinical or behavioral status endangers the health of individuals in the facility.
5. The resident *has failed, after reasonable and appropriate notice, to pay for* (or to have paid under Medicare or Medicaid) his or her stay at the facility *which applies if:*
 - *the resident does not submit the necessary paperwork for third party payment; or*
 - *the third party, including Medicare or Medicaid, denies the claim and the resident refuses to pay for his or her stay.*
6. The facility ceases to operate.

For concerns related to a facility not permitting a resident to return, the surveyor should investigate to determine if the basis for discharge meets one of the requirements *listed* above *which are also found at* F622, §483.15(c)(1)(i)(A) *through (F)*.

As noted at §483.15(c)(2)(i)(B), when the facility transfers or discharges a resident for the resident's welfare, or because the resident's needs cannot be met in the facility, the medical record must contain documentation of the specific resident needs that cannot be met, facility attempts to meet those needs, and the service available at the receiving facility to meet the needs.

Resident decisions to refuse care should not be considered a basis for transfer or discharge unless the refusal poses a risk to the resident's or other individuals' health and/or safety. In situations where a resident's choice to refuse care or treatment poses a risk to the resident's or others' health or safety, the comprehensive care plan must identify the care or service being declined, the risk the declination poses to the resident, and efforts by the interdisciplinary team to educate the resident and the representative, as appropriate (See F656, §483.21(b)(1)(ii), Comprehensive Care Plans.)

If unable to resolve situations where a resident's refusal for care poses a risk to the resident's or others' health or safety, the facility administration, nursing and medical director may wish to

convene an ethics meeting, which includes legal consultation, in order to determine if the facility can meet the resident's needs, or if the resident should be transferred or discharged.

If a facility does not permit a resident who went on therapeutic leave to return, the facility must meet the requirements for a facility-initiated discharge at F622. Because the facility was able to care for the resident prior to therapeutic leave, documentation related to the basis for discharge must clearly show why the facility can no longer care for the resident.

Additionally, facilities must not treat situations where a resident goes on therapeutic leave and returns later than agreed upon, as a resident-initiated discharge. The resident must be permitted to return and be appropriately assessed for any ill-effects from being away from the facility longer than expected, and provide any needed medications or treatments which were not administered because they were out of the building. If a resident has not returned from therapeutic leave as expected, the medical record should show evidence that the facility attempted to contact the resident and resident representative. The facility must not initiate a discharge unless it has ascertained from the resident or resident representative that the resident does not wish to return.

***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.*

A facility may have concerns about permitting a resident to return to the facility after a hospital stay due to the resident's clinical or behavioral condition at the time of transfer.

The facility must not evaluate the resident based on his or her condition when originally transferred to the hospital. If the facility determines it will not be permitting the resident to return, the medical record should show evidence that the facility made efforts to:

- Determine if the resident still requires the services of the facility and is eligible for Medicare skilled nursing facility or Medicaid nursing facility services.
- Ascertain an accurate status of the resident's condition—this can be accomplished via communication between hospital and nursing home staff and/or through visits by nursing home staff to the hospital.
- Find out from the hospital the treatments, medications, and services the facility would need to provide to meet the resident's needs *upon returning to the facility*. If the facility is unable to provide the treatments, medications, and services needed, the facility may not be able to meet the resident's needs. For example, a resident *now requires ventilator care or dialysis*, and the nursing home is unable to provide this same level of care.
- Work with the hospital to ensure the resident's condition and needs are within the nursing home's scope of care, based on its facility assessment, prior to hospital discharge. For example, the nursing home could ask the hospital to:
 - Attempt reducing a resident's psychotropic medication prior to discharge and

- monitor symptoms so that the nursing home can determine whether it will be able to meet the resident's needs upon return;
- Convert IV medications to oral medications and ensure that the oral medications adequately address the resident's needs.

If the facility does not permit a resident's return to the facility (i.e., initiates a discharge) based on inability to meet the resident's needs, documentation must be in accordance with requirements at §483.15(c)(2)(i)(B). The facility must notify the resident, his or her representative, and the LTC ombudsman in writing of the discharge, including notification of appeal rights. (§483.15(c)(3) and (5)(iv)) If the resident chooses to appeal the discharge, the facility must allow the resident to return to his or her room or an available bed in the nursing home during the appeal process, unless there is documented evidence that the resident's return would endanger the health or safety of the resident or other individuals in the facility. (§483.15(c)(1)(ii))

For concerns regarding notification of discharge, and the resident's right to appeal the discharge, refer to the regulation and guidance at §§483.15(c)(3)-(5)(F623).

Composite Distinct Part

If a facility does not have a composite distinct part, §483.15(e)(2) does not apply. When a resident is returning to a composite distinct part, he/she must be allowed to return to an available bed in the particular location of the composite distinct part in which he/she resided previously, or the next available bed in that location.

NOTE: *If there are concerns as to whether or not a facility is appropriately certified as a distinct or composite distinct part, consult with the CMS Regional Office for clarification.*

INVESTIGATIVE PROTOCOL

Use the Critical Element (CE) Pathways for Discharge, or Hospitalization, as appropriate, along with the above interpretive guidelines when determining if the facility meets the requirements for, or investigating concerns related to the facility requirements to permit residents to return following hospitalization or therapeutic leave.

Summary of Investigative Procedure

If concerns arise regarding facility failure to permit a resident to return, review the medical record for evidence of whether a notice of transfer and discharge and notice of bed-hold were provided. Determine the basis for discharge and how the facility evaluated the resident. The surveyor may have to obtain hospital records for further investigation. Review any other documentation necessary to ascertain the extent to which the facility made efforts to enable the resident to return.

In cases where a facility did not allow a resident to return due to lack of an available bed, the surveyor should review facility admissions beginning with when the resident was ready to return to determine *whether the facility held the resident's bed in accordance with its bed-hold policies, or, if the resident's stay outside of the facility exceeded the bed-hold period, whether there was an available bed at the time the resident sought return to the facility. If there was not an available bed at the time the resident sought return to the facility, the surveyor should*

determine whether or not the resident was allowed to return to the first available bed in a semi-private room.

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

KEY ELEMENTS OF NONCOMPLIANCE to cite deficient practice at F626, the surveyor's investigation will generally show that the facility failed to:

- Establish and/or implement a policy that is in accordance with the State Medicaid plan, and addresses returning to the facility following hospitalization or therapeutic leave; or
- Ensure that residents whose hospitalization or therapeutic leave exceeds the State's bed-hold period are returned to their previous room and/or the first available bed in a semi-private room; or
- Permit a resident to return to the same composite distinct part in which they previously resided.

DEFICIENCY CATEGORIZATION

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

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

Facility failed to allow a resident to return following therapeutic leave to a family member's home, resulting in the resident being found living on the street, without adequate food *and* shelter, and susceptible to serious accidents.

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

- Facility failed to allow a resident to return to *an available* bed in the same location of the composite distinct part *in* which they resided previously. The new location was *not on the same campus where the resident previously resided, and was farther* from the resident's family, resulting in the resident expressing sustained and persistent sadness and withdrawal.
- *After transfer to a behavioral health hospital, a facility failed to allow a resident to return to the facility where the resident had lived for several months. The facility then refused to allow the resident to return to the facility when the hospitalization ended, resulting in the resident being transferred from the hospital to a different nursing home 40 minutes away, where he did not know anyone, and where he developed increased anxiety and depression.*

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

- Facility failed to allow a resident to return to his/her previous room (even though it was available) upon return from the hospital, which resulted in no more than minimal harm as the resident adjusted to the new room. This noncompliance has the potential to cause more than minimal psychosocial harm.

An example of Severity Level 1 noncompliance: No actual harm with potential for minimal harm includes, but is not limited to:

A facility which is a composite distinct part permitted a resident to return following hospitalization or therapeutic leave, however, the resident returned to a different location in the composite distinct part even though a bed was available in the same location where the resident had resided prior to transfer. The resident did not express displeasure with the situation.

F641

(Rev. 208; Issued:10-21-22; Effective: 10-21-22; Implementation:10-24-22)

§483.20(g) Accuracy of Assessments.

The assessment must accurately reflect the resident's status.

INTENT §483.20(g)

To assure that each resident receives an accurate assessment, reflective of the resident's status at the time of the assessment, by staff qualified to assess relevant care areas and are knowledgeable about the resident's status, needs, strengths, and areas of decline.

GUIDANCE §483.20(g)

“Accuracy of Assessment” means that the appropriate, qualified health professionals correctly document the resident's medical, functional, and psychosocial problems and identify resident strengths to maintain or improve medical status, functional abilities, and psychosocial status using the appropriate Resident Assessment Instrument (RAI) (i.e. comprehensive, quarterly, significant change in status).

Facilities are responsible for ensuring that all participants in the assessment process have the requisite knowledge to complete an accurate assessment.

The determination of appropriate participation of health professionals must be based on the physical, mental and psychosocial condition of each resident. This includes an appropriate level of involvement of physicians, nurses, rehabilitation therapists, activities professionals, medical social workers, dietitians, and other professionals, such as developmental disabilities specialists, in assessing the resident, and in correcting resident assessments. Involvement of other disciplines is dependent upon resident status and needs.

The assessment must represent an accurate picture of the resident's status during the observation period of the MDS. The Observation Period (also known as the Look-back period)

is the time period over which the resident's condition or status is captured by the MDS assessment and ends at 11:59 p.m. on the day of the Assessment Reference Date (ARD). Be aware that different items on the MDS have different Observation Periods.

When the MDS is completed, only those occurrences during the observation period will be captured on the assessment. In other words, if it did not occur during the observation period, it is not coded on the MDS.

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

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

PROBES §483.20(g)

- Based on your total review of the resident, observations, interviews and record reviews, does each portion of the MDS assessment accurately reflect the resident's status as of the Assessment Reference Date?
- Is there evidence that the health professionals who assessed the resident had the skills and qualifications to conduct the assessment? For example, has the resident's nutritional status been assessed by someone who is knowledgeable in nutrition and capable of correctly assessing a resident?

F656

(Rev. 208; Issued:10-21-22; Effective: 10-21-22; Implementation:10-24-22)

§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, §483.70(e)
- *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.

F658

(Rev. 208; Issued:10-21-22; Effective: 10-21-22; Implementation:10-24-22)

§483.21(b)(3) Comprehensive Care Plans

The services provided or arranged by the facility, as outlined by the comprehensive care plan, must—

- (i) Meet professional standards of quality.**

INTENT §483.21(b)(3)(i)

The intent of this regulation is to assure that services being provided meet professional standards of quality.

GUIDANCE §483.21(b)(3)(i)

“Professional standards of quality” means that care and services are provided according to accepted standards of clinical practice. Standards may apply to care provided by a particular clinical discipline or in a specific clinical situation or setting. Standards regarding quality care practices may be published by a professional organization, licensing board, accreditation body or other regulatory agency. Recommended practices to achieve desired resident outcomes may also be found in clinical literature. Possible reference sources for standards of practice include:

- Current manuals or textbooks on nursing, social work, physical therapy, etc.
- Standards published by professional organizations such as the American Dietetic Association, American Medical Association, American Medical Directors Association, American Nurses Association, National Association of Activity Professionals, National Association of Social Work, etc.
- Clinical practice guidelines published by the Agency for Healthcare Research and Quality.
- Current professional journal articles.

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

***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, determine if non-compliance exists related to the practitioner not adhering to professional standards of quality for assessing and diagnosing a resident. This practice may also require referrals by the facility and/or the survey team to State Medical Boards or Boards of Nursing.*

PROCEDURES AND PROBES §483.21(b)(3)(i)

There is no requirement for the surveyor to cite a reference or source (e.g., current textbooks, professional organizations or clinical practice guidelines) for the standard of practice that has not been followed related to care and services provided within professional scopes of practice, such as failure of nursing staff to assess a change in the resident's condition. However, in cases where the facility provides a reference supporting a particular standard of practice for which the surveyor has concerns, the surveyor must provide evidence that the standard of practice the facility is using is not up-to-date, widely accepted, or supported by recent clinical literature. Such evidence should include a citation for the reference or source (e.g., current textbooks, professional organizations or clinical practice guidelines) for the current standard of practice from which facility deviated.

If a negative or potentially negative resident outcome is determined to be related to the facility's failure to meet professional standards and the team determines a deficiency has occurred, it should also be cited under the appropriate quality of care or other relevant requirement. For example, if a resident develops a pressure injury because the facility's nursing staff failed to provide care in accordance with professional standards of quality, the team should cite the deficiency at both F658 and F686 (Skin Integrity).

- Do the services provided or arranged by the facility, as outlined in the comprehensive care plan, reflect accepted standards of practice?
- Are the references for standards of practice, used by the facility, up to date, and accurate for the service being delivered?

KEY ELEMENTS OF NONCOMPLIANCE:

To cite deficient practice at F658, the surveyor's investigation will generally show that the facility did one or more of the following:

- Provided or arranged for services or care that did not adhere to accepted standards of quality;
- Provided a service or care when the accepted standards of quality dictate that the service or care should not have been provided;
- Failed to provide or arrange for services or care that accepted standards of quality dictate should have been provided.

F659

(Rev. 208; Issued:10-21-22; Effective: 10-21-22; Implementation:10-24-22)

§483.21(b)(3) Comprehensive Care Plans

The services provided or arranged by the facility, as outlined by the comprehensive care plan, must—

- (ii) **Be provided by qualified persons in accordance with each resident's written plan of care.**

GUIDANCE

The facility must ensure that services provided or arranged *in accordance with the resident's plan of care* are delivered by individuals who have the skills, experience and knowledge to do a particular task or activity. This includes proper licensure or certification, if required.

INVESTIGATIVE PROCEDURES AND PROBES

NOTE: Provision of services by qualified individuals would be cited here, but implementation of the care plan would be cited in F656.

- Are the services identified in the comprehensive care plan being provided by qualified persons?
- Do staff assigned to the resident have the skills, experience and knowledge to provide care and services that meet the resident's needs?

DEFICIENCY CATEGORIZATION

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

- The facility had no qualified staff on duty knowledgeable or competent in how to care for a resident with a tracheostomy, posing a risk for serious injury, harm, impairment or death for the resident.

An example of Level 3, actual harm that is not immediate jeopardy includes, but is not limited to:

- The facility utilized a staff member who was not qualified to draw a resident's blood, according to the resident's care plan, resulting in the resident sustaining extensive bruising, swelling, pain and decreased ability to use the arm after the blood draw

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

- The facility failed to ensure staff were qualified to perform blood pressure (BP) readings. During survey, staff were observed taking and reporting resident BPs that were abnormal. After further investigation, it was determined that staff were using the incorrect size BP cuff, yielding inaccurate BP readings, resulting in the potential for more than minimal harm.

Non-compliance with this regulation places the resident at risk for more than minimal harm. Therefore, Severity Level 1 does not apply for this regulatory requirement.

F675

(Rev. 208; Issued:10-21-22; Effective: 10-21-22; Implementation:10-24-22)

§ 483.24 Quality of life

Quality of life is a fundamental principle that applies to all care and services provided to facility residents. Each resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, consistent with the resident’s comprehensive assessment and plan of care.

INTENT

The intent of this requirement is to specify the facility’s responsibility to create and sustain an environment that humanizes and individualizes each resident’s quality of life by:

- Ensuring all staff, across all shifts and departments, understand the principles of quality of life, and honor and support these principles for each resident; and
- Ensuring that the care and services provided are person-centered, and honor and support each resident’s preferences, choices, values and beliefs.

DEFINITIONS §483.24

“Person Centered Care” – For the purposes of this subpart, person-centered care means to focus on the resident as the locus of control and support the resident in making their own choices and having control over their daily lives. (Definitions - §483.5)

“Pervasive” For the purposes of this guidance, pervasive means spread through or embedded within every part of something.

“Quality of Life” refers to an individual’s “sense of well-being, level of satisfaction with life and feeling of self-worth and self-esteem. For nursing home residents, this includes a basic sense of satisfaction with oneself, the environment, the care received, the accomplishments of desired goals, and control over one’s life.” *Adapted from the 1986 Institute of Medicine (IOM) published report “Improving the Quality of Care in Nursing Homes,” located at: <https://www.ncbi.nlm.nih.gov/books/NBK217548/#ddd00037>*

GUIDANCE §483.24

Noncompliance at F675 identifies outcomes which rise to the level of immediate jeopardy and reflect an environment of pervasive disregard for the quality of life of the facility’s residents. This can include the cumulative effect of noncompliance at other regulatory tags on one or more residents. To cite noncompliance at F675, the survey team must have evidence that outcomes at other regulatory tags demonstrate a pervasive disregard for the principles of quality of life.

Principles of Quality of Life

According to the 1986 Institute of Medicine (IOM) published report “Improving the Quality of Care in Nursing Homes,” principles of Quality of Life included:

- A sense of well-being, satisfaction with life, and feeling of self-worth and self-esteem; and
- A sense of satisfaction with oneself, the environment, the care received, the accomplishments of desired goals, and control over one’s life.

The report also identified that a sense of well-being, self-esteem, and self-worth was enhanced by personal control over choices, such as mealtimes, activities, clothing, and bedtime; privacy during visits, and treatments; and “opportunities to engage in religious, political, civic, recreational or other social activities. Based upon the regulatory requirement stating that quality of life is an overarching principle that applies to all care and services, the principles as identified in the IOM report above, will be used for determining whether a resident’s quality of life is being supported and or enhanced. Refer to this link for the entire IOM report: <https://www.ncbi.nlm.nih.gov/books/NBK217548/#ddd00037>

Facilities must create and sustain an environment that humanizes and promotes each resident’s well-being, and feeling of self-worth and self-esteem. This requires nursing home leadership to establish a culture that treats each resident with respect and dignity as an individual, and addresses, supports and/or enhances his/her feelings of self-worth including personal control over choices, such as mealtimes, activities, clothing, and bedtime; privacy during visits, and treatments; and opportunities to engage in religious, political, civic, recreational or other social activities.

Facility leadership must be aware of the culture that exists in its facility and may use various methods to assess the attitudes and values prevalent amongst staff. These methods include, reviewing complaints or grievances, which could reasonably impact a resident’s quality of life, or allegations of abuse, neglect or mistreatment. In order to identify whether staff supports each resident’s quality of life, leadership should observe and evaluate verbal and nonverbal interactions between staff and residents. Negative observations could include staff actions such as, *but not limited to*, the following:

- Verbalizing negative or condescending remarks, or refusing to provide individualized care to a resident due to his/her age, race, or cognitive or physical impairments, his/her political or cultural beliefs, or sexual preferences;
- Dehumanizing an individual through verbal and nonverbal actions such as talking to others over a resident without acknowledging his/her presence, treating the resident as if he/she were an object rather than a human being, mistreating, or physically, sexually or mentally abusing a resident.

These types of staff actions and attitudes do not recognize nor value the individual. An individual’s life experiences, values, needs, choices and relationships must not be diminished, to the extent possible, due to admission to a nursing home. Treating a nursing home resident in any manner that does not uphold a resident’s sense of self-worth, dignity and individuality dehumanizes the resident and creates an environment that perpetuates an unhealthy, unsafe attitude towards the resident(s).

In order to achieve a culture and environment that supports quality of life, the facility must ensure that all staff, across all shifts and departments, understand the principles of quality of life, and honor and support these principles for each resident and that the care and services that are provided by the facility are person-centered, and honor and support each resident’s preferences, choices, values and beliefs.

The Link between Noncompliance at other Regulatory Tags and Noncompliance at Quality of Life

Quality of Life at F675 should not automatically be cited when noncompliance has been identified in Resident's Rights/Quality of Care/Abuse-Neglect or other regulatory tags, unless the cumulative effect of the noncompliance creates an environment that reflects a complete disregard of one or more residents' well-being, and rises to the level of Immediate Jeopardy.

See below for an example of noncompliance at F675 demonstrating the cumulative effect of noncompliance at other tags for multiple residents:

The facility failed to provide an environment which supported and enhanced each resident's quality of life, which was the result of the cumulative effect of noncompliance cited at dignity, abuse, staffing, and continence care. This noncompliance was found to be pervasive and created an environment reflecting a complete disregard of one or more residents' well-being and quality of life, which has caused or is likely to cause serious harm related to one or more residents' self-worth, self-esteem, and well-being.

A complaint investigation revealed facility staff members posted unauthorized videos and photographs on social media of several residents during bathing, going to the bathroom, and grooming, including nude photos and photos of genitalia. As a result, the residents suffered public humiliation and dehumanization. Facility staff interviewed were aware of this abuse, but did not report to administration due to fear of retaliation by the perpetrators and fear of losing their jobs.

During a resident council meeting, several residents reported that they heard staff describing the photos, laughing about the postings and had seen staff passing around cell phones. As a result, the residents stated that they were afraid to take a shower or bath, and were extremely uncomfortable when requesting assistance to go to the bathroom because they thought it might happen to them, and that they had shared these concerns with other residents in the facility. (Refer to noncompliance cited at §483.12, F600 – Abuse)

When discussing going to the bathroom, the residents stated that in addition to being afraid of asking for help, when they did, there were not enough staff to answer call lights. They said that staff would ignore their call light, walk by or would answer the light and leave without assisting the residents. This had resulted in episodes of incontinence of urine and feces, which they stated was extremely embarrassing, humiliating and degrading to them. (Refer to noncompliance cited at §483.10(a)(1), F550 – Dignity; §483.35, F725 – Insufficient Staff, Nursing Services; and §483.25(e)(1), F690 – Incontinence, Quality of Care.)

Several residents stated that they were afraid to ask for staff assistance for the need to use the bathroom, based on their fear related to the postings on social media. In addition, they stated that when they were receiving care, if staff pulled out a cell phone, they didn't know if staff were taking and posting pictures of them.

When asked if these concerns had been reported to the administration, the residents stated that they identified the issue with the call lights and not enough staff multiple times during council meetings, but that the administration only said, we will look into it, and nothing was done. They said they were afraid to report the cell phone concerns. One resident said that an aide told him/her that if they didn't quit complaining to the administrator, no one would help them and they would be transferred to another facility. When the resident began to cry, the aide laughed and walked out of the room, verbally taunting him/her for crying.

See below for an example of noncompliance at F675 demonstrating the cumulative effect of noncompliance at other tags for one resident:

The facility failed to provide an environment which supported one resident's quality of life, which was the result of the cumulative effect of noncompliance cited at §483.10(a), Dignity, and §483.10(b)(2), Freedom from discrimination, F550; §483.12(a) Abuse; §483.10(h), Personal Privacy – F583; §483.10(f), Self-Determination - F561; §483.21(b), Comprehensive, Person-Centered Care Planning - F656; and §483.60(c)(4), Menus and Nutritional Adequacy – F803. This complete disregard of the residents' quality of life, caused serious harm related to her self-worth, self-esteem, and well-being.

The surveyor identified a resident who was admitted 6 weeks ago, and had religious beliefs which differed from the resident population in the nursing home, and those of the staff. During interviews, the resident and her family reported that staff continually made derogatory remarks about the resident's culture/religion to each other within earshot of the resident, or while in the room providing ADL care to the resident. This occurred during all shifts. Additionally, the resident reported that discriminatory remarks were made by housekeeping and dietary staff as well. The resident's family reported this was particularly worse on weekends when facility leadership were not in the building. The family members reported they would take turns visiting the resident on weekends, to support the resident and assist with her care. When asked if this was reported to facility management, the resident said her family had reported it to the Administrator on several occasions, but that nothing had changed. Interview with the Administrator revealed that an in-service was planned for the future. (Refer to noncompliance cited at §483.10(a)(1), Dignity, and §483.10(b)(2) Freedom from Discrimination - F550, §483.12(a), Abuse – F600)

The resident described frequent occurrences of disregard of her personal privacy including not covering her body completely, allowing full view of her arms, legs and buttocks when transporting her to the shower. The surveyor observed, on one occasion, staff not pulling the privacy curtain when assisting her to dress, resulting in anyone walking in the hallway being able to view her as she was dressed. (Refer to noncompliance cited at §483.10(h), Personal Privacy – F583)

On multiple occasions, the resident reported that she was assigned a male care giver, which is against her religious belief that a person of the opposite sex cannot provide care. On these occasions, the resident would tearfully refuse to get dressed, or call her family

to assist her. On at least one occasion, the resident was forced to receive a shower with the assistance of a male aide, which resulted in the resident crying uncontrollably until her family arrived. Progress notes in her medical record noted this occasion as the resident becoming uncontrollable while receiving a shower. Additionally, when dressing her for the day, staff would not cover her hair, arms and legs, and would say that her scarf was missing, only to be found when her family arrived. On interview, staff said they were unaware that this was a violation of her religion. This noncompliance resulted in the resident frequently refusing to shower, or, according to family, calling her family, begging for them to come get her dressed. (Refer to noncompliance cited at §483.10(f), Self-Determination - F561.)

The surveyor observed the meal tray set up and found it did not honor the resident's preferences identified on the meal tray card and care plan. The resident reported that this happened on most days, and even if she requested an alternative, she would be given a food item that was prohibited according to her religion, and therefore, she would not eat that meal. The resident's family stated that they frequently brought food in to the resident because she could not eat what was brought to her.

On interview, dietary staff stated they did not have the time to prepare a special diet for this one resident, and stated to the surveyor, "They should have thought of that before they came to this country." Additionally, the dietary staff reported that he/she was not aware of the dietary requirements of this resident's religion. An interview with the consulting dietitian revealed that he/she was not aware that this resident had been admitted to the facility, and she agreed that the menu did not meet this resident's religious preferences. (Refer to noncompliance cited at 483.60(c)(4), Menus and Nutritional Adequacy – F803)

Review of the resident's care plans revealed that there was no identification of this resident's preferences or dietary requirements related to her religion. (Refer to noncompliance cited at §483.21(b), Comprehensive, Person-Centered Care Plan – F656)

As the result of cumulative effect of the noncompliance identified, this resident suffered loss of religious and cultural identity, had ongoing feelings of extreme sadness and humiliation, and expressed a wish to die.

Noncompliance which reflects a pervasive disregard for one or more residents' quality of life must be carefully considered for the impact to the resident(s) affected. For concerns which may rise to the level of Immediate Jeopardy, refer to Appendix Q.

F679

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§483.24(c) Activities

§483.24(c)(1) The facility must provide, based on the comprehensive assessment and care plan and the preferences of each resident, an ongoing program to support

residents in their choice of activities, both facility-sponsored group and individual activities and independent activities, designed to meet the interests of and support the physical, mental, and psychosocial well-being of each resident, encouraging both independence and interaction in the community.

INTENT §483.24(c)

To ensure that facilities implement an ongoing resident centered activities program that incorporates the resident's interests, hobbies and cultural preferences which is integral to maintaining and/or improving a resident's physical, mental, and psychosocial well-being and independence. To create opportunities for each resident to have a meaningful life by supporting his/her domains of wellness (security, autonomy, growth, connectedness, identity, joy and meaning).

DEFINITIONS §483.24(c)

“Activities” refer to any endeavor, other than routine ADLs, in which a resident participates that is intended to enhance her/his sense of well-being and to promote or enhance physical, cognitive, and emotional health. These include, but are not limited to, activities that promote self-esteem, pleasure, comfort, education, creativity, success, and independence.

NOTE: ADL-related activities, such as manicures/pedicures, hair styling, and makeovers, may be considered part of the activities program.

GUIDANCE §483.24(c)

Opportunities for each resident to have a meaningful life may be created by supporting his/her domains of well-being (e.g., security, autonomy, growth, connectedness, identity, joy and meaning) as identified by the Eden Alternative philosophy of care. More information may be found at: <http://www.edenalt.org/about-the-eden-alternative/the-eden-alternative-domains-of-well-being/>).

Research findings and the observations of positive resident outcomes confirm that activities are an integral component of residents' lives. Residents have indicated that daily life and involvement should be meaningful. Activities are meaningful when they reflect a person's interests and lifestyle, are enjoyable to the person, help the person to feel useful, and provide a sense of belonging. Maintaining contact and interaction with the community is an important aspect of a person's well-being and facilitates feelings of connectedness and self-esteem. Involvement in community includes interactions such as assisting the resident to maintain his/her ability to independently shop, attend the community theater, local concerts, library, and participate in community groups.

Activity Approaches for Residents with Dementia

All residents have a need for engagement in meaningful activities. For residents with dementia, the lack of engaging activities can cause boredom, loneliness and frustration, resulting in distress and agitation. Activities must be individualized and customized based on the resident's previous lifestyle (occupation, family, hobbies), preferences and comforts. https://www.caringkindnyc.org/_pdf/CaringKind-PalliativeCareGuidelines.pdf

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The facility may have identified a resident's pattern of behavioral symptoms and may offer activity interventions, whenever possible, prior to the behavior occurring. Once a behavior escalates, activities may be less effective or may even cause further stress to the resident (some behaviors may be appropriate reactions to feelings of discomfort, pain, or embarrassment, such as aggressive behaviors exhibited by some residents with dementia during bathing¹⁶).

Examples of activities-related interventions that a facility may provide to try to minimize distressed behavior may include, but are not limited, to the following:

For the resident who exhibits unusual amounts of energy or walking without purpose:

- Providing a space and environmental cues that encourages physical exercise, decreases exit-seeking behavior and reduces extraneous stimulation (such as seating areas spaced along a walking path or garden; a setting in which the resident may manipulate objects; or a room with a calming atmosphere, for example, using music, light, and rocking chairs);
- Providing aroma(s)/aromatherapy that is/are pleasing and calming to the resident; and
- Validating the resident's feelings and words; engaging the resident in conversation about who or what they are seeking; and using one-to-one activities, such as reading to the resident or looking at familiar pictures and photo albums.

For the resident who engages in behaviors not conducive with a therapeutic home like environment:

- Providing a calm, non-rushed environment, with structured, familiar activities such as folding, sorting, and matching; using one-to-one activities or small group activities that comfort the resident, such as their preferred music, walking quietly with the staff, a family member, or a friend; eating a favorite snack; looking at familiar pictures;
- Engaging in exercise and movement activities; and
- Exchanging self-stimulatory activity for a more socially-appropriate activity that uses the hands, if in a public space.

For the resident who exhibits behavior that require a less stimulating environment to discontinue behaviors not welcomed by others sharing their social space:

- Offering activities in which the resident can succeed, that are broken into simple steps, that involve small groups or are one-to-one activities such as using the computer, that are short and repetitive, and that are stopped if the resident becomes overwhelmed (reducing excessive noise such as from the television);
- Involving in familiar occupation-related activities. (A resident, if they desire, can do paid or volunteer work and the type of work would be included in the resident's plan of care, such as working outside the facility, sorting supplies, delivering resident mail, passing juice and snacks (refer to §483.10(f)(9) *Right to Perform Facility Services or Refuse*);
- Involving in physical activities such as walking, exercise or dancing, games or projects requiring strategy, planning, and concentration, such as model building, and creative programs such as music, art, dance or physically resistive activities, such as kneading clay, hammering, scrubbing, sanding, using a punching bag, using stretch bands, or lifting weights; and
- Slow exercises (e.g., slow tapping, clapping or drumming); rocking or swinging motions (including a rocking chair).

For the resident who goes through others' belongings:

- Using normalizing life activities such as stacking canned food onto shelves, folding laundry; offering sorting activities (e.g., sorting socks, ties or buttons); involving in organizing tasks (e.g., putting activity supplies away); providing rummage areas in plain sight, such as a dresser; and
- Using non-entry cues, such as "Do not disturb" signs or removable sashes, at the doors of other residents' rooms; providing locks to secure other resident's belongings (if requested).

For the resident who has withdrawn from previous activity interests/customary routines and isolates self in room/bed most of the day:

- Providing activities just before or after meal time and where the meal is being served (out of the room);
- Providing in-room volunteer visits, music or videos of choice;
- Encouraging volunteer-type work that begins in the room and needs to be completed outside of the room, or a small group activity in the resident's room, if the resident agrees; working on failure-free activities, such as simple structured crafts or other activity with a friend; having the resident assist another person;
- Inviting to special events with a trusted peer or family/friend;
- Engaging in activities that give the resident a sense of value (e.g., intergenerational activities that emphasize the resident's oral history knowledge);
- Inviting resident to participate on facility committees;
- Inviting the resident outdoors; and
- Involving in gross motor exercises (e.g., aerobics, light weight training) to increase energy and uplift mood.

For the resident who excessively seeks attention from staff and/or peers: Including in social programs, small group activities, service projects, with opportunities for leadership.

For the resident who lacks awareness of personal safety, such as putting foreign objects in her/his mouth or who is self-destructive and tries to harm self by cutting or hitting self, head banging, or causing other injuries to self:

- Observing closely during activities, taking precautions with materials (e.g., avoiding sharp objects and small items that can be put into the mouth);
- Involving in smaller groups or one-to-one activities that use the hands (e.g., folding towels, putting together PVC tubing);
- Focusing attention on activities that are emotionally soothing, such as listening to music or talking about personal strengths and skills, followed by participation in related activities; and
- Focusing attention on physical activities, such as exercise.

For the resident who has delusional and hallucinatory behavior that is stressful to her/him:

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

The outcome for the resident, the decrease or elimination of the behavior, either validates the activity intervention or suggests the need for a new approach.

The facility may use, but need not duplicate, information from other sources, such as the RAI/MDS assessment, including the CAAs, assessments by other disciplines, observation, and resident and family interviews. Other sources of relevant information include the resident's lifelong interests, spirituality, life roles, goals, strengths, needs and activity pursuit patterns and preferences. This assessment should be completed by or under the supervision of a qualified professional.

NOTE: Some residents may be independently capable of pursuing their own activities without intervention from the facility. This information should be noted in the assessment and identified in the plan of care.

Surveyors need to be aware that some facilities may take a non-traditional approach to activities. In nursing homes where culture change philosophy has been adopted, all staff may be trained as nurse aides or "universal workers," (workers with primary role but multiple duties outside of primary role) and may be responsible to provide activities, which may resemble those of a private home. The provision of activities should not be confined to a department, but rather may involve all staff interacting with residents.

Residents, staff, and families should interact in ways that reflect daily life, instead of in formal activities programs. Residents may be more involved in the ongoing activities in their living area, such as care-planned approaches including chores, preparing foods, meeting with other residents to choose spontaneous activities, and leading an activity. Some *nursing homes may* not have a traditional activities calendar, *but* instead focus on community life to include activities. Instead of an “activities director,” some homes have a Community Life Coordinator, a Community Developer, or other title for the individual directing the activities program

For more information on activities in homes changing to a resident-directed culture, the following websites are available as resources: www.pioneernetwork.net; www.qualitypartnersri.org; and www.edenalt.org.

INVESTIGATIVE SUMMARY

Use the Activities Critical Element pathway and the guidance above to investigate concerns related to activities which are based on the resident’s comprehensive assessment and care plan, and meet the resident’s interests and preferences, and support his or her physical, mental, and psychosocial well-being.

F686

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§483.25(b) Skin Integrity

§483.25(b)(1) Pressure ulcers.

Based on the comprehensive assessment of a resident, the facility must ensure that—

- (i) A resident receives care, consistent with professional standards of practice, to prevent pressure ulcers and does not develop pressure ulcers unless the individual’s clinical condition demonstrates that they were unavoidable; and**
- (ii) A resident with pressure ulcers receives necessary treatment and services, consistent with professional standards of practice, to promote healing, prevent infection and prevent new ulcers from developing.**

INTENT

The intent of this requirement is that the resident does not develop pressure ulcers/injuries (PU/PIs) unless clinically unavoidable and that the facility provides care and services consistent with professional standards of practice to:

- Promote the prevention of pressure ulcer/injury development;
- +Promote the healing of existing pressure ulcers/injuries (including prevention of infection to the extent possible); and
- Prevent development of additional pressure ulcer/injury.

NOTE: CMS is aware of the array of terms used to describe alterations in skin integrity due to pressure. Some of these terms include: pressure ulcer, pressure injury, pressure sore, decubitus ulcer and bed sore. Clinicians may use and the medical record may reflect any of these terms, as long as the primary cause of the skin alteration is related to

pressure. For example, the medical record could reflect the presence of a Stage 2 pressure injury, while the same area would be coded as a Stage 2 pressure ulcer on the MDS.

CMS often refers to the National Pressure Ulcer Advisory Panel's (NPUAP) terms and definitions, which it has adapted, within its patient and resident assessment instruments and corresponding assessment manuals, which includes the Minimum Data Set (MDS). We intend to continue our adaptation of NPUAP terminology for coding the resident assessment instrument while retaining current holistic assessment instructions definitions and terminology. The adapted terminology was used in the development of this guidance.

Additional information can be found on the NPUAP website at <https://www.npuap.org/resources/educational-and-clinical-resources>.

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DEFINITIONS

Definitions are provided to clarify clinical terms related to pressure injuries and their evaluation and treatment.

“Pressure Ulcer/Injury (PU/PI)” refers to localized damage to the skin and/or underlying soft tissue usually over a bony prominence or related to a medical or other device. A pressure injury will present as intact skin and may be painful. A pressure ulcer will present as an open ulcer, the appearance of which will vary depending on the stage and may be painful. The injury occurs as a result of intense and/or prolonged pressure or pressure in combination with shear. *Soft tissue damage related to* pressure and shear may also be affected by skin temperature and moisture, nutrition, perfusion, co-morbidities and condition of the soft tissue.

Avoidable/Unavoidable

- “Avoidable” means that the resident developed a pressure ulcer/injury and that the facility did not do one or more of the following: evaluate the resident’s clinical condition and risk factors; define and implement interventions that are consistent with resident needs, resident goals, and professional standards of practice; monitor and evaluate the impact of the interventions; or revise the interventions as appropriate.
- “Unavoidable” means that the resident developed a pressure ulcer/injury even though the facility had evaluated the resident’s clinical condition and risk factors; defined and implemented interventions that are consistent with resident needs, goals, and professional standards of practice; monitored and evaluated the impact of the interventions; and revised the approaches as appropriate.

Colonized/Infected

- “Colonized” refers to the presence of micro-organisms on the surface or in the tissue of a wound without the signs and symptoms of an infection.
- “Infected” refers to the presence of micro-organisms in sufficient quantity to overwhelm the defenses of viable tissues and produce the signs and symptoms of infection.

Debridement- Debridement is the removal of devitalized/necrotic tissue and foreign matter from a wound to improve or facilitate the healing process. Debridement methods may include a range of treatments such as the use of enzymatic dressings to surgical debridement in order to remove tissue or matter from a wound to promote healing.

Eschar/Slough

- “Eschar” is dead or devitalized tissue that is hard or soft in texture; usually black, brown, or tan in color, and may appear scab-like. Necrotic tissue and eschar are usually firmly adherent to the base of the wound and often the sides/ edges of the wound.
- “Slough” is non-viable yellow, tan, gray, green or brown tissue; usually moist, can be soft, stringy and mucinous in texture. Slough may be adherent to the base of the wound or present in clumps throughout the wound bed.

Exudate

- “Exudate” is any fluid that has been forced out of the tissues or its capillaries because of inflammation or injury. It may contain serum, cellular debris, bacteria and leukocytes.
- “Purulent exudate/drainage/discharge” is any product of inflammation that contains pus (e.g., leukocytes, bacteria, and liquefied necrotic debris).
- “Serous drainage or exudate” is watery, clear, or slightly yellow/tan/pink fluid that has separated from the blood and presents as drainage.

Friction/Shearing

- “Friction” is the mechanical force exerted on skin that is dragged across any surface.
- “Shearing” occurs when layers of skin rub against each other or when the skin remains stationary and the underlying tissue moves and stretches and angulates or tears the underlying capillaries and blood vessels causing tissue damage.

Granulation Tissue - “Granulation tissue” is the pink-red moist tissue that fills an open wound, when it starts to heal. It contains new blood vessels, collagen, fibroblasts, and inflammatory cells.

Tunnel/Sinus Tract/Undermining - The terms tunnel and sinus tract are often used interchangeably.

- A “tunnel” is a passageway of tissue destruction under the skin surface that has an opening at the skin level from the edge of the wound.
- A “sinus tract” is a cavity or channel underlying a wound that involves an area larger than the visible surface of the wound.
- “Undermining” is the destruction of tissue or ulceration extending under the skin edges (margins) so that the pressure ulcer is larger at its base than at the skin surface. Undermining often develops from shearing forces and is differentiated from tunneling by the larger extent of the wound edge involved and the absence of a channel or tract extending from the pressure ulcer under the adjacent intact skin.

GUIDANCE STAGING

Staging of a PU/PI is performed to indicate the characteristics and extent of tissue injury, and should be conducted according to professional standards of practice. *Determining whether damage to the skin and underlying tissue is a PI or PU depends on the staging of the damaged tissue. See stages below.*

NOTE: Regardless of the staging system or wound definitions used by the facility, the facility is responsible for completing the MDS utilizing the staging guidelines found in the RAI Manual.

Stage 1 Pressure Injury: Non-blanchable erythema of intact skin

Intact skin with a localized area of non-blanchable erythema (redness). In darker skin tones, the PI may appear with persistent red, blue, or purple hues. The presence of blanchable erythema or changes in sensation, temperature, or firmness may precede visual changes. Color changes of intact skin may also indicate a deep tissue PI (see below).

Stage 2 Pressure Ulcer: Partial-thickness skin loss with exposed dermis

Partial-thickness loss of skin with exposed dermis, presenting as a shallow open ulcer. The wound bed is viable, pink or red, moist, and may also present as an intact or open/ruptured blister. Adipose (fat) is not visible and deeper tissues are not visible. Granulation tissue, slough and eschar are not present. This stage should not be used to describe moisture associated skin damage including incontinence associated dermatitis, intertriginous dermatitis (inflammation of skin folds), medical adhesive related skin injury, or traumatic wounds (skin tears, burns, abrasions).

Stage 3 Pressure Ulcer: Full-thickness skin loss

Full-thickness loss of skin, in which subcutaneous fat may be visible in the ulcer and granulation tissue and epibole (rolled wound edges) are often present. Slough and/or eschar may be visible but does not obscure the depth of tissue loss. The depth of tissue damage varies by anatomical location; areas of significant adiposity can develop deep wounds. Undermining and tunneling may occur. Fascia, muscle, tendon, ligament, cartilage and/or bone are not exposed. If slough or eschar obscures the wound bed, it is an Unstageable PU/PI.

Stage 4 Pressure Ulcer: Full-thickness skin and tissue loss

Full-thickness skin and tissue loss with exposed or directly palpable fascia, muscle, tendon, ligament, cartilage or bone in the ulcer. Slough and/or eschar may be visible on some parts of the wound bed. Epibole (rolled edges), undermining and/or tunneling often occur. Depth varies by anatomical location. If slough or eschar obscures the wound bed, it is an unstageable PU/PI.

Unstageable Pressure Ulcer: Obscured full-thickness skin and tissue loss

Full-thickness skin and tissue loss in which the extent of tissue damage within the ulcer cannot be confirmed because the wound bed is obscured by slough or eschar. Stable eschar (i.e. dry, adherent, intact without erythema or fluctuance) should only be removed after careful clinical consideration and consultation with the resident's physician, or nurse practitioner, physician assistant, or clinical nurse specialist if allowable under state licensure laws. If the slough or eschar is removed, a Stage 3 or Stage 4 pressure ulcer will be revealed. If the anatomical depth of the tissue damage involved can be determined, then the reclassified stage should be assigned. The pressure ulcer does not have to be completely debrided or free of all slough or eschar for reclassification of stage to occur.

Other staging considerations include:

- **Deep Tissue Pressure Injury (DTPI): Persistent non-blanchable deep red, maroon or purple discoloration**

Intact skin with localized area of persistent non-blanchable deep red, maroon, purple discoloration due to damage of underlying soft tissue. This area may be preceded by tissue that is painful, firm, mushy, boggy, warmer or cooler as compared to adjacent tissue. These changes often precede skin color changes and discoloration may appear differently in darkly pigmented skin. This injury results from intense and/or prolonged pressure and shear forces at the bone-muscle interface. The wound may evolve rapidly to reveal the actual extent of tissue injury, or may resolve without tissue loss. If necrotic tissue, subcutaneous tissue, granulation tissue, fascia, muscle or other underlying structures are visible, this indicates a full thickness pressure ulcer. Once a deep tissue injury opens to an ulcer, reclassify the ulcer into the appropriate stage. Do not use DTPI to describe vascular, traumatic, neuropathic, or dermatologic conditions.

- **Medical Device Related Pressure Ulcer/Injury:** Medical device related PU/PIs result from the use of devices designed and applied for diagnostic or therapeutic purposes. The resultant pressure injury generally conforms to the pattern or shape of the device. The injury should be staged using the staging system.
- **Mucosal Membrane Pressure Ulcer/Injury:** Mucosal membrane PU/PIs are found on mucous membranes with a history of a medical device in use at the location of the injury. Due to the anatomy of the tissue, these ulcers cannot be staged.

PREVENTION OF PRESSURE ULCERS/NJURIES

A pressure ulcer/injury (PU/PI) can occur wherever pressure has impaired circulation to the tissue. A facility must:

- Identify whether the resident is at risk for developing or has a PU/PI upon admission and thereafter;
- Evaluate resident specific risk factors and changes in the resident's condition that may impact the development and/or healing of a PU/PI;
- Implement, monitor and modify interventions to attempt to stabilize, reduce or remove underlying risk factors; and
- If a PU/PI is present, provide treatment *and services* to heal it and *to* prevent *infection and* the development of additional PU/PIs.

The first step in the prevention of PU/PIs, is the identification of the resident at risk of developing PU/PIs. This is followed by implementation of appropriate individualized interventions and monitoring for the effectiveness of the interventions.

ASSESSMENT

An admission evaluation helps identify residents at risk of developing a PU/PI, and residents with existing PU/PIs. Because a resident at risk can develop a PU/PI within hours of the onset of pressure, the at-risk resident needs to be identified and have interventions implemented promptly to attempt to prevent PU/PI. The admission evaluation helps define those initial care approaches.

In addition, the admission evaluation may identify pre-existing signs suggesting that tissue damage has already occurred and additional tissue loss may occur. For example, a deep tissue pressure injury identified on admission could lead to the appearance of an unavoidable Stage 3 or 4 pressure ulcer. A Stage 1 PI can progress to an ulcer with eschar or exudate within days after admission. Some situations, which may have contributed to this tissue damage prior to admission, include pressure resulting from immobility during hospitalization or surgical procedures, during prolonged ambulance transport, or while waiting to be assisted after a debilitating event, such as a fall or a cerebral vascular accident.

It may be harder to identify erythema in a resident with darkly pigmented skin, putting those residents more at risk for developing PU/PIs. It may be necessary, in darker skinned residents to focus more on other evidence of PU/PI development such as changes in sensation, skin temperature or firmness.

Multiple factors, including pressure intensity, pressure duration, and tissue tolerance, significantly affect the potential for the development and healing of PUs/PIs. The comprehensive assessment, which includes the RAI, evaluates the resident's intrinsic risks, the resident's skin condition, and other factors (including causal factors) which place the resident at risk for the development of or hinder the healing of PU/PIs. An

individual may also have various intrinsic risks due to aging, such as decreased subcutaneous tissue and lean muscle mass, decreased skin elasticity, and impaired circulation or sensation.

The comprehensive assessment should address those factors that have been identified as having an impact on the development, treatment and/or healing of PU/PIs, including, at a minimum: risk factors, pressure points, under-nutrition and hydration deficits, and moisture and the impact of moisture on skin. The assessment also helps identify the resident who has multi-system organ failure or an end-of-life condition or who is refusing care and treatment. If the resident is refusing care, an evaluation of the basis for the refusal, and the identification and evaluation of potential alternatives is indicated.

Risk Factors

Not all risk factors are fully modifiable or can be completely addressed. Some risk factors, such as a permanent lack of sensation to an area, may not be modifiable. Some potentially modifiable risk factors, such as malnutrition or uncontrolled blood sugars, may take time to correct, despite prompt intervention. Other risk factors, such as pressure, can be modified promptly. Many studies and professional literature identify risk factors that increase a resident's susceptibility to develop or to not heal pressure PU/PIs.

Examples of these risk factors include, but are not limited to:

- Impaired/decreased mobility and decreased functional ability;
- Co-morbid conditions, such as end stage renal disease, thyroid disease or diabetes mellitus;
- Drugs such as steroids that may affect healing;
- Impaired diffuse or localized blood flow, for example, generalized atherosclerosis or lower extremity arterial insufficiency;
- Resident refusal of some aspects of care and treatment;
- Cognitive impairment;
- Exposure of skin to urinary and fecal incontinence;
- Under nutrition, malnutrition, and hydration deficits; and
- The presence of a previously healed PU/PI. The history of any healed PU/PI, its origin, treatment, its stages [if known] is important assessment information, since areas of healed Stage 3 or 4 PU/PIs are more likely to have recurrent breakdown.

Although the requirements do not mandate the use of any specific assessment tool (other than the RAI), many validated instruments are available to aid in assessing the risk for developing PU/PIs. It is important to keep in mind that research has shown that in a skilled nursing facility, 80 percent of PU/PIs develop within two weeks of admission and 96 percent develop within three weeks of admission. (Reference: Lyder CH, Ayello EA. Pressure Ulcers: A Patient Safety Issue. In: Hughes RG, editor. Patient Safety and Quality: An Evidence-Based Handbook for Nurses. Rockville (MD): Agency for Healthcare Research and Quality (US); 2008 Apr. Chapter 12. Available from: <http://www.ncbi.nlm.nih.gov/books/NBK2650/>)

Many clinicians utilize a standardized pressure ulcer/injury risk assessment tool to assess a resident's PU/PI risks upon admission, weekly for the first four weeks after admission, then *quarterly* or whenever there is a change in the resident's condition.

A resident's risk may increase due to an acute illness or condition change (e.g., upper respiratory infection, pneumonia, or exacerbation of underlying congestive heart failure) and may require additional evaluation. The frequency of assessment should be based upon each resident's specific needs.

Regardless of any resident's total risk score on an assessment tool, clinicians are responsible for evaluating each existing and potential risk factor for developing a pressure injury and determining the resident's overall risk. It is acceptable if the clinician's assessment places the resident at a higher risk level than the overall score of the assessment tool based on assessment factors that are not captured by the tool. Documentation of the clinician's decision should be placed in the medical record.

Pressure Points and Tissue Tolerance

Assessment of a resident's skin condition helps define prevention strategies. The skin assessment should include an evaluation of the skin integrity.

Tissue closest to the bone may be the first tissue to undergo changes related to pressure. PU/PIs are usually located over a bony prominence, such as the sacrum, heel, the greater trochanter, ischial tuberosity, fibular head, scapula, and ankle (malleolus).

An at-risk resident who sits too long in one position may be more prone to developing an ulcer/injury over the ischial tuberosity. Slouching in a chair may predispose an at-risk resident to pressure ulcers/injuries of the spine, scapula, or elbow. Elbow pressure injury is often related to arm rests or lap boards. Friction and shearing are also important factors in tissue ischemia, necrosis and PU/PI formation.

PU/PIs may develop at other sites where pressure has impaired the circulation to the tissue, such as pressure from positioning or use of medical devices applied for diagnostic or therapeutic purposes. The resultant PU/PI generally conforms to the pattern or shape of the device. Mucosal membrane PU/PIs are found on mucous membranes with a history of a medical device in use at the location of the injury. Due to the anatomy of mucous membranes, these ulcers cannot be staged.

PU/PIs on the sacrum and heels are most common. PU/PIs may also develop from pressure on an ear lobe related to positioning of the head; on areas (for example, nares, urinary meatus, extremities) caused by tubes, casts, orthotics, braces, cervical collars, or other medical devices; pressure on the labia or scrotum related to positioning (for example, against a pommel type cushion); the foot related to ill-fitting shoes causing blistering; or on legs, arms and fingers due to contractures or deformity.

Nutrition and Hydration

Adequate nutrition and hydration are essential for overall functioning. Nutrition provides vital energy and building blocks for all of the body's structures and processes. Any organ or body system may require additional energy or structural materials for repair or function. The skin is the body's largest organ system. It may affect, and be affected by, other body processes and organs. Skin condition reflects overall body function therefore, the presence of skin breakdown may be the most visible evidence of a health issue.

Weight reflects a balance between intake and utilization of energy. Significant unintended weight loss may indicate under-nutrition or worsening health status. Weight stability (in the absence of fluid excess or loss) is a useful indicator of overall caloric balance. Severely impaired organs (heart, lungs, kidneys, liver, etc.) may be unable to use nutrients effectively. A resident with a PU/PI who continues to lose weight either needs additional caloric intake or correction (where possible) of conditions that are creating a hypermetabolic state. Continuing weight loss and failure of a PU/PI to heal despite reasonable efforts to improve caloric and nutrient intake may indicate the resident is in multi-system failure or an end-stage or end-of-life condition warranting an additional assessment of the resident's overall condition.

Before instituting a nutritional care plan, it helps to summarize resident specific evidence, including: severity of nutritional compromise, rate of weight loss or appetite decline, probable causes, the individual's prognosis and projected clinical course, and the resident's wishes and goals. Because there are no wound-specific nutritional measures, the interdisciplinary team should develop nutritional goals for the whole person and address nutritional status and needs in the care plan as appropriate.

NOTE: Although some laboratory tests may help clinicians evaluate nutritional issues in a resident with PU/PIs, no laboratory test is specific or sensitive enough to warrant serial/repeated testing. A practitioner may order test(s) that provide useful additional information or help with management of treatable conditions at their discretion

Water is essential to maintain adequate body functions. As a major component of blood, water dissolves vitamins, minerals, glucose, amino acids, etc.; transports nutrients into cells; removes waste from the cells; and helps maintain circulating blood volume as well as fluid and electrolyte balance. It is critical that each resident at risk for hydration deficit or imbalance, including the resident who has or is at risk of developing a PU/PI, be identified and assessed to determine appropriate interventions.

NOTE: The surveyor should refer to the Guidance at 42 CFR 483.25(g), F692, Assisted Nutrition and Hydration, for investigation of potential non-compliance with the nutrition and hydration requirements. A low albumin level combined with the facility's lack of supplementation, for example, is not by itself sufficient to cite a nutrition related deficiency.

Moisture

Both urine and feces contain substances that may irritate the epidermis and may make the skin more susceptible to breakdown and moisture-related skin damage. Fecal incontinence may pose a greater threat to skin integrity, due to bile acids and enzymes in the feces. Irritation or maceration resulting from prolonged exposure to urine and feces may hasten skin breakdown, and moisture may make skin more susceptible to damage from friction and shear during repositioning.

It may be difficult to differentiate dermatitis related to incontinence from partial thickness PU/PI. This differentiation should be based on the clinical evidence and review of presenting risk factors. The dermatitis may occur in the area where the incontinence brief or underpad has been used.

Prevention and Treatment Strategies

The comprehensive assessment should provide the basis for defining approaches to address residents at risk of developing or already having a PU/PI. A determination that a resident is at risk for developing a PU/PI has significant implications for preventive and treatment strategies, but does not by itself indicate that development of a PU/PI was unavoidable. Effective prevention and treatment are based upon consistently providing routine and individualized interventions.

Based upon the assessment and the resident's clinical condition, choices and identified needs, basic or routine care could include, but is not limited to, interventions to:

- Redistribute pressure (such as repositioning, protecting and/or offloading heels, etc.);
- Minimize exposure to moisture and keep skin clean, especially of fecal contamination;
- Provide appropriate, pressure-redistributing, support surfaces;
- Provide non-irritating surfaces; and
- Maintain or improve nutrition and hydration status, where feasible. Adverse drug reactions related to the resident's drug regimen may worsen risk factors for development of, or for non-healing PU/PIs (for example, by causing lethargy or anorexia or creating/increasing confusion) and should be identified and addressed. These interventions should be incorporated into the plan of care and revised as the condition of the resident indicates.

Resident Choices

In the context of the resident's choices, clinical condition, and physician input, the resident's care plan should establish relevant goals and approaches to stabilize or improve co-morbidities, such as attempts to minimize clinically significant blood sugar fluctuations, and other interventions aimed at limiting the effects of risk factors associated with PU/PIs. Alternatively, facility staff and practitioners should document clinically valid reasons why such interventions were not appropriate or feasible.

In order for a resident to exercise his or her right appropriately to make informed choices about care and treatment or to decline treatment, the facility and the resident (or if applicable, the resident representative) must discuss the resident's condition, treatment options, expected outcomes, and consequences of refusing treatment. The facility is expected to address the resident's concerns and offer relevant alternatives, if the resident has declined specific treatments. (See §483.10(c), F552, Planning and implementing care.)

Pressure Injuries at End of Life

Residents at the end of life, in terminal stages of an illness or having multiple system failures may have written directions for his or her treatment goals (or a decision has been made by the resident's representative, in accordance with State law). The facility's care must reflect the resident's goals for care and wishes as expressed in a valid Advance Directive, if one was formulated, in accordance with State law. However, the presence of an Advance Directive does not absolve the facility from giving supportive and other pertinent care that is not prohibited by the resident's Advance Directive. It is important for surveyors to understand that when a facility has implemented individualized approaches for end-of-life care in accordance with the resident's wishes, the development, continuation, or worsening of a PU/PI may be considered unavoidable. If the facility has implemented appropriate efforts to stabilize the resident's condition (or indicted why the condition cannot or should not be stabilized) and has provided care to prevent or treat existing PU/PIs (including pertinent, routine, lesser aggressive approaches, such as, cleaning, turning, repositioning), the PU/PI may be considered unavoidable and consistent with regulatory requirements.

The Kennedy Terminal Ulcer (KTU) The facility is responsible for accurately assessing and classifying an ulcer as a KTU or other type of PU/PI and demonstrate that appropriate preventative measures were in place to prevent non-KTU pressure ulcers.

KTUs have certain characteristics which differentiate them from pressure ulcers such as the following:

- KTUs appear suddenly and within hours;
- Usually appear on the sacrum and coccyx but can appear on the heels, posterior calf muscles, arms and elbows;
- Edges are usually irregular and are red, yellow, and black as the ulcer progresses, often described as pear, butterfly or horseshoe shaped; and

- Often appear as an abrasion, blister, or darkened area and may develop rapidly to a Stage 2, Stage 3, or Stage 4 injury.

Repositioning

Repositioning or relieving constant pressure is a common, effective intervention for an individual with a PU/PI or who is at risk of developing one. Assessment of a resident's skin integrity after pressure has been reduced or redistributed should guide the development and implementation of repositioning plans. Such plans should be addressed in the comprehensive care plan consistent with the resident's need and goals.

Repositioning is critical for a resident who is immobile or dependent upon staff for repositioning, as the resident is unable to make small movements on their own that would help to relieve prolonged pressure to one area. The care plan for a resident at risk of friction or shearing during repositioning may require the use of lifting devices for repositioning. Positioning the resident on an existing PU/PI should be avoided since it puts additional pressure on tissue that is already compromised and may impede healing.

Determine repositioning frequency with consideration to the individual's:

- Level of activity and mobility,
- General medical condition,
- Overall treatment objectives,
- Skin condition, and
- Comfort.

The resident's skin condition and general comfort should be regularly assessed. The efficacy of repositioning must be monitored and revisions to the care plan considered, if the individual is not responding as expected to the repositioning interventions.

Facilities should consider the following repositioning issues:

1. The time an individual spends seated in a chair without pressure relief should be limited. Seated individuals should be repositioned so as to maintain stability and full range of activities. An acceptable seated posture minimizes the pressure and shear exerted on the skin and soft tissues, which may involve using pressure relieving devices/cushions or adjusting the seat tilt, foot rests, elevated leg rests and other support devices to prevent prolonged pressure to areas of the body that may be at particular risk for developing a PU/PI.
2. If able, the resident should be taught to shift his or her weight while sitting in a chair. A resident who can change positions independently may need supportive devices to facilitate position changes. The resident also may need instruction about why repositioning is important and how to do it, encouragement to change positions regularly, and monitoring of frequency of repositioning.
3. Many clinicians recommend a position change "off - loading" hourly for dependent residents who are sitting or who are in a bed or a reclining chair with the head of the bed or back of the chair raised 30 degrees or more. The resident may require more

frequent position changes based on an assessment of their skin condition or their comfort. A “microshift,” meaning a small change in the resident’s position for a short period of time, may not be adequate since this approach does not allow sufficient capillary refill and tissue perfusion for a resident at risk of developing PU/PI’s. Ongoing monitoring of the resident’s skin integrity and tissue tolerance is critical to prevent development or deterioration of PU/PI’s.

4. Wheelchairs are often used for transporting residents, but they may severely limit repositioning options and increase the risk of PU/PI development. Therefore, wheelchairs with sling seats may not be optimal for prolonged sitting during activities or meals, etc. However, available modifications to the seating can provide a more stable surface and provide better pressure reduction.
5. The care plan for a resident who is reclining and is dependent on staff for repositioning should address position changes to maintain the resident’s skin integrity. This may include repositioning at least every 2 hours or more frequently depending upon the resident’s condition and specific needs. Depending on the individualized assessment, more frequent repositioning may be warranted for individuals who are at higher risk for PU/PI development or who show evidence that repositioning at 2-hour intervals is inadequate. With rare exception (such as when both sacral and ischial PU/PI’s are present) the resident should not be placed directly on the greater trochanter for more than momentary placement. Elevating the head of the bed or the back of a reclining chair to or above a 30 degree angle creates pressure comparable to that exerted while sitting, and requires the same considerations regarding repositioning as those for a dependent resident who is seated.

Support Surfaces and Pressure Redistribution

Pressure redistribution refers to the function or ability to distribute a load over a surface or contact area. Redistribution results in shifting pressure from one area to another and requires attention to all affected areas. Pressure redistribution has incorporated the concepts of both pressure reduction and pressure relief.

Appropriate support surfaces or devices should be chosen by matching a device’s potential therapeutic benefit with the resident’s specific situation; such as multiple injuries, limited turning surfaces, ability to maintain position. The effectiveness of pressure redistribution devices (such as gel mattresses, air fluidized mattresses, and low loss air mattresses) is based on their potential to address the individual resident’s risk, the resident’s response to the product, and the characteristics and condition of the product. For example, an overinflated overlay product, or one that “bottoms out” (when the overlay is underinflated or loses inflation creating less than one inch between the resident and support material) is unlikely to effectively reduce the pressure risk. These products are more likely to reduce pressure effectively if they are used in accord with the manufacturer’s instructions. The effectiveness of each product used needs to be evaluated on an ongoing basis. Surveyors should consider the following pressure redistribution issues:

- Static pressure redistribution devices (such as a gel mattress) may be indicated when a resident is at risk for PU/PI development or delayed healing. A

- specialized pressure redistribution cushion or surface, for example, might be used to extend the time a resident is sitting in a chair; however, the cushion does not eliminate the necessity for periodic repositioning and skin assessment.
- Dynamic pressure reduction surfaces may be helpful when:
 - The resident cannot assume a variety of positions without bearing weight on a PU/PI;
 - The resident completely compresses a static device that has retained its original integrity; or
 - The PU/PI is not healing as expected, and it is determined that pressure may be contributing to the delay in healing.
 - Because the heels and elbows have relatively little surface area, it is difficult to redistribute pressure on these two surfaces. Therefore, it is important to pay particular attention to reducing the pressure on these areas for the resident at risk in accord with resident's overall goals and condition. Pillows used to support the entire lower leg may effectively raise the heel from contact with the bed, but use of the pillows needs to take into account the resident's other conditions. The use of donut-type cushions is not recommended by the clinicians.
 - A resident with severe flexion contractures also may require special attention to effectively reduce pressure on bony prominences or prevent breakdown from skin-to-skin contact.

Some products serve mainly to provide comfort and reduce friction and shearing forces, e.g., sheepskin, heel and elbow protectors. Although these products are not effective at redistributing pressure, they (in addition to pillows, foam wedges, or other measures) may be employed to prevent bony prominences from rubbing together or on other surfaces, such as armrests, the bed, or side rails.

Monitoring

Staff should remain alert to potential changes in the skin condition and should evaluate, report and document changes as soon as identified. For example, a resident's complaint about pain or burning at a site where there has been pressure or observation during the resident's bath that there is a change in skin condition should be reported so that the resident may be evaluated further.

After completing a thorough evaluation, the interdisciplinary team should develop a relevant care plan that includes measurable goals for prevention and management of PU/PIs with appropriate interventions. Many clinicians recommend evaluating skin condition (skin color, moisture, temperature, integrity, and turgor) at least weekly, or more often if indicated, such as when the resident is using a medical device that may cause pressure. Defined interventions should be implemented and monitored for effectiveness.

Assessment and Treatment of Pressure Ulcers/Injuries

It is important that each existing PU/PI be identified, whether present on admission or developed after admission, and that factors that influenced its development, the potential

for development of additional PU/PIs or the deterioration of the PU/PIs be recognized, assessed and addressed. Any new PU/PI suggests a need to reevaluate the adequacy of prevention measures in the resident's care plan.

When assessing the PU/PI itself, it is important that documentation addresses:

- The type of injury (pressure-related versus non-pressure-related) because interventions may vary depending on the specific type of injury;
- The PU/PI's stage;
- A description of the PU/PI's characteristics;
- The progress toward healing and identification of potential complications;
- If infection is present;
- The presence of pain, what was done to address it, and the effectiveness of the intervention; and
- A description of dressings and treatments.

Types of Injuries

Three of the more common types of skin injuries are pressure, vascular insufficiency/ischemia (venous stasis and arterial ischemic ulcers) and neuropathic. See §483.25, F684, Quality of Care, for definition and description of injury types other than PU/PIs.

At the time of the assessment, clinicians (physicians, advance practice nurses, physician assistants, and certified wound care specialists, etc.) should document the clinical basis (for example, type of skin injury, location, shape, edges and wound bed, condition of surrounding tissues) for any determination that an injury is not pressure-related, especially if the injury has characteristics consistent with a pressure injury, but is determined not to be one.

Pressure Ulcer/Injury Characteristics

It is important that the facility have a system in place to assure that the protocols for daily monitoring and for periodic documentation of measurements, terminology, frequency of assessment, and documentation are implemented consistently throughout the facility.

When a PU/PI is present, daily monitoring, (with accompanying documentation, when a complication or change is identified), should include:

- An evaluation of the PU/PI, if no dressing is present;
- An evaluation of the status of the dressing, if present (whether it is intact and whether drainage, if present, is or is not leaking);
- The status of the area surrounding the PU/PI (that can be observed without removing the dressing);
- The presence of possible complications, such as signs of increasing area of ulceration or soft tissue infection (for example: increased redness or swelling around the wound or increased drainage from the wound); and

- Whether pain, if present, is being adequately controlled.

The amount of observation possible will depend upon the type of dressing that is used, since some dressings are meant to remain in place for several days, according to manufacturers' guidelines.

With each dressing change or at least weekly (and more often when indicated by wound complications or changes in wound characteristics), an evaluation of the PU/PI should be documented. At a minimum, documentation should include the date observed and:

- Location and staging;
- Size (perpendicular measurements of the greatest extent of length and width of the PU/PI), depth; and the presence, location and extent of any undermining or tunneling/sinus tract;
- Exudate, if present: type (such as purulent/serous), color, odor and approximate amount;
- Pain, if present: nature and frequency (e.g., whether episodic or continuous);
- Wound bed: Color and type of tissue/character including evidence of healing (e.g., granulation tissue), or necrosis (slough or eschar); and
- Description of wound edges and surrounding tissue (e.g., rolled edges, redness, hardness/induration, maceration) as appropriate.

Photographs may be used to support this documentation, if the facility has developed a protocol consistent with professional standards and issues related to resident privacy and dignity are considered and maintained.

Healing Pressure Ulcers/Injuries

Ongoing evaluation and research have indicated that PU/PIs do not heal in a reverse sequence, that is, the body does not replace the types and layers of tissue (muscle, fat and dermis) that were lost during development. The healing process varies depending on the stage of the pressure injury.

There are different types of clinical documentation to describe the progression of the healing PU/PI. Facilities are required to use the RAI. Directions on describing PU/PIs can be found in the RAI manual – these are intended for coding purposes of the MDS. (NOTE: Information on coding for the MDS is located on the CMS MDS website (http://www.cms.gov/NursingHomeQualityInits/45_NHQIMDS30TrainingMaterials.asp#TopOfPage))

It is important to evaluate and modify interventions for a resident with an existing PU/PI such as the following:

- Residents with PU/PIs on the sacrum/coccyx or ischia should limit sitting to three times a day in periods of 60 minutes or less. Consult a seating specialist to prescribe an appropriate seating surface and/or positioning techniques to avoid or minimize pressure on the PU/PI. While sitting is important for overall health, every effort should be made to avoid or minimize pressure on the PU/PI.

- Residents with an ischial injury should not be seated in a fully erect posture in chair or in bed. Modify sitting time schedules and re-evaluate the seating surface and the individual's posture if the *PU/PI* worsens or fails to improve.

If a *PU/PI* fails to show some evidence of progress toward healing within 2-4 weeks, the area and the resident's overall clinical condition should be reassessed. Re-evaluation of the treatment plan includes determining whether to continue or modify the current interventions. Results may vary depending on the resident's overall condition and interventions/treatments used. The complexity of the resident's condition may limit responsiveness to treatment or tolerance for certain treatment modalities. The clinicians, if deciding to retain the current regimen, should document the rationale for continuing the present treatment to explain why some, or all, of the plan's interventions remain relevant despite little or no apparent healing.

Pressure ulcers/injuries may progress or may be associated with complications, such as infection of the soft tissues around the wound (cellulitis), infection of the bone (osteomyelitis), infection of a joint (septic arthritis), abscess, spread of bacteria into the bloodstream (bacteremia/septicemia), chronic infection, or development of a sinus tract. Sometimes these complications may occur despite apparent improvement in the *PU/PI* itself. The physician's involvement is integral whenever significant changes in the nature of the wound or overall resident condition are identified.

Infections

A *PU/PI* infection may be acute or chronic. In acute wounds, the classic signs of inflammation (redness, edema, pain, increased exudate, and periwound surface warmth) persist beyond the normal time frame of three to four days. In residents who are immunosuppressed, the signs of inflammation often are diminished or masked because of an ineffective immune response. Often the only observable symptom of infection is a complaint of pain.

All chronic wounds, including *PU/PIs*, have bacteria. Since bacteria reside in non-viable tissue, debridement of this tissue and wound cleansing are important to reduce bacteria and avoid adverse outcomes such as sepsis.

The first sign of infection may be a delay in healing and an increase in exudates. In a chronic wound, the signs of infection may be more subtle. Signs may include the following:

- Increase in amount or change in characteristics of exudate,
- Decolorization and friability of granulation tissue,
- Undermining,
- Abnormal odor,
- Epithelial bridging (a bridge of epithelial tissue across a wound bed) at the base of the wound, or
- Sudden pain.

The physician diagnosis of infections present in a PU/PI are based on resident history and clinical findings, such as a wound culture. Pus, slough or necrotic tissue should not be cultured. Findings such as an elevated white blood cell count, bacteremia, sepsis, or fever may signal an infection related to a PU/PI area or a co-existing infection from a different source. The treatment of an infection will depend on the type of infection present.

Pain

The assessment and treatment of a resident's pain are integral components of PU/PI prevention and management. Pain that interferes with movement and/or affects mood may contribute to immobility and contribute to the potential for developing or for delayed healing or non-healing of an already existing PU/PI. Refer to §483.25(k), F697, for additional guidance related to Pain Management.

Dressings and Treatments

Determination of the need for treatment for a PU/PI is based upon the individual practitioner's clinical judgment, facility protocols, and current professional standards of practice.

Product selection should be based upon the relevance of the specific product to the identified PU/PI(s) characteristics, the treatment goals, and the manufacturer's recommendations for use. Current literature does not indicate significant advantages of any single specific product over another, but does confirm that not all products are appropriate for all PU/PIs. Wound characteristics should be assessed throughout the healing process to assure that the treatments and dressings being used are appropriate to the nature of the wound.

Evidenced-based practice suggests that PU/PI dressing protocols may use clean technique rather than sterile, but that appropriate sterile technique may be needed for those wounds that recently have been surgically debrided or repaired. Clean technique (also known as non-sterile) involves approved hand hygiene and glove use, maintaining a clean environment by preparing a clean field, using clean instruments, and preventing direct contamination of materials and supplies. Clean technique is considered most appropriate for long-term care; for residents who are not at high risk for infection; and for residents receiving routine dressings for chronic wounds such as venous ulcers, or wounds healing by secondary intention with granulation tissue.

A facility should be able to show that its treatment protocols are based upon current professional standards of practice and are in accord with the facility's policies and procedures as developed with the medical director's review and approval.

INVESTIGATIVE PROTOCOL

Use

Use the Pressure Ulcer Critical Element (CE) Pathway, along with the above interpretive guidelines when determining if the facility meets requirements to ensure a resident receives care consistent with professional standards of practice, to prevent pressure

ulcers/injuries development, prevent the development of additional pressure ulcers/injuries, and to promote the healing of existing pressure ulcers/injuries.

Summary of Skin Integrity Investigative Procedure

Briefly review the comprehensive assessments, care plans, and physician orders to identify whether the facility has practices in place to identify if a resident is at risk for a pressure ulcer/injury, evaluate a resident for pressure ulcers/injuries, and intervene to prevent and/or heal pressure ulcers. During this review, identify the extent to which the facility has developed and implemented interventions in accordance with ensuring a resident receives care consistent with professional standards of practice. If the resident has been in the facility for less than 14 days (before completion of all the Resident Assessment Instrument (RAI) is required), review the baseline care plan which must be completed within 48 hours to determine if the facility is providing appropriate care and services based on information available at the time of admission.

This information will guide observations and interviews to be made to corroborate concerns identified.

KEY ELEMENTS OF NONCOMPLIANCE

To cite deficient practice at F686, the surveyor's investigation will generally show that the facility failed to do one or more of the following:

- Provide preventive care, consistent with professional standards of practice, to residents who may be at risk for development of pressure injuries; or
- Provide treatment, consistent with professional standards of practice, to an existing pressure injury; or
- Ensure that a resident did not develop an avoidable PU/PI.

NOTE: To cite F686, it is not necessary to prove that a PU/PI developed. F686 can be cited when it has been determined that the provider failed to implement interventions to prevent the development of a PU/PI for a resident identified at risk.

DEFICIENCY CATEGORIZATION

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

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

- The facility failed to implement interventions to prevent PU/PI development for a resident who was admitted without PU/PIs, but who had multiple co-morbidities and was totally dependent on staff, placing her at increased risk for PU/PI development; and failed to provide ongoing skin assessments for the same resident. The resident developed a stage *IV* pressure ulcer on her heel within three weeks of her admission.
- Development of avoidable Stage IV pressure ulcer(s): As a result of the facility's non-compliance, permanent tissue damage (whether or not healing occurs) has

compromised the resident, increasing the potential for serious complications including osteomyelitis and sepsis.

- Admitted with a Stage IV pressure ulcer(s) that has shown no signs of healing or shows signs of deterioration: As a result of the facility's non-compliance, a Stage IV pressure ulcer has shown signs of deterioration or a failure to progress towards healing with an increased potential for serious complications including osteomyelitis and sepsis.
- Stage III or IV pressure ulcers with associated soft tissue or systemic infection: As a result of the facility's failure to assess or treat a resident with an infectious complication of a pressure ulcer, *the resident developed Stage III or IV pressure ulcers with associated soft tissue or systemic infection.* (See discussion in guidelines and definitions that distinguishes colonization from infection.)
- Extensive failure in multiple areas of pressure ulcer care: As a result of the facility's extensive noncompliance in multiple areas of pressure ulcer care, the resident developed recurrent and/or multiple, avoidable Stage III or Stage IV pressure ulcer(s).

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

- The facility failed to provide necessary equipment, interventions, monitoring, and care, for a resident who was identified to be at risk for developing PU/PIs due to the presence of contractures and had no PU/PIs upon admission. The facility's occupational therapist (OT) assessed the resident and provided a pressure relieving device for use on the resident's left hand, which was to be in place at all times except when daily hygiene was being provided. The interventions were not recorded on the resident's care plan. During observation and interviews with staff, the assistive device was unable to be located and was not in use. This resulted in the resident developing a Stage *III* pressure injury.
- The development of recurrent or multiple avoidable Stage II pressure ulcer(s): As a result of the facility's non-compliance, the resident developed multiple and/or recurrent avoidable Stage II ulcers.
- Failure to implement the comprehensive care plan for a resident who has a pressure ulcer: As a result of a facility's failure to implement a portion of an existing plan related to pressure ulcer care, such as failure to provide for pressure redistribution, or inappropriate treatment/dressing changes, a wound increased in size or failed to progress towards healing as anticipated, or the resident experienced untreated pain.

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

- The facility failed to assure that a resident with a healed Stage *I* PI in the coccyx area received care to prevent the development of another PU/PI. The resident's care plan identified the use of a pressure-relieving device while up in the chair

and repositioning every 30 minutes. During observations, the pressure relieving device was not present on the seat of the wheelchair but staff did reposition resident every 30 minutes. The device was available, but the staff person interviewed stated that although it was usually on his wheelchair, it had not been placed that day. The resident's skin was intact and did not indicate the presence of a stage *I* PI based on observation, but the likelihood existed of a PU/PI developing as a result of not implementing care as identified in the plan of care.

- The facility failed to assess the skin condition of a resident who used continual oxygen for management of a chronic respiratory disease. The resident's oxygen was provided via nasal cannula and the resident voiced discomfort and irritation with the tubing on his nares. There was a small reddened area where the tubing contacted the nares. The resident had mentioned this to the staff, but was not addressed, and the resident continued to experience discomfort and irritation.
- Failure to implement an element of the care plan for a resident who has a pressure ulcer however, there has been no evidence of decline or failure to heal.
- Failure to recognize or address the potential for developing a pressure ulcer: As a result of the facility's non-compliance, staff failed to identify the risks, develop a plan of care and/or consistently implement a plan that has been developed to prevent pressure ulcers.

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

The failure of the facility to provide appropriate care and services to prevent pressure ulcers/injuries or heal existing pressure ulcers/injuries is more than minimal harm. Therefore, Severity Level 1 does not apply for this regulatory requirement.

POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION

During the investigation of F686, the surveyor may have determined that concerns may also be present with related outcome, process and/or structure requirements. The surveyor is cautioned to investigate these related requirements before determining whether non-compliance may be present. Some examples of related requirements that should be considered include §483.20 Resident Assessment, §483.21 Comprehensive Person-Centered Care Planning, §483.24 Quality of Life, §483.30 Physician Services, §483.35 Nursing Services, §483.70 Administration, and §483.75 QAPI.

F687

(Rev. 208; Issued:10-21-22; Effective: 10-21-22; Implementation:10-24-22)

§483.25(b)(2) Foot care.

To ensure that residents receive proper treatment and care to maintain mobility and good foot health, the facility must:

- (i) Provide foot care and treatment, in accordance with professional standards of practice, including to prevent complications from the resident's medical condition(s) and**
- (ii) If necessary, assist the resident in making appointments with a qualified person, and arranging for transportation to and from such appointments.**

INTENT

To ensure that the foot care provided is consistent with professional standards of practice and to clarify that foot care includes treatment to prevent complications from conditions such as diabetes, peripheral vascular disease, or immobility. Also includes assisting the resident in making necessary appointments with qualified healthcare providers such as podiatrists and arranging *for* transportation to and from *such* appointments.

GUIDANCE

Facilities are responsible for providing the necessary treatment and foot care to residents. Treatment also includes preventive care to avoid podiatric complications in residents with diabetes and circulatory disorders who are prone to developing foot problems. Foot care that is provided in the facility, such as toe nail clipping for residents without complicating disease processes, *should* be provided by staff who have received education and training to provide this service. *Foot care and treatment must be provided* within professional standards of practice *and state scope of practice, as applicable*. Residents requiring foot care who have complicating disease processes must be referred to qualified professionals *such as those* listed *as examples* below.

Facilities are also responsible for providing residents access to qualified professionals who can treat foot disorders, by making necessary appointments and arranging transportation. Examples include podiatrist, Doctor of Medicine, and Doctor of Osteopathy. Foot disorders which may require treatment include, but are not limited to: corns, neuromas, calluses, hallux valgus (bunions), digiti flexus (hammertoe), heel spurs, and nail disorders. The facility is also responsible for assisting residents in making appointments and arranging transportation to obtain needed services.

Facility staff must follow proper infection prevention practices for foot care equipment/devices, including but not limited to nail clippers, scalers, files, and burr tools. Facility staff must separate used or contaminated foot care equipment from clean equipment. Reusable medical devices (e.g., scalers, electronic nail file, and surgical instruments) that are used on one resident must be cleaned and reprocessed (disinfection or sterilization) for use according to manufacturer's instructions prior to use on another resident. If the manufacturer does not provide such instructions, the device may not be suitable for multi-patient use. Recommendations for the cleaning, disinfection, and sterilization of medical devices are available in CDC's Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008 (available at: <https://www.cdc.gov/infectioncontrol/guidelines/disinfection/index.html>). Please see guidance at §483.80, Infection Control, for more information.

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

PROBES: For residents selected for review, determine the following:

- According to the medical record, does the resident have a diagnosis or condition that poses a risk to foot health (e.g., diabetes, peripheral vascular disease, ingrown toenails)?
- Does the comprehensive care plan adequately address the resident’s risk with appropriate interventions?
- Observe residents’ feet for lack of nail care, presence of calluses, and/or other foot problems.
- Are residents with foot concerns seen either within the facility or community by a qualified foot care specialist? Do residents with mobility concerns have foot care concerns, and did the facility address these concerns?
- Are qualified healthcare providers available to see residents either in the facility or in the community?
- What preventive foot care do staff provide and to what resident population?
- Are staff *providing* foot care to the resident when needed and ordered?
- *Do staff maintain separation of clean and contaminated podiatry equipment? If no, refer to §483.80, Infection Control F880.*

F689

(Rev. 208; Issued:10-21-22; Effective: 10-21-22; Implementation:10-24-22)

§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.¹ 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.² 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.³ 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.⁴ 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.⁵ 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.⁶ 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.⁷

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 483.70(e) (F838) for facility responsibilities regarding the facility's physical environment.

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

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

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).⁸ 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.⁹ 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.¹⁰

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.¹¹

Table 1. Time and Temperature Relationship to Serious Burns

Water Temperature		Time Required for a 3 rd 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.¹²

- 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.¹³

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.¹⁴ 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.¹⁵

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.¹⁶ 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 devices 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.¹⁷

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."¹⁸ 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.¹⁹

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.²⁰

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.²¹

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 <http://www.ncoa.org/center-for-healthy-aging/falls-resource-center>

Centers for Disease Control and Prevention at <http://www.cdc.gov/homeandrecreationalafety/falls/>

World Health Organization Fall Prevention in Older Age at http://www.who.int/ageing/projects/falls_prevention_older_age/en/

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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- ¹ Bressler, K., Redfern, R.E., and Brown, M.(2011). Elimination of position-change alarms in an Alzheimer's and dementia long-term care facility. *Am J Alzheimers Dis Other Demen* 26(8), 599.
- ² Panel on Prevention of Falls in Older Persons, American Geriatrics Society and British Geriatrics. (2010). Summary of the updated American Geriatrics Society/British Geriatrics Society clinical practice guideline for prevention of falls in older persons. *J Am Geriatr Soc*, 2011, 59(1), 148-57.
- ³ Taylor, J.A., Parmelee, P., Brown, H., and Ouslander, J. The Falls Management Program: A Quality Improvement Initiative for Nursing Facilities. Agency for Healthcare Research and Quality, 2005, <https://www.ahrq.gov/patient-safety/settings/long-term-care/resource/injuries/fallspx.html>
- ⁴ Shorr, R.I., Chandler, M., Mion, L.C., Waters, T.M., Liu, M., Daniels, M.J., Kessler, L.A., and Miller, S.T. (2012). Effects of an intervention to increase bed alarm use to prevent falls in hospitalized patients. *Annals of Internal Medicine* 157(10), 698.
- ⁵ Capezuti, E., Brush, B.L., Lane, S., Rabinowitz, H.U., and Secic, M. (2009). Bed-exit alarm effectiveness. *Arch Gerontol Geriatr* 49(1) 27-31.
- ⁶ MASSPRO (n.d.). Nursing home alarm elimination program: It's possible to reduce falls by eliminating resident alarms.
- ⁷ Becker, C., Rapp, K. (2010) Fall Prevention in Nursing Homes. *Clinics in Geriatric Medicine* 26(4)693-704.
- ⁸ *US Dept. of Health and Human Services*, Agency for Toxic Substances & Disease Registry, *Toxicological Profiles*, <http://www.atsdr.cdc.gov/toxprofiles/index.asp>.
- ⁹ US Dept. of Labor, Occupational Safety and Health Standards, 29 CFR 1910.1200 (g)(1) and (2).
- ¹⁰ Katcher, L.K. (1981). Scald Burns from Hot Tap Water. *Journal of Am Med Assoc.*, 246(11), 1219-1222.

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- ¹¹ 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.
- ¹² 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>.
- ¹³ *Electrical Safety Foundation International Resource Library*.
- ¹⁴ Tideiksaar, R. (1998). *Falls in Older Persons: Prevention and Management* (2nd Edition). Baltimore, MD: Health Profession Press.
- ¹⁵ Warren, M. (2001), *Occupational Therapy Practice Guidelines for Adults with Low Vision*, The American Occupational Therapy Association, Inc.
- ¹⁶ Taylor, J.A., Brown, A.K., Meredith, S., Ray, W.A. (2002). *The fall reduction program: a comprehensive program for reduction of falls and injuries in long-term care residents*. Nashville, TN: Department of Preventive Medicine, Vanderbilt University School of Medicine.
- ¹⁷ 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.
- ¹⁸ *Gastmans, C. and Milisens, K. (March 2006). Use of physical restraint in nursing homes: clinical-ethical considerations. J Med Ethics, 32(3), 148–152.*
- ¹⁹ US Dept. of Health and Human Services. Food and Drug Administration, Bed Rail Safety, <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/HospitalBeds/ucm123676.htm>.
- ²⁰ US Dept. of Health and Human Services, Food and Drug Administration, Recommendations for Consumers and Caregivers about Bed Rails. <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/ConsumerProducts/BedRailSafety/ucm362843.htm>.
- ²¹ Miles, S. (June 2002). Death between bedrails and air pressured mattresses. *J Am Geriatr Soc*, 50(6), 1124-5

F690

(Rev. 208; Issued:10-21-22; Effective: 10-21-22; Implementation:10-24-22)

§483.25(e) Incontinence.

§483.25(e)(1) The facility must ensure that a resident who is continent of bladder and bowel on admission receives services and assistance to maintain continence unless his or her clinical condition is or becomes such that continence is not possible to maintain.

§483.25(e)(2) For a resident with urinary incontinence, based on the resident’s comprehensive assessment, the facility must ensure that—

- (i) A resident who enters the facility without an indwelling catheter is not catheterized unless the resident’s clinical condition demonstrates that catheterization was necessary;**
- (ii) A resident who enters the facility with an indwelling catheter or subsequently receives one is assessed for removal of the catheter as soon as possible unless the resident’s clinical condition demonstrates that catheterization is necessary; and**
- (iii) A resident who is incontinent of bladder receives appropriate treatment and services to prevent urinary tract infections and to restore continence to the extent possible.**

§483.25(e)(3) For a resident with fecal incontinence, based on the resident’s comprehensive assessment, the facility must ensure that a resident who is incontinent of bowel receives appropriate treatment and services to restore as much normal bowel function as possible.

INTENT

The intent of this requirement is to ensure that:

- Each resident who is continent of bladder receives the necessary services and assistance to maintain continence, unless it is clinically not possible.
- Each resident who is incontinent of urine is identified, assessed and provided appropriate treatment and services to achieve or maintain as much normal bladder function as possible;
- An indwelling catheter is not used unless there is valid medical justification for catheterization and the catheter is discontinued as soon as clinically warranted;
- A resident, with or without an indwelling catheter, receives the appropriate care and services to prevent urinary tract infections to the extent possible;
- Services are provided to restore or improve normal bladder function to the extent possible, after the removal of the indwelling catheter; *and*
- A resident *with fecal incontinence* is identified, assessed and provided appropriate treatment and services to restore as much normal bowel function as possible, *unless it is not clinically possible*;

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

DEFINITIONS

“Bacteremia” is the presence of bacteria in the bloodstream.

“Bacteriuria” is defined as the presence of bacteria in the urine.

“Continence” refers to any void that occurs voluntarily, or as the result of prompted, assisted, or scheduled use of the bathroom.

“Sepsis” is the body’s overwhelming and life-threatening response to an infection which can lead to tissue damage, organ failure, and death.

“Urinary Incontinence” is the involuntary loss or leakage of urine.

“Urinary Retention” is the inability to completely empty the urinary bladder by micturition.

“Urinary Tract Infection (UTI)” is a clinically detectable condition associated with invasion by disease causing microorganisms of some part of the urinary tract, including the urethra (urethritis), bladder (cystitis), ureters (ureteritis), and/or kidney (pyelonephritis). An infection of the urethra or bladder is classified as a lower tract UTI and infection involving the ureter or kidney is classified as an upper tract UTI.

GUIDANCE §483.25(e)

A resident who is continent of bladder on admission must receive care, including assistance, and services to maintain continence unless his/her clinical condition is or becomes such that continence is not possible to maintain. If a resident is admitted with incontinence of bladder, he/she receives appropriate treatment and services to prevent urinary tract infections and to restore as much normal bladder function as possible.

Urinary incontinence generally involves a number of transitory or progressive factors that affect the bladder and/or the urethral sphincter. Any condition, medication, or factor that affects lower urinary tract function, bladder capacity, urination, or the ability to toilet can predispose residents to urinary incontinence and may contribute to incomplete bladder emptying.

Assessment

A resident should be assessed at admission regarding continence status and whenever there is a change in urinary tract function, such as if a resident is admitted who is continent of urine, and subsequently becomes incontinent. The identification of reversible and irreversible (e.g., bladder tumors, spinal cord disease) causes of incontinence, including the type of incontinence, provides direction for the development of appropriate interventions. It is important that staff, when completing the comprehensive assessment, consider the following:

- Prior history of bladder functioning, including status of continence, history of urinary incontinence, including onset, duration and characteristics, precipitants of urinary incontinence, associated symptoms (e.g., dysuria, polyuria, hesitancy) and previous treatment and/or management, including the response to the interventions and the occurrence of persistent or recurrent UTI;
- Voiding patterns (such as frequency, volume, nighttime or daytime, quality of stream) and, for those already experiencing urinary incontinence, voiding patterns over several days;
- Medication review, particularly those that might affect continence, such as medications with anticholinergic properties (may cause urinary retention and possible overflow incontinence), sedative/hypnotics (may cause sedation leading to functional incontinence), diuretics (may cause urgency, frequency, overflow incontinence), narcotics, alpha-adrenergic agonists (may cause urinary retention in men) or antagonists (may cause stress incontinence in women) calcium channel blockers (may cause urinary retention);
- Patterns of fluid intake, such as amounts, time of day, alterations and potential complications, such as decreased or increased urine output;
- Use of urinary tract stimulants or irritants (e.g., frequent caffeine intake);

- Pelvic and rectal examination to identify physical features that may directly affect urinary continence, such as prolapsed uterus or bladder, prostate enlargement, significant constipation or fecal impaction, use of a urinary catheter, atrophic vaginitis, distended bladder, or bladder spasms;
- Functional and cognitive capabilities that could enhance urinary continence and limitations that could adversely affect continence, such as impaired cognitive function or dementia, impaired immobility, decreased manual dexterity, the need for task segmentation, decreased upper and lower extremity muscle strength, decreased vision, pain with movement;
- Type and frequency of physical assistance necessary to assist the resident to access the toilet, commode, urinal, etc. and the types of prompting needed to encourage urination;
- Pertinent diagnoses such as congestive heart failure, stroke, diabetes mellitus, obesity, and neurological disorders (e.g., Multiple Sclerosis, Parkinson's Disease or tumors) that could affect the urinary tract or its function);
- Identification of and/or potential of developing complications such as skin irritation or breakdown;
- Tests or studies indicated to identify the type(s) of urinary incontinence (e.g., post-void residual(s) for residents who have, or are at risk of, urinary retention, results of any urine culture if the resident has clinically significant systemic or urinary symptoms), or evaluations assessing the resident's readiness for bladder rehabilitation programs; and
- Environmental factors and assistive devices that may restrict or facilitate a resident's ability to access the toilet (e.g., grab bars, raised or low toilet seats, inadequate lighting, distance to toilet or bedside commodes, and availability of urinals, use of bed rails or restraints, or fear of falling).

Types of Urinary Incontinence

Identifying the nature of the incontinence is a key aspect of the assessment and helps identify the appropriate program/interventions to address incontinence. There are several types of urinary incontinence, and the individual resident may experience more than one type at a time. Some of the more common types include:

- **Urge Incontinence** is associated with detrusor muscle over activity (excessive contraction of the smooth muscle in the wall of the urinary bladder) resulting in a sudden, strong urge (also known as urgency) to expel moderate to large amounts of urine before the bladder is full). It is characterized by abrupt urgency, frequency, and nocturia (part of the overactive bladder diagnosis). It may be age-related or have neurological causes (e.g., stroke, diabetes mellitus, Parkinson's disease, multiple sclerosis) or other causes such as bladder infection, urethral irritation, etc. The resident can feel the need to void, but is unable to inhibit voiding long enough to reach and sit on the commode. It is the most common cause of urinary incontinence in elderly persons.
- **Stress Incontinence** (outlet incompetence) is associated with impaired urethral closure (malfunction of the urethral sphincter) which allows small amounts of urine leakage when intra-abdominal pressure on the bladder is increased by

sneezing, coughing, laughing, lifting, standing from a sitting position, climbing stairs, etc. Urine leakage results from an increase in intra-abdominal pressure on a bladder that is not over distended and is not the result of detrusor contractions. It is the second most common type of urinary incontinence in older women.

- **Mixed Incontinence** is the combination of urge incontinence and stress incontinence. Many elderly persons (especially women) will experience symptoms of both urge and stress.
- **Overflow Incontinence** is associated with leakage of small amounts of urine when the bladder has reached its maximum capacity and has become distended from urine retention. Symptoms of overflow incontinence may include: weak stream, hesitancy, or intermittency; dysuria; nocturia; frequency; incomplete voiding; frequent or constant dribbling. Urine retention may result from outlet obstruction (e.g., benign prostatic hypertrophy (BPH), prostate cancer, and urethral stricture), hypotonic bladder (detrusor under activity) or both. Hypotonic bladder may be caused by outlet obstruction, impaired or absent contractility of the bladder (neurogenic bladder) or other causes. Neurogenic bladder may also result from neurological conditions such as diabetes mellitus, spinal cord injury, or pelvic nerve damage from surgery or radiation therapy. In overflow incontinence, post void residual (PVR) volume (the amount of urine remaining in the bladder within 5 to 10 minutes following urination) exceeds 200 milliliters (ml). Normal PVR is usually 50 ml. or less. A PVR of 150 to 200 may suggest a need for retesting to determine if this finding is clinically significant. Overflow incontinence may mimic urge or stress incontinence but is less common than either of those.
- **Functional Incontinence** refers to loss of urine that occurs in a resident whose urinary tract function is sufficiently intact that he/she should be able to maintain continence, but who cannot remain continent because of external factors other than inherently abnormal urinary tract function. Examples may include the failure of staff to respond to a request for assistance to the toilet, or the inability to utilize the toilet facilities in time. It may also be related to:
 - Physical weakness or poor mobility/dexterity (e.g., due to poor eyesight, arthritis, deconditioning, stroke, contracture);
 - Cognitive problems (e.g., confusion, dementia, unwillingness to toilet);
 - Medications (e.g., anti-cholinergics, diuretics); or
 - Environmental impediments including excessive distance from the toilet facilities, poor lighting, low chairs that are difficult to get out of, physical restraints and toilets that are difficult to access.

Refer to §483.10(e) (3), F558, Accommodation of Needs for issues regarding unmet environmental needs (e.g., handicap toilet, lighting, assistive devices).

NOTE: Treating the physiological causes of incontinence, without attending to functional components that may have an impact on the resident's continence, may fail to solve the incontinence problem.

- **Transient Incontinence** refers to temporary or occasional incontinence that may be related to a variety of causes, for example: delirium, infection, atrophic urethritis or vaginitis, some pharmaceuticals (such as sedatives/hypnotics, diuretics, anticholinergic agents), increased urine production, restricted mobility or fecal impaction. The incontinence is transient because it is related to a potentially improvable or reversible cause.

Interventions

A number of factors may contribute to the development of incontinence, or decline or lack of improvement in urinary continence, such as an underlying medical condition, an inaccurate assessment of the resident's type of incontinence, or lack of knowledge about the resident's voiding patterns. This may contribute to inappropriate interventions or unnecessary use of an indwelling catheter. Facility practices that may promote achieving the highest practicable level of functioning, may prevent the development of incontinence, or minimize a decline or lack of improvement in degree of continence include providing treatment and services to address factors that are potentially modifiable, such as:

- Managing pain and/or providing adaptive equipment to improve function for residents suffering from arthritis, contractures, neurological impairments, etc.;
- Removing or improving environmental impediments that affect the resident's level of continence (e.g., improved lighting, use of a bedside commode or reducing the distance to the toilet);
- Treating underlying conditions that have a potentially negative impact on the degree of continence (e.g., delirium causing urinary incontinence related to acute confusion);
- Possibly adjusting medications affecting continence (e.g., medication cessation, dose reduction, selection of an alternate medication, change in time of administration); and
- Implementing a fluid and/or bowel management program to meet the assessed needs.

Options for managing urinary incontinence in nursing home residents include primarily behavioral programs and medication therapy. Other measures and supportive devices used in the management of urinary incontinence and/or urinary retention may include intermittent catheterization; pelvic organ support devices (pessaries); biofeedback; the use of incontinence products, garments and an external collection system for men and women; and environmental accommodation and/or modification.

Behavioral Programs

Interventions involving the use of behavioral programs are among the least invasive approaches to address urinary incontinence and have no known adverse complications. Behavior programs involve efforts to modify the resident's behavior and/or environment. Critical aspects of a successful behavioral program include education of the caregiver and the resident, availability of the staff and the consistent implementation of the interventions.

NOTE: It is important for the comprehensive assessment to identify the essential skills the resident must possess, such as the resident's ability to: comprehend and follow instructions; identify urinary urge; control the urge to void until reaching a toilet; and/or respond to prompts to void. Voiding records help detect urinary patterns or intervals between incontinence episodes and facilitate planning care to avoid or reduce the frequency of episodes.

Programs that require the resident's cooperation and motivation in order for learning and practice to occur include the following:

- **“Bladder Rehabilitation/Bladder Retraining”** is a behavioral technique that requires the resident to resist or inhibit the sensation of urgency (the strong desire to urinate), to postpone or delay voiding, and to urinate according to a timetable rather than to the urge to void. Depending upon the resident's successful ability to control the urge to void, the intervals between voiding may be increased progressively. Bladder training generally consists of education, scheduled voiding with systematic delay of voiding, and positive reinforcement. This program is difficult to implement in cognitively impaired residents and may not be successful in frail, elderly, or dependent residents. The resident who may be appropriate for a bladder rehabilitation (retraining) program is usually fairly independent in activities of daily living, has occasional incontinence, is aware of the need to urinate (void), may wear incontinence products for episodic urine leakage, and has a goal to maintain his/her highest level of continence and decrease urine leakage. Successful bladder retraining usually takes at least several weeks. Residents who are assessed with urge or mixed incontinence and are cognitively intact may be candidates for bladder retraining. This is not to be confused with habit training/scheduled voiding (see below); and
- **“Pelvic Floor Muscle Rehabilitation,”** also called Kegel and pelvic floor muscle exercise, is performed to strengthen the voluntary periurethral and perivaginal muscles that contribute to the closing force of the urethra and the support of the pelvic organs. These exercises are helpful in dealing with urge and stress incontinence. Pelvic floor muscle exercises (PFME) strengthen the muscular components of urethral supports and are the cornerstone of noninvasive treatment of stress urinary incontinence. PFME requires residents who are able and willing to participate and the implementation of careful instructions and monitoring provided by the facility. Poor resident adherence to the exercises may occur even with close monitoring.

Programs that are dependent on staff involvement and assistance, as opposed to resident function, include the following:

- **“Prompted Voiding”** is a behavioral technique appropriate for use with dependent or more cognitively impaired residents. Prompted voiding has three components: regular monitoring with encouragement to report continence status; prompting to toilet on a scheduled basis; and praise and positive feedback when

the resident is continent and attempts to toilet. These methods require training, motivation and continued effort by the resident and caregivers to ensure continued success. Prompted voiding focuses on teaching the resident, who is incontinent, to recognize bladder fullness or the need to void, to ask for help, or to respond when prompted to toilet.

Residents who are assessed with urge or mixed incontinence and are cognitively impaired may be candidates for prompted voiding. As the resident's cognition changes, the facility should consider other factors, such as mobility, when deciding to conduct a voiding trial to determine feasibility of an ongoing program to use the bathroom; and

- **“Habit Training/Scheduled Voiding”** is a behavioral technique that calls for scheduled use of the bathroom at regular intervals on a planned basis to match the resident's voiding habits. Unlike bladder retraining, there is no systematic effort to encourage the resident to delay voiding and resist urges. This is not considered to be a bladder rehabilitation/retraining program. Habit training includes timed voiding with the interval based on the resident's usual voiding schedule or pattern. Scheduled voiding is timed voiding, usually every three to four hours while awake. Residents who cannot self-toilet may be candidates for habit training or scheduled voiding programs.

Intermittent Catheterization

Sterile insertion and removal of a catheter through the urethra every 3-6 hours for bladder drainage may be appropriate for the management of acute or chronic urinary retention. See additional discussion below in “Catheterization”.

Medication Therapy

Medications are often used to treat specific types of incontinence, including stress incontinence and those categories associated with an overactive bladder, which may involve symptoms including urge incontinence, urinary urgency, frequency and nocturia. The current literature identifies classifications and names of medications used for various types of incontinence. When using medications, potentially problematic anticholinergic and other side effects must be recognized. The use of medication therapy to treat urinary incontinence may not be appropriate for some residents because of potential adverse interactions with their other medications or other co-morbid conditions. The resident/representative must be provided with the risks and benefits of using medications for continence management.

Pessary

A pessary is an intra-vaginal device used to treat pelvic muscle relaxation or prolapse of pelvic organs. Women whose urine retention or urinary incontinence is exacerbated by bladder or uterine prolapse may benefit from placement of a pessary. Female residents may be admitted to the nursing home with a pessary device. The assessment should note whether the resident has a pessary in place or has had a history of successful pessary use.

If a pessary is used, the plan of care must address the use, care and ongoing management of the pessary including monitoring for complications.

Absorbent Products, Devices, and External Collection Devices

Absorbent incontinence products include perineal pads or panty liners for slight leakage, undergarments and protective underwear for moderate to heavy leakage, guards and drip collection pouches for men, and products (called adult briefs) for moderate or heavy loss. Absorbent products can be a useful, rational way to manage incontinence; however, every absorbent product has a saturation point. Factors contributing to the selection of the type of product to be used should include the severity of incontinence, gender, fit, and ease of use.

Advantages of using absorbent products to manage urinary incontinence include the ability to contain urine (some may wick the urine away from the skin), provide protection for clothing, and preserve the resident's dignity and comfort.

NOTE: Although many residents have used absorbent products prior to admission to the nursing home and the use of absorbent products may be appropriate, absorbent products should not be used as the primary long term approach to continence management until the resident has been appropriately evaluated and other alternative approaches have been considered.

It is important that residents using various devices, absorbent products, external collection devices, etc., be checked (and changed as needed) on a schedule based upon the resident's voiding pattern, professional standards of practice, and the manufacturer's recommendations.

Skin-Related Complications

Skin problems associated with incontinence and moisture can range from irritation to increased risk of skin breakdown. Moisture may make the skin more susceptible to damage from friction and shear during repositioning. For a resident with an external catheter, compromise to the skin may also occur.

One form of early skin breakdown is maceration or the softening of tissue by soaking. Macerated skin has a white appearance and a very soft, sometimes "soggy" texture. The persistent exposure of perineal skin to urine and/or feces can irritate the epidermis and can cause severe dermatitis, skin erosion and/or ulcerations. Skin erosion is the loss of some or all of the epidermis (comparable to a deep chemical peel) leaving a slightly depressed area of skin.

Because frequent washing with soap and water can dry the skin, the use of a perineal rinse may be indicated.

CATHETERIZATION

Sections 483.25(e)(2)(i) and (ii), Incontinence, requires that a resident who enters the facility without an indwelling catheter is not catheterized unless the resident's clinical

condition demonstrates that catheterization was necessary; or that a resident who enters the facility with an indwelling urinary catheter or subsequently receives one is assessed for removal of the catheter as soon as possible unless the resident's clinical condition demonstrates that catheterization is necessary. The facility is responsible for the assessment of the resident at risk for urinary catheterization and the ongoing assessment for the resident who currently has a catheter, including the removal of the catheter *as soon as possible* when the resident's clinical condition demonstrates the catheter is no longer necessary. While the use of a catheter may promote skin integrity and assessment of output, it is also associated with the increase risk of catheter associated urinary tract infections (CAUTI), including the development of sepsis.

A catheter that is used for appropriate indications and in a dignified manner may enhance an individual's independence and dignity. Conversely, an improperly or indiscreetly used catheter may negatively impact independence and dignity.

NOTE: For concerns related to the care for a resident with a urostomy or nephrostomy, refer to §483.25(f) - Colostomy, urostomy, or ileostomy care at tag F691.

In addition, according to the Centers for Disease Control and Prevention (CDC), the definition of a suprapubic catheter is one that "is surgically inserted into the bladder through an incision above the pubis. For care of a resident with a suprapubic catheter, refer to current professional guidelines such as the following;
http://c.ymcdn.com/sites/www.wocn.org/resource/resmgr/publications/Care_&_Mgmt_Pts_w_Urinary_Ca.pdf

Assessment

Regardless of the admission status, a comprehensive assessment should address those factors that predispose the resident to the development of urinary incontinence and the use of an indwelling urinary catheter. An admission evaluation of the resident's medical history and a physical examination helps identify the resident at risk for requiring the use of an indwelling urinary catheter. This evaluation is to include detection of reversible causes of incontinence and identification of individuals with incontinence caused by conditions that may not be reversible, such as bladder tumors and spinal cord diseases.

The assessment of continence/incontinence is based upon a comprehensive, interdisciplinary review and assessment. The comprehensive assessment should include identifying the underlying factors which support the clinical indication for the initiation and continuing need for catheter use, determination of which factors can be modified or reversed (or rationale for why those factors should not be modified), and the development of a plan for removal. The clinician's decision to use an indwelling catheter in the elderly should be based on valid clinical indicators.

For the resident with an indwelling catheter, the facility's documented assessment and staff knowledge of the resident should include information to support the use of an indwelling catheter. Because of the risk of substantial complications with the use of indwelling urinary catheters, they should be reserved primarily for short-term

decompression of acute urinary retention. The assessment should include consideration of the risks and benefits of an indwelling (suprapubic or urethral) catheter; the potential for removal of the catheter; and consideration of complications resulting from the use of an indwelling catheter, such as symptoms of blockage of the catheter with associated bypassing of urine, expulsion of the catheter, pain, discomfort and bleeding.

Intermittent Catheterization

Intermittent catheterization can often manage overflow incontinence effectively. Residents who have new onset incontinence from a transient, hypotonic/atonic bladder (usually seen following indwelling catheterization in the hospital) may benefit from intermittent bladder catheterization until the bladder tone returns (e.g., up to approximately 7 days). A voiding trial and post void residual can help identify when bladder tone has returned.

Indwelling Urinary Catheter Use

If the facility provides care for a resident with an indwelling catheter, in collaboration with the medical director and director of nurses, and based upon current professional standards of practice, resident care policies and procedures must be developed and implemented that address catheter care and services, including but not limited to:

- Documentation of the involvement of the resident *and/or resident* representative in the discussion of the risks and benefits of the use of a catheter, removal of the catheter when criteria or indication for use is no longer present, and the right to decline the use of the catheter;
- Timely and appropriate assessments related to the indication for use of an indwelling catheter;
- Identification and documentation of clinical indications for the use of a catheter; as well as criteria for the discontinuance of the catheter when the indication for use is no longer present;
- Insertion, ongoing care and catheter removal protocols that adhere to professional standards of practice and infection prevention and control procedures;
- Response of the resident during the use of the catheter; and
- Ongoing monitoring for changes in condition related to potential CAUTI's *and* recognizing, reporting and addressing such changes.

(See **NOTE** below for examples of clinical indications for use.)

The resident's record must include how and when the resident/representative was involved and informed of care and treatment including the potential use and indications for the need for a catheter, how long use is anticipated, and when and why a catheter must be removed. The resident/representative must be included in the development of the care plan including the use of the catheter and associated interventions. In addition, the resident/representative has the right to decline the treatment. Based on current professional standards of practice, information and education of the resident/representative on the identification of risks and benefits for the use of a catheter must be documented.

Anecdotally, it has been reported that residents or their representatives have requested the use of and/or declined to allow the removal of an indwelling urinary catheter. The record must contain documentation as to why a resident/representative chooses to have or chooses to continue to use a catheter in the absence of clinical indications for use. After determining the reasons, staff and the attending practitioner must document the provision of counseling to assist the resident in understanding the clinical implications and risks associated with the use of a catheter without an indication for continued use. The care plan must be revised to address the education being provided, including interventions to restore as much urinary function as possible without the use of catheter.

Documentation in the resident's record must reflect the attending practitioner's valid clinical indication to support the use of an indwelling catheter.

NOTE: The following Table from the CDC, includes examples for appropriate indications for indwelling catheter use and includes both acute and long term care. This table has been adapted to include only those examples relevant for a long term care setting. For the full table and for guidance related to indwelling catheter management and care refer to: http://www.cdc.gov/hicpac/cauti/02_cauti2009_abbrev.html

A. Examples of Appropriate Indications for Indwelling Urethral Catheter Use

- Resident has acute urinary retention or bladder outlet obstruction;
- Need for accurate measurements of urinary output;
- To assist in healing of open sacral or perineal wounds in incontinent residents;
- Resident requires prolonged immobilization (e.g., potentially unstable thoracic or lumbar spine, multiple traumatic injuries such as pelvic fractures); and
- To improve comfort for end of life care, if needed.

B. Examples of Inappropriate Uses of Indwelling Catheters

- As a substitute for nursing care of the resident with incontinence; and
- As a means of obtaining urine for culture or other diagnostic tests when the resident can voluntarily void.

NOTE: These *above* indications are based on expert consensus.

Additional care practices related to catheterization include:

- Recognizing and assessing for complications and their causes, and maintaining a record of any catheter-related problems;
- Attempts to remove the catheter as soon as possible when no indications exist for its continuing use;
- Monitoring for excessive post void residual, after removing a catheter that was inserted for obstruction or overflow incontinence;
- Keeping the catheter anchored to prevent excessive tension on the catheter, which can lead to urethral tears or dislodging the catheter; and
- Securing the catheter to facilitate flow of urine, preventing kinking of the tubing and position below the level of the bladder. (Also refer to F880 – Infection

Control for policies and procedures related to care of the catheter and equipment, such as tubing, bags, etc.).

NOTE: Refer to the CDC site for current information on catheter use, management and care at: http://www.cdc.gov/HAI/ca_uti/uti.html

Catheter-Related Complications

An indwelling catheter may be associated with significant complications, including bacteremia, febrile episodes, bladder stones, fistula formation, erosion of the urethra, epididymitis, chronic renal inflammation and pyelonephritis and sepsis related to urinary tract infections. In addition, indwelling catheters are prone to blockage. Risk factors for catheter blockage include alkaline urine, poor urine flow, proteinuria, and preexisting bladder stones.

Some residents with indwelling catheters experience persistent leakage around the catheter. Examples of factors that may contribute to leakage include irritation by a large balloon or by catheter materials, excessive catheter diameter, fecal impaction, and improper catheter positioning. Changing indwelling catheters or drainage bags at routine, fixed intervals is not recommended.

(Refer to: <https://www.cdc.gov/hicpac/pdf/CAUTI/CAUTIguideline2009final.pdf>)

Catheterization is an important, potentially modifiable, risk factor for UTI. The potential for complications can be reduced by:

- Identifying specific clinical indications for the use of an indwelling catheter;
- Assessing whether other treatments and services would appropriately address those conditions; and
- Assessing whether residents are at risk for other possible complications resulting from the continuing use of the catheter, such as obstruction resulting from catheter encrustation, urethral erosion, bladder spasms, hematuria, and leakage around the catheter.

URINARY TRACT INFECTIONS

Catheter-Related Bacteriuria and UTIs

Bacteriuria (e.g., pyuria) alone in a catheterized individual should not be treated with antibiotics. Someone with nonspecific symptoms such as a change in function or mental status, foul smelling or cloudy urine and/or, bacteriuria (e.g. pyuria), does not necessarily warrant antibiotic treatment. The decision to treat a UTI is based upon the attending practitioner conducting a thorough evaluation and assessment of the resident and providing documentation of a rationale for the indication of use of an antibiotic.

NOTE: For a non-catheterized resident with symptoms associated with a UTI, the attending practitioner should order a urine culture prior to the initiation of antibiotic therapy to help guide treatment. According to current standard of practice, an accurate urine culture for a non-catheterized resident should be obtained by a clean catch or mid-stream specimen for residents who are able to follow instructions. For those unable to

provide a clean-catch, a specimen may be obtained preferably by a freshly placed condom catheter for males, or in and out catheterization for females or males unable to provide a specimen by a condom catheter. If the resident has a long-term indwelling urethral catheter, a specimen should be obtained from a freshly placed indwelling catheter. Reference - the IDSA Guidelines for Evaluation of Fever and Infection in Older Adult Residents of Long-Term Care Facilities. (High et al. Clinical Infectious Diseases, 2009:48-149-71).

The surveyor should determine if facility policy for obtaining urine for cultures is based upon current standards of practice, understanding that these standards may be revised and updated over time. The facility should be able to provide the most current standard that supports the policy that they have developed and implemented. (Also refer to F880 Infection Control and F881 for antibiotic stewardship program for infection assessment tools.)

Unnecessary treatment of a UTI with antibiotics may lead to the development of multi drug resistant organisms (e.g., Methicillin-Resistant Staphylococcus Aureus) and other complications such as the development of clostridium-difficile infection, which may predispose the person to prolonged treatment potential hospitalization and may pose a threat of infection to other residents. (Also refer to F881 for antibiotic stewardship program for infection assessment tools.)

NOTE: Standards of practice may be revised and updated over time.

One current professional standard of practice that addresses criteria for use of antibiotics for UTI's, includes:

“Minimum criteria for initiating antibiotics for an indication of urinary tract infection were considered for residents with no indwelling urinary catheters and for residents with chronic indwelling catheters.

1. 2. For residents who do not have an indwelling catheter, minimum criteria for initiating antibiotics include: $>10^5$ CFU/mL (positive) or pending urine culture and dysuria alone or two or more of the following: fever ($>37.9^{\circ}\text{C}$ [100°F] or 1.5°C [2.4°F] increase above baseline temperature on two occasions over last 12 hours), new or worsening urgency, frequency, suprapubic pain, gross hematuria, costovertebral angle tenderness (flank pain), urinary incontinence, or shaking chills.
2. For residents who have an indwelling catheter or a suprapubic catheter), minimum criteria for initiating antibiotics include the presence of: $>10^5$ CFU/mL (positive) or pending urine culture and one or more of the following: fever ($>37.9^{\circ}\text{C}$ [100°F] or 1.5°C [2.4°F] increase above baseline temperature on two occasions over last 12 hours), new costovertebral tenderness, rigors (shaking chills), or new onset of delirium.”Reference - Loeb M, Brazil K, Lohfeld L, et al. Effect of a multifaceted intervention on number of antimicrobial prescriptions for suspected urinary tract

infections in residents of nursing homes: cluster randomised controlled trial. *BMJ*. 2005;331:669. [PMC free article] [PubMed]

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Follow-Up of UTIs

The goal of treating a UTI is to alleviate systemic or local symptoms, not to eradicate all bacteria. Therefore, a post-treatment urine culture is not necessary but may be useful if UTI signs and symptoms continue or do not respond to antibiotic treatment. Continued bacteriuria without residual symptoms does not warrant repeat or continued antibiotic therapy. Recurrent UTIs (2 or more in 6 months) in a noncatheterized individual may warrant additional evaluation (such as a determination of an abnormal post void residual (PVR) urine volume or a referral to a urologist) to rule out structural abnormalities such as enlarged prostate, prolapsed bladder, periurethral abscess, strictures, bladder calculi, polyps and tumors.

Recurrent UTIs in a catheterized individual should lead the facility to look for possible impairment of free urine flow through the catheter, to re-evaluate the techniques being used for catheter care and for perineal hygiene including the removal of fecal soiling, and to reconsider the relative risks and benefits of continuing the use of an indwelling catheter.

Because the major factors (other than an indwelling catheter) that predispose individuals to bacteriuria, including physiological aging changes and chronic comorbid illnesses, cannot be modified readily, the facility should demonstrate that they:

- Employ infection prevention and control practices (e.g. Standard Precautions) in managing catheters and associated drainage system;
- Keep the resident and catheter clean of feces to minimize bacterial migration into the urethra and bladder (e.g., cleaning fecal material away from, rather than towards, the urinary meatus), however, routine perineal care with an antiseptic is not recommended;
- Maintain free urine flow through any indwelling catheter; and
- Assess for fluid needs and implement a fluid management program (using alternative approaches as needed) based on those assessed needs.

FECAL INCONTINENCE

Fecal incontinence (FI) involves the unintentional loss of solid or liquid stool. A resident experiencing FI may experience feelings of shame, embarrassment, loss of independence, may tend to isolate himself/herself creating a decrease in social interactions/activities due to fear of “accidents” with associated odors, leakage and soiling of clothing or

furnishings. It is important for the facility and the attending practitioner to complete a comprehensive assessment and determine, with the resident/representative, potential treatment and care plan interventions, and to provide ongoing evaluation of the response to those interventions. The resident should be re-evaluated whenever there is a change in bowel function. If the resident has FI that has already been investigated, documented, and determined to be irreversible or not significantly improvable, additional studies may be of limited value, unless there has been advancement in available treatments.

Risk factors for Fecal Incontinence

Risk factors for FI may include, aging and dependency in daily activities, smoking and pulmonary disease, arthritis in adults over 75 years of age, older adults with rectal cancer, comorbidities such as kidney disease, transient ischemic attacks in men, women with arterial hypertension, acute stroke (FI may depend on the severity of a stroke), functional dependency and need for assistance with toilet access 3 months after stroke in men and women, and poor general health and dementia.

<http://archive.ahrq.gov/downloads/pub/evidence/pdf/fuiad/fuiad.pdf>

Assessment:

To ensure that a resident who is incontinent of bowel receives appropriate treatment and services, the facility must conduct an assessment to identify the presenting symptoms and type of FI, including the potential reversible/irreversible causes and risks. Symptoms or types of FI may include (as noted in

<http://s3.gi.org/physicians/guidelines/FecalIncontinence.pdf>):

- **“Passive incontinence** —which is the involuntary discharge of fecal matter or flatus without any awareness. This suggests a loss of perception and/or impaired rectoanal reflexes either with or without sphincter dysfunction;
- **Urge incontinence** — which is the discharge of fecal matter or flatus in spite of active attempts to retain these contents. Here, there is a predominant disruption of the sphincter function or the rectal capacity to retain stool; and/or
- **Fecal seepage** — which is the undesired leakage of stool, often after a bowel movement with otherwise normal continence and evacuation. This condition is mostly due to incomplete evacuation of stool and/or impaired rectal sensation. The sphincter function and pudendal nerve function are mostly intact”.

Causes and Treatment of Fecal Incontinence

For reference, the following potential causes and treatments of FI have been adapted from the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) to address the long term care setting. For the full description of causes and treatment for FI, refer to:

<http://www.niddk.nih.gov/health-information/health-topics/digestive-diseases/fecal-incontinence/Pages/facts.aspx>

Potential causes for FI may include:

- Diarrhea;
- Constipation Muscle Damage or Weakness;
- Trauma, childbirth injuries, cancer surgery, and hemorrhoid surgery;
- Nerve Damage;
- Loss of Stretch in the Rectum;
- Childbirth by Vaginal Delivery;
- Hemorrhoids and Rectal Prolapse;
- Rectocele and;
- Inactivity

Potential treatment/interventions for FI should be based upon the type of FI. Potential treatment options and interventions may include:

- Eating increased amounts of fiber;
- Drinking sufficient liquids;
- Use of medications to develop more solid stools that are easier to control;
- Pelvic Floor Exercises and Biofeedback that strengthen the pelvic floor muscles may improve bowel control. Success with pelvic floor exercises depends on the cause of fecal incontinence, its severity, and the person's motivation and ability to follow the health care provider's recommendations;
- Surgery may be an option for fecal incontinence that fails to improve with other treatments or for fecal incontinence caused by pelvic floor or anal sphincter muscle injuries;
- Electrical Stimulation also called sacral nerve stimulation or neuromodulation, involves placing electrodes in the sacral nerves to the anus and rectum and continuously stimulating the nerves with electrical pulses.

Care Plan

For the resident with fecal incontinence, the care plan must reflect the results of the resident's assessment and include resident specific interventions for any potential reversible causes and, if irreversible, appropriate interventions for management of fecal incontinence. Interventions and the provision of care should address treating the resident with respect, enhancing dignity and self-worth and reducing embarrassment and shame in relation to FI. Based upon the increased risk for transmission of infection resulting from fecal contamination, the care plan should also identify the PPE appropriate for use during the delivery of care.

Complications Potentially Related to Fecal Incontinence

Complications related to fecal incontinence may include, but are not limited to, emotional distress, loss of self-esteem, social isolation, physical complications such as skin irritation/excoriation, itching, pain, and in addition, frequent loose stool may be an indicator of fecal impaction.

KEY ELEMENTS OF NONCOMPLIANCE

To cite deficient practice at F690, the surveyor's investigation will generally show that the facility failed to do one or more of the following:

- Provide appropriate and sufficient services and assistance to:
 - Maintain bladder continence and/or bowel function in continent residents; or
 - Restore bladder continence and/or bowel function as possible, based on a comprehensive assessment and clinical condition; or
 - Prevent urinary tract infections to the extent possible;
- Ensure that a resident is not catheterized unless required by his/her clinical condition; or
- Ensure that a urinary catheter is removed as soon as possible unless the catheter is necessary because of the residents' clinical condition.

INVESTIGATIVE PROTOCOL

Use

Use the Bladder and Bowel Incontinence Critical Element (CE) Pathway, and/or Urinary Catheter and UTI CE Pathway, for the condition being evaluated, along with the above interpretive guidelines when determining if the facility provides the necessary care and services to meet the resident's needs.

Summary of Procedure

Briefly review the most recent comprehensive assessments, comprehensive care plan and orders to identify whether the facility has assessed and developed an individualized care plan based on professional standards of practice and provided by qualified, competent staff. During this review, identify the extent to which the facility has implemented interventions in accordance with the resident's needs, goals for care and professional standards of practice, consistently across all shifts. This information will guide observations and interviews to be made in order to corroborate concerns identified.

NOTE: Always observe for visual cues of psychosocial distress and harm (see Appendix P, Guidance on Severity and Scope Levels and Psychosocial Outcome Severity Guide).

DEFICIENCY CATEGORIZATION

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

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

- The facility failed to ensure that a resident who entered the facility with an indwelling catheter was assessed for removal of the catheter as soon as possible, resulting in the resident continuing to have the catheter in place for three weeks and developing a urinary tract infection, leading to sepsis. The facility failed to provide appropriate treatment and services for a resident with fecal incontinence, resulting in the resident having severely excoriated and ulcerated areas of skin

around the rectal area, with odor, and purulent exudate. The resident expressed severe pain and refused to leave her room.

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

- The facility failed to assure that a resident who entered the facility with an indwelling catheter was assessed for removal of the catheter as soon as possible, unless the resident's clinical condition demonstrates that catheterization is necessary. During the survey, a resident was identified as having an indwelling urinary catheter in place for several months. The resident was currently being treated with an antibiotic for a symptomatic urinary tract infection. Staff interviewed were unable to provide the clinical indication for use for the catheter, and the record did not contain documentation for the initial use of the catheter or for the continued use of a urinary catheter. The resident was unable to be interviewed, but his representative was interviewed but did not know why the catheter was in place, except that the resident had a problem with incontinence. Record review indicated that the resident had experienced repeated complications such as recurrent symptomatic UTIs which required treatment with antibiotics.
- The facility failed to assure that a resident who was incontinent of bladder received the appropriate treatment and services to restore continence to the extent possible. A resident was identified as incontinent of bladder. Based upon the resident's assessment and identification of the type of urinary incontinence, the facility developed interventions for a restorative program to restore continence. However, based on observations, staff were not implementing the interventions on the care plan, did not respond to the resident's request for assistance with use of the bathroom, and were not monitoring the progress of the interventions. The resident stated that she was frustrated and embarrassed regarding the odors and wetness that occurred as a result of the incontinence episodes. She also stated that she did not attend activities or go for meals as she needed close access to the toilet, and that she didn't want to be around others when she had incontinent episodes. She stated that she felt that she was not improving with her bladder continence, and that it was worse now than when she started the restorative program. Staff interviewed stated that they were aware of the program, but they were not able to implement the program, consistently on all shifts, as they had other resident's and duties assigned during their shifts and were unable to respond. The record reflected a decline in continence since the program began. (Also cited at sufficient staffing at F726)

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

- The facility failed to provide appropriate treatment and services for care of a resident with a clinically-justified indwelling catheter. During observations of

care for a resident with an indwelling catheter, urine was noted to be leaking. Staff interviewed stated that they were not sure why the catheter leaked, but that they kept the resident as dry as possible. In addition, it was observed several times throughout the survey, that the catheter drainage bag and tubing were placed directly on the floor in the resident's room. There were no indications of skin maceration and/or irritation, or symptoms of a UTI symptoms.

- The facility failed to provide appropriate treatment and services for care of a resident who had intermittent fecal incontinence. During the survey, a resident was observed to stay in her room, did not attend activities and had meals served in her room. The resident was identified as alert and aware of her care needs. She stated that she had problems with intermittent fecal incontinence and was on a bowel management program that included extra fiber and liquids. She stated that recently there were changes in meal service and she was not receiving the extra fiber. She also stated that staff were to assist her with hygiene when incontinence episodes occurred, but they had not consistently provided the care. She stated that when she had the fecal incontinence episodes, she did not attend activities she enjoyed attending, and was irritated that she was unable to attend due to not receiving hygiene when needed.

Severity Level 1: No actual harm with potential for minimal harm

The failures of the facility to provide appropriate care and services to maintain or improve continence, manage indwelling catheters, and minimize negative outcome places residents at risk for more than minimal harm. Therefore, Severity Level 1 does not apply for this regulatory requirement.

Resources

Research into appropriate practices to prevent, manage, and treat urinary incontinence, urinary catheterization, and UTI continues to evolve. Many recognized clinical resources on the prevention and management of urinary incontinence, infection, and urinary catheterization exist. Some of these resources include:

- The American Medical Directors Association (AMDA) - Clinical Practice Guidelines: Clinical Practice Guidelines, 1996 - <http://www.amda.com/tools/guidelines.cfm>
 - <http://www.mc.vanderbilt.edu/documents/cqa/files/Incontinence%20Management/Vanderbilt%20Incontinence%20Management%20Module.pdf>
 - Association for Professionals in Infection Control and Epidemiology (APIC) at www.apic.org;
 - Centers for Disease Control at www.cdc.gov;
 - The Annals of Long Term Care publications: <http://www.annalsoflongtermcare.com/search?keywords=urinary%20catheters>
 - Urology Care Foundation – The Official Foundation of the American Urological Association - <http://www.urologyhealth.org/>
 - The American Geriatrics Society at www.americangeriatrics.org

- <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3538836/>
Surveillance Definitions of Infections in Long-Term Care Facilities: Revisiting the McGeer Criteria

Resources for Fecal Incontinence:

- https://www.fascrs.org/sites/default/files/downloads/publication/clinical_practice_guideline_for_the_treatment_of_fecal_incontinence.pdf
- <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2614622/>

F694

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§483.25(h) Parenteral Fluids.

Parenteral fluids must be administered consistent with professional standards of practice and in accordance with physician orders, the comprehensive person-centered care plan, and the resident's goals and preferences.

INTENT §483.25(h)

The intent of this requirement is that the facility assures that each resident receives care and services for the provision of parenteral fluids consistent with professional standards of practice in order to provide:

- Safe administration of parenteral fluids by qualified, competent and trained staff in accordance with State laws/practice acts;
- Care consistent with the resident's input, goals and preferences, as delineated in the care plan; and
- Ongoing support of the resident, during *parenteral* treatments, including monitoring the resident's status, monitoring for complications and assuring the provision of appropriate infection control practices.

DEFINITION §483.25(h)

Parenteral fluid is *the delivery of fluid or medication through an intravenous, subcutaneous, intramuscular, or mucosal route (Taber's Online Medical Dictionary, <https://www.tabers.com/tabersonline/>)* to maintain adequate hydration, restore and/or maintain fluid volume, reestablish lost electrolytes, or provide nutrition which includes Total Parenteral Nutrition (TPN).

Intravenous (IV) therapy is the administration of parenteral fluids or medications through an IV catheter to treat a condition.

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

GUIDANCE §483.25(h)

There is no requirement that a facility must offer IV *therapy*. If the facility has an arrangement with an outside contractor for the provision of IV *therapy*, the facility must inform each resident before or at the time of admission, and periodically during the resident's stay, of *such* services if available in the facility.

Residents of a facility may receive IV *therapy* through options such as *the following*:

- The facility provides the IV *therapy* either directly or *under* contract *with* individuals to provide the services; however, these individuals must be qualified, trained and competent in accordance with professional standards of practice, licensure and State practice acts/laws; or
- If a current resident needs and agrees to receive IV *therapy* and the facility does not allow *such* services *to be administered onsite*, the facility must assist the resident with the transfer to another facility or *with* the relocation to *another* setting (e.g. private home, or residential/assisted living facility) of his/her choice that provides IV *therapy*.

For facilities who offer IV therapy, the facility must develop and implement resident care policies based upon current professional standards of practice for the preparation, insertion, administration, maintenance and discontinuance of *an* IV, as well as *for the* prevention of infection at the site to the extent possible. The procedures must include the care and use of all equipment, such as pumps, tubing, syringes, fluids, etc.

The facility minimizes risks to a resident receiving IV therapy by developing and implementing policies that adhere to professional standards of practice, which may include, but are not limited to:

- Use of appropriate hand hygiene during all aspects of IV *therapy*;
- Use of aseptic technique when placing a venous access device;
- *Use of appropriate antiseptic (e.g., chlorhexidine, povidone iodine, an iodophor, or 70 percent alcohol, which is recommended in CDC guidelines) to scrub IV ports, needleless connectors, and hubs prior to access or use.*
- Use of personal protective equipment (PPE) (based on potential for exposure to blood, bodily fluids, and infectious agents);
- Competency of staff to:
 - Use infusion equipment;
 - Accurately perform IV insertion, and maintain vascular access; and
 - Assess for complications.
- Administration of solutions according to orders (correct solution, administration route (central/peripheral line), duration, frequency, and infusion rate);
- Labeling and dating, as appropriate, infusion fluids and lines;
- *Frequency of assessment of IV catheter to assess the insertion site for signs and symptoms of infection or inflammation (i.e., at least daily or with each use). Frequency may depend upon such factors as the:*

- *Ability of resident to report symptoms of pain, redness, etc.*
- *Type of infusion—is it an irritant or vesicant?*
- *Location of IV catheter—is it inserted in an area of flexion; and*
- *Facility policy based on long-term care pharmacy IV policies and procedures.*
- *Assessment of continued need for the catheter if not being used for IV fluids or medications.*

According to the CDC, the following terminology has been used to describe IV catheters: “Terminology and Estimates of Risk - The terminology used to identify different types of catheters is confusing, because many clinicians and researchers use different aspects of the catheter for informal reference. A catheter can be designated by:

- The type of vessel it occupies (e.g., peripheral venous, central venous, or arterial);
 - Its intended life span (e.g., temporary or short-term versus permanent or long-term);
 - Its site of insertion (e.g., subclavian, femoral, internal jugular, peripheral, and *midline* or peripherally inserted central catheter [PICC]);
 - Its pathway from skin to vessel (e.g., tunneled versus nontunneled);
 - Its physical length (e.g., long versus short); or
 - Some special characteristic of the catheter (e.g., presence or absence of a cuff, impregnation with heparin, antibiotics or antiseptics, and the number of lumens).
- To accurately define a specific type of catheter, all of these aspects should be described (Table 1).” - <https://www.cdc.gov/hai/pdfs/bsi-guidelines-2011.pdf>.

Complications/Risks of Intravenous Fluid Administration

Administration of IV fluids may be required to restore or maintain adequate hydration, replace electrolytes, or provide partial nutrition. However, because it is invasive, administration of IV fluids has associated risks such as:

- Infiltration;
- Bruising;
- Embolism (Air or Blood);
- Phlebitis;
- Fluid overload;
- Electrolyte imbalance; and
- Infections (Cellulitis, Septicemia).

NOTE: Refer to Centers for Disease Control (CDC) guidelines for the prevention of intravascular catheter related infections found at: <https://www.cdc.gov/hai/pdfs/bsi-guidelines-2011.pdf>.

In addition to adhering to professional standards of practice, facilities are responsible to administer IV therapy according to the resident-centered care plan and in accordance with

physician's orders and the resident's goals, preferences, and advance directives, as applicable and according to State law.

INVESTIGATIVE PROCEDURES

Observations: Observe the resident to determine:

- Are there signs of inflammation or infiltration at the insertion site and has site been changed according to current, professional standards of practice?
- If the rate of parenteral fluid being administered reflects that which was ordered by the physician.
- If the resident received the amount of fluid during the past 24 hours that he/she should have received according to the physician's orders (allow flexibility up to 150cc unless an exact fluid intake is critical for the resident)?

Observe staff *accessing the port and* changing the IV site, tubing, or bottle/bag, if possible. *Determine if the central venous or peripheral access port, needleless connector, and hub was scrubbed with an appropriate antiseptic prior to access or use.* Determine whether aseptic technique is maintained in accordance with current, professional standards of practice.

Record Review:

Review the medical record and comprehensive care plan (or baseline if the resident's admission was within 14 days of the review) *for residents receiving IV therapy* to determine:

- If the *clinical record includes documentation to support the need for IV therapy;*
- If the resident has orders for parenteral fluid, *Note* the solution type, administration route, frequency, and infusion rate to compare to observations.
- How frequently staff are to change IV tubing.

Review facility policies and procedures related to *IV* therapy to determine if policies and/or procedures address:

- Aseptic technique for IV insertion;
- Maintenance of IV site;
- Frequency of IV site, tubing, and bag changes, and do they reflect current, professional standards of practice?
- *Documentation for the continued need for the IV catheter if no longer being used for IV fluid or medication.*

Interviews:

Interview the resident or, if applicable, the *resident* representative to determine:

- If they understand why the resident is receiving parenteral fluid;
- If the resident has had any complications or concerns related to the *IV therapy*

Interview staff to determine if there are specific qualifications and/or competencies required for staff who perform IV insertion, IV maintenance, and parenteral fluid administration.

DEFICIENCY CATEGORIZATION §483.25(h)

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

- Facility's failure to adhere to sterile technique during maintenance of *IV* therapy that lead to sepsis and resulted in the resident's hospitalization or death.
- Facility's failure to monitor administration *of* fluid that resulted in overload of cardiovascular system, resulting in hospitalization or death.

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

- Facility's failure to monitor for complications related to *IV* therapy, resulting in infiltration of the IV, causing the resident to experience pain and swelling.
- Facility's failure to ensure a resident received fluids as ordered, resulting in dehydration, which was later reversed after staff became aware.

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

- Facility's failure to consistently flush a resident's IV site, resulting in the IV becoming clogged and requiring replacement.
- Facility's failure to anchor the IV needle and tubing, resulting in leakage around the IV site that required topical treatment and resolved without complications.

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

The failures of the facility to provide appropriate care and services related to parenteral fluids places the resident at risk for more than minimal harm. Therefore, Severity *level* 1 does not apply for this regulatory requirement.

POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION:

- If noncompliance with parenteral therapy is related to staff competency issues, also consider F725, §483.35(a)(3), Nursing Services
- If noncompliance with parenteral therapy is related to accuracy of fluid type, or amount, also consider F755, §483.45 Pharmacy Services.
- If noncompliance with parenteral therapy is related to lack of equipment such as IV tubing, pumps, etc., also consider F907 §483.90(*d*) Space and equipment.

If noncompliance with parenteral therapy is related to the provision of adequate nutrition/hydration, also consider F692 §483.25(g), Assisted Nutrition and Hydration.

F695

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§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(h) Medical Director) The policies and procedures, based on the type of respiratory care and services provided, may include, but are not limited to:

- Oxygen services, including the safe handling, humidification, cleaning, storage, and dispensing of oxygen;
- Types of respiratory exercises provided such as coughing/deep breathing and if provided therapeutic percussion/vibration and bronchopulmonary drainage;
- Aerosol drug delivery systems (nebulizers/metered-dose inhalers) and medications (preparation and/or administration) used for respiratory treatments;
- BiPAP/CPAP treatments;
- Delineation for all aspects of the provision of mechanical ventilation/tracheostomy care, including monitoring, oversight and supervision of mechanical ventilation, tracheostomy care and suctioning, and how to set, monitor and respond to ventilator alarms;
- Emergency care which includes staff training and competency for implementation of emergency interventions for, at a minimum, cardiac/respiratory complications, and include provision of appropriate equipment at the resident's bedside for immediate access, such as for unplanned extubation;
- Procedures to follow in the advent of adverse reactions to respiratory treatments or interventions, including mechanical ventilation, tracheostomy care and provision of oxygen;
- Respiratory assessment including who can conduct each aspect of the assessment, what is contained in an assessment, when and how it is conducted, the type of documentation required;
- Maintenance of equipment for respiratory care in accordance with the manufacturer specifications and consistent with federal, state, and local laws and regulations, such as oxygen equipment, or equipment for mechanical ventilation if provided, how and by whom the equipment is serviced and how it is maintained;

- Emergency power for essential equipment such as mechanical ventilation, if provided;
- Infection control measures during implementation of care, handling, cleaning, storage and disposal of equipment, supplies, biohazardous waste and including infection control practices for mechanical ventilation/tracheostomy care including the use of humidifiers; and
- Posting of cautionary and safety signs indicating the use of oxygen; and

Staffing and Qualified Personnel

Refer to §483.65 specialized rehabilitative services, for review of provision of services by qualified personnel. When providing respiratory care, the facility must, based on professional standards of practice:

- Have sufficient numbers of trained, competent, qualified staff, consistent with State practice acts/laws; and
- Identify who is authorized to perform each type of respiratory care service, such as responding to mechanical ventilator alarms, suctioning and tracheostomy care.

NOTE: Surveyors are expected to determine the scope of practice and state laws regarding who may provide mechanical ventilation and/or tracheostomy care in their state.

Monitoring and Documentation of Respiratory Services/Response

Staff should document, based on current professional standards of practice, the assessment and monitoring of the resident's respiratory condition, including response to therapy provided, and any changes in the respiratory condition. Depending on the type of respiratory services the resident receives, physician orders and the individualized respiratory care plan, documentation should include, as appropriate:

- Vital signs, including the respiratory rate;
- Chest movement and respiratory effort, and the identification of abnormal breath sounds;
- Signs of dyspnea, cyanosis, coughing, whether position affects breathing, characteristics of sputum, signs of potential infection, or the presence of behavioral changes that may reflect hypoxia including anxiety, apprehension, level of consciousness; and
- Instructions for the resident on how to participate/assist in the respiratory treatments as appropriate.

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 (O₂) 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 SpO₂ 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 SpO₂ 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 CO₂ 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.

F697

(Rev. 208; Issued:10-21-22; Effective: 10-21-22; Implementation:10-24-22)

§483.25(k) Pain Management.

The facility must ensure that pain management is provided to residents who require such services, consistent with professional standards of practice, the comprehensive person-centered care plan, and the residents' goals and preferences.

INTENT §483.25(k)

Based on the comprehensive assessment of a resident, the facility must ensure that residents receive the treatment and care in accordance with professional standards of practice, the comprehensive care plan, and the resident's choices, related to pain management.

DEFINITIONS §483.25(k)

"Adjuvant Medication" describes any medication with a primary indication other than pain management but with analgesic properties in some painful conditions.²

"Adverse Consequence" is an unpleasant symptom or event that is due to or associated with a medication, such as impairment or decline in a resident's mental or physical condition or functional or psychosocial status. It may include various types of adverse drug reactions and interactions (e.g., medication-medication, medication-food, and medication-disease).

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

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

NOTE: Adverse drug reaction (ADR) is a form of adverse consequences. It may be either a secondary effect of a medication that is usually undesirable and different from the therapeutic effect of the medication or any response to a medication that is noxious and unintended and occurs in doses for prophylaxis, diagnosis, or treatment. The term "side effect" is often used interchangeably with ADR; however, side effects are but one of five ADR categories, the others being hypersensitivity, idiosyncratic response, toxic reactions, and adverse medication interactions. A side effect is an expected, well-known reaction that occurs with a predictable frequency and may or may not constitute an adverse consequence.

GUIDANCE §483.25(k)

Recognition and Management of Pain - In order to help a resident attain or maintain his or her highest practicable level of well-being and to prevent or manage pain, the facility, to the extent possible:

- Recognizes when the resident is experiencing pain and identifies circumstances when pain can be anticipated;
- Evaluates the existing pain and the cause(s), and
- Manages or prevents pain, consistent with the comprehensive assessment and plan of care, current professional standards of practice, and the resident's goals and preferences.

Overview of Pain Recognition and Management

Nursing home residents are at high risk for having pain that may affect function, impair mobility, impair mood, or disturb sleep, and diminish quality of life. It is important, therefore, that a resident's reports of pain, or nonverbal signs suggesting pain, be evaluated. The resident's needs and goals as well as the etiology, type, and severity of pain are relevant to developing a plan for pain management. It should be noted that while analgesics can reduce pain and enhance the quality of life, they do not necessarily address the underlying cause of pain. It is important to consider treating the underlying cause, where possible.

Strategies for Pain Management

Strategies for the prevention and management of pain may include but are not limited to the following:

- Assessing the potential for pain, recognizing the onset, presence and duration of pain, and assessing the characteristics of the pain;
- Addressing/treating the underlying causes of the pain, to the extent possible;
- Developing and implementing both non-pharmacological and pharmacological interventions/approaches to pain management, depending on factors such as whether the pain is episodic, continuous, or both;
- Identifying and using specific strategies for preventing or minimizing different levels or sources of pain or pain-related symptoms based on the resident-specific assessment, preferences and choices, a pertinent clinical rationale, and the resident's goals and; using pain medications judiciously to balance the resident's desired level of pain relief with the avoidance of unacceptable adverse consequences;
- Monitoring appropriately for effectiveness and/or adverse consequences (e.g., constipation, sedation) including defining how and when to monitor the resident's symptoms and degree of pain relief; and
- Modifying the approaches, as necessary.

***Use of Opioids for Pain Management**—Prescribing practitioners may find that opioid medications are the most appropriate treatment for acute pain as well as chronic pain in some residents. However, because of increasing opioid addiction, abuse, and overdoses, prescribers should use caution when prescribing opioids, and consider using alternative*

pain management approaches, when appropriate. When opioids are used, the lowest possible effective dosage should be prescribed for the shortest amount of time possible after considering all medical needs and the resident should be monitored for effectiveness and any adverse effects. Long-acting opioids may provide more consistent pain relief with less breakthrough pain. However, if using opioids in residents with dementia, immediate release forms of opioids are generally preferred over long-acting forms to reduce overdose risk, unless clinically indicated.

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

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

For additional information, refer to:

- *Exposure-Response Association Between Concurrent Opioid and Benzodiazepine Use and Risk of Opioid-Related Overdose in Medicare Part D Beneficiaries, <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2685628>.*
- *National Institute on Drug Abuse Benzodiazepines and Opioids, <https://www.drugabuse.gov/drugs-abuse/opioids/benzodiazepines-opioids>*
- *Geriatricpain.org, Resources and Tools for Quality Pain Care, <https://geriatricpain.org/>*
- *The Society for Post-Acute and Long-Term Care Medicine (AMDA) opioid guidelines, <https://paltc.org/opioids%20in%20nursing%20homes>*

Additionally, the Centers for Disease Control and Prevention website has resources specifically related to the use of opioids in treating chronic pain (pain lasting longer than three months or past the time of normal tissue healing) available at <https://www.cdc.gov/drugoverdose/prescribing/guideline.html>. These guidelines do not apply to individuals being treated for pain related to active cancer treatment, palliative care, and end-of-life care. Individual states also have initiatives and requirements related to opioid use for acute and chronic pain.

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

Pain Recognition

Because pain can significantly affect a person's well-being, it is important that the facility recognize and address pain promptly. The facility's evaluation of the resident at admission and during ongoing assessments helps identify the resident who is experiencing pain or for whom pain may be anticipated during specific procedures, care, or treatment. In addition, it is important that a resident be monitored for the presence of pain and be evaluated when there is a change in condition and whenever new pain or an exacerbation of pain is suspected. As with many symptoms, pain in a resident with moderate to severe cognitive impairment may be more difficult to recognize and assess.

Expressions of pain may be verbal or nonverbal and are subjective. A resident may avoid the use of the term "pain." Other words used to report or describe pain may differ by culture, language and/or region of the country. Examples of descriptions may include heaviness or pressure, stabbing, throbbing, hurting, aching, gnawing, cramping, burning, numbness, tingling, shooting or radiating, spasms, soreness, tenderness, discomfort, pins and needles, feeling "rough," tearing or ripping. Verbal descriptions of pain can help a practitioner identify the source, nature, and other characteristics of the pain. Nonverbal indicators which may represent pain need to be viewed in the entire clinical context with consideration given to pain as well as other clinically pertinent explanations. Examples of possible indicators of pain include, but are not limited to the following:

- Negative verbalizations and vocalizations (e.g., groaning, crying/whimpering, or screaming);
- Facial expressions (e.g., grimacing, frowning, fright, or clenching of the jaw);
- Changes in gait (e.g., limping), skin color, vital signs (e.g., increased heart rate, respirations and/or blood pressure), perspiration;
- Behavior such as resisting care, distressed pacing, irritability, depressed mood, or decreased participation in usual physical and/or social activities;
- Loss of function or inability to perform Activities of Daily Living (ADLs) (e.g., rubbing a specific location of the body, or guarding a limb or other body parts);
- Difficulty eating or loss of appetite; and
- Difficulty sleeping (insomnia).

In addition to the pain item sections of the MDS, many sections such as sleep cycle, change in mood, decline in function, instability of condition, weight loss, and skin conditions can be potential indicators of pain. Any of these findings may indicate the need for additional and more thorough evaluation.

Many residents have more than one active medical condition and may experience pain from several different causes simultaneously. Many medical conditions may be painful such as pressure injuries, diabetes with neuropathic pain, immobility, amputation, post-CVA, venous and arterial ulcers, multiple sclerosis, oral health conditions, and infections. In addition, common procedures, such as moving a resident or performing physical or occupational therapies or changing a wound dressing may be painful. Understanding the underlying causes of pain is an important step in determining optimal approaches to prevent, minimize, or manage pain.

Observations at rest and during movement, particularly during activities that may increase pain (such as dressing changes, exercises, turning and positioning, bathing, rising from a chair, walking) can help to identify whether the resident is having pain. Observations during eating or during the provision of oral hygiene may also indicate dental, mouth and/or facial pain.

Recognizing the presence of pain and identifying those situations where pain may be anticipated involves the participation of health care professionals and direct care and ancillary staff who have contact with the resident. Information may be obtained by talking with the resident, directly examining the resident, and observing the resident's behavior. Staffing consistency and familiarity with the residents has a significant effect on the staff's ability to identify and differentiate pain-related behavior from other behavior of cognitively impaired residents.

Nursing assistants may be the first to notice a resident's symptoms; therefore, it is important that they are able to recognize a change in the resident and the resident's functioning and to report the changes to a nurse for follow-up. Family members or friends may also recognize and report when the resident experiences pain and may provide information about the resident's pain symptoms, pain history and previously attempted interventions. Other staff, e.g., dietary, activities, therapy, housekeeping, who have direct contact with the resident may also report changes in resident behavior or resident complaints of pain.

Assessment

In addition to the Resident Assessment Instrument (RAI), it is important that the facility identifies how they will consistently assess pain. Some facilities may use assessment tools that are appropriate for use with their resident population. There are many reliable and valid evidenced based practice tools available to facility staff to assist in the assessment of pain. Pain assessment tools that can be used with cognitively intact and impaired residents can be obtained on the Geriatric Pain website at <http://www.geriatricpain.org/Content/Assessment>.

An assessment or an evaluation of pain based on professional standards of practice may necessitate gathering the following information, as applicable to the resident:

- History of pain and its treatment (including non-pharmacological and pharmacological treatment and whether or not each treatment has been effective);
- *History of addiction, past and/or ongoing and related treatment for OUD;*
- Characteristics of pain, such as: (intensity, pattern, location, frequency and duration)
- Impact of pain on quality of life (e.g., sleeping, functioning, appetite, and mood);
- Factors such as activities, care, or treatment that precipitate or exacerbate pain as well as those that reduce or eliminate the pain;
- Additional symptoms associated with pain (e.g., nausea, anxiety);

- Physical and psychosocial issues (physical examination of the site of the pain, movement, or activity that causes the pain, as well as any discussion with resident about any psychological or psychosocial concerns that may be causing or exacerbating the pain);
- Current medical conditions and medications *including medication assisted treatment for OUD*; and
- The resident's goals for pain management and his or her satisfaction with the current level of pain control.

While it may be difficult to conduct a thorough assessment of all of the above factors in a cognitively impaired or non-responsive resident, the facility staff is responsible for obtaining as much information as possible and evaluating the resident's pain through all available means. Observing the resident during care, activities, and treatments helps not only to detect whether pain is present, but also to potentially identify its location and the limitations it places on the resident.

Management of Pain

Based on the evaluation, the facility, in collaboration with the attending physician/prescriber, other health care professionals, and the resident and/or his/her representative, develops, implements, monitors and revises as necessary interventions to prevent or manage each individual resident's pain, beginning at admission. These interventions may be integrated into components of the comprehensive care plan, addressing conditions or situations that may be associated with pain, or may be included as a specific pain management need or goal.

The interdisciplinary team and the resident and/or representative collaborate to arrive at pertinent, realistic and measurable goals for treatment, such as reducing pain sufficiently to allow the resident to ambulate comfortably to the dining room for each meal or to participate in 30 minutes of physical therapy. Depending on the situation and the resident's wishes, the target may be to reduce the pain level, but not necessarily to become pain-free. To the extent possible, the interdisciplinary team educates the resident and/or representative about the need to report pain when it occurs and about the various approaches to pain management and the need to monitor the effectiveness of the interventions used.

The basis for effective interventions includes several considerations, such as the resident's needs and goals; the source(s), type and severity of pain (recognizing that the resident may experience pain from one or more sources either simultaneously or at different times) and awareness of the available treatment options. Often, sequential trials of various treatment options are needed to develop the most effective approach.

It is important for pain management approaches to follow pertinent professional standards of practice and to identify who is to be involved in managing the pain and implementing the care or supplying the services (e.g., facility staff, such as RN, LPN, CNA; attending physician or other practitioner; certified hospice; or other contractors

such as therapists). Pertinent current professional standards of practice may provide recommended approaches to pain management even when the cause cannot be or has not been determined.

Non-pharmacological interventions

Research supports physical activity and exercise as a part of most treatment programs for chronic pain. Activity can be supported by conventional physical therapy and exercise approaches, or by a wide range of movement therapies.

Some non-pharmacologic interventions may need to be ordered by the provider while others can be provided by facility staff during routine care. Examples of non-pharmacological interventions may include, but are not limited to:

- Altering the environment for comfort (such as adjusting room temperature, tightening and smoothing linens, using pressure redistributing mattress and positioning, comfortable seating, and assistive devices);
- Physical modalities, such as ice packs or cold compresses (to reduce swelling and lessen sensation), mid heat (to decrease joint stiffness and increase blood flow to an area), neutral body alignment and repositioning, baths, transcutaneous electrical nerve stimulation (TENS), massage, acupuncture/acupressure, chiropractic, or rehabilitation therapy;
- Exercises to address stiffness and prevent contractures as well as restorative nursing programs to maintain joint mobility; and
- Cognitive/Behavioral interventions (e.g., relaxation techniques, reminiscing, diversions, activities, music therapy, offering spiritual support and comfort, as well as teaching the resident coping techniques and education about pain).

Pharmacological interventions

The interdisciplinary team (nurses, practitioner, pharmacists, etc.) is responsible for developing a pain management regimen that is specific to each resident who has pain or who has the potential for pain, such as during a treatment. The regimen considers factors such as the causes, location, and severity of the pain, the potential benefits, risks and adverse consequences of medications; and the resident's desired level of relief and tolerance for adverse consequences. The resident may accept partial pain relief in order to experience fewer significant adverse consequences (e.g., desire to stay alert instead of experiencing drowsiness/confusion). The interdisciplinary team works with the resident to identify the most effective and acceptable route for the administration of analgesics, such as orally, rectally, topically, by injection, by infusion pump, and/or transdermally.

It is important to follow a systematic approach for selecting medications and doses to treat pain. Developing an effective pain management regimen may require repeated attempts to identify the right interventions. General guidelines for choosing appropriate categories of medications in various situations are widely available to the provider, pharmacist and nurses.

Factors influencing the selection and doses of medications include the resident's medical condition, current medication regimen, nature, severity, and cause of the pain and the course of the illness. Analgesics may help manage pain; however, they often do not address the underlying cause of pain. Examples of different approaches may include, but are not limited to: administering lower doses of medication initially and titrating the dose slowly upward, administering medications "around the clock" rather than "on demand" (PRN); or combining longer acting medications with PRN medications for breakthrough pain. Recurrent use of or repeated requests for PRN medications may indicate the need to reevaluate the situation, including the current medication regimen. Some clinical conditions or situations may require using several analgesics and/or adjuvant medications (e.g., antidepressants or anticonvulsants) together. Documentation helps to clarify the rationale for a treatment regimen and to acknowledge associated risks.

Opioids or other potent analgesics have been used for residents who are actively dying, those with complex pain syndromes, and those with more severe acute or chronic pain that has not responded to non-opioid analgesics or other measures. Opioids should be selected and dosed in accordance with current professional standards of practice and manufacturers' guidelines in order to optimize their effectiveness and minimize their adverse consequences. Adverse consequences may be especially problematic when the resident is receiving other medications with significant effects on the cardiovascular and central nervous systems. Therefore, careful titration of dosages based on monitoring/evaluating the effectiveness of the medication and the occurrence of adverse consequences is necessary. The clinical record should reflect the ongoing communication between the prescriber and the staff is necessary for the optimal and judicious use of pain medications.

Other interventions have been used for some residents with more advanced, complex, or poorly controlled pain such as radiation therapy, neurostimulation, spinal delivery of analgesics (implanted catheters and pump systems), and neurolytic procedures (chemical or surgical) ^{that} are administered under the close supervision of expert practitioners. Referrals to pain management clinics and pain management specialists may also be appropriate in these situations.

Monitoring, Reassessment, and Care Plan Revision

Monitoring the resident over time helps identify the extent to which pain is controlled, relative to the individual's goals and the availability of effective treatment. The ongoing evaluation of the status (presence, increase or reduction) of a resident's pain is vital, including the status of underlying causes, the response to interventions to prevent or manage pain, and the possible presence of adverse consequences of treatment. Adverse consequences related to analgesics can often be anticipated and to some extent prevented or reduced. For example, opioids routinely cause constipation, which may be minimized by an appropriate bowel regimen.

Identifying target signs and symptoms (including verbal reports and non-verbal indicators from the resident) and using standardized assessment tools can help the interdisciplinary

team evaluate the resident's pain and responses to interventions and determine whether the care plan should be revised, for example:

- If pain has not been adequately controlled, it may be necessary to reconsider the current approaches and revise or supplement them as indicated; or
- If pain has resolved or there is no longer an indication or need for pain medication, the facility works with the practitioner to discontinue or taper (as needed to prevent withdrawal symptoms) analgesics.

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

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

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

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

The SAMHSA website houses a number of resources related to opioid management including this document intended for prescribers which addresses appropriate prescribing, monitoring for adverse effects, and treating overdoses: SAMHSA Opioid Overdose Prevention Toolkit:

Information for Prescribers, <https://store.samhsa.gov/system/files/information-for-prescribers.pdf>.

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

KEY ELEMENTS OF NONCOMPLIANCE

To cite deficient practice at F697, the surveyor's investigation will generally show that the facility failed to do one or more of the following:

- Provide pain management to a resident experiencing pain; or
- Provide pain management that met professional standards of practice; or
- Provide pain management that was in accordance with the resident's comprehensive care plan, and the resident's goals for care and preferences.

INVESTIGATIVE SUMMARY

Use the Pain Recognition and Management Critical Element (CE) Pathway, along with the above interpretive guidelines when determining if the facility provides pain management that meets professional standards of practice; and that is in accordance with the resident's comprehensive care plan, goals for care and preferences.

Summary of Procedure

Briefly review the most recent comprehensive assessments, comprehensive care plan and orders to identify whether the facility has assessed and developed an individualized care plan based on professional standards of practice and provided by qualified, competent staff. During this review, identify the extent to which the facility has implemented interventions in accordance with the resident's needs, goals for care and professional standards of practice, consistently across all shifts. This information will guide observations and interviews to be made in order to corroborate concerns identified.

NOTE: Always observe for visual cues of psychosocial distress and harm (see Guidance on Severity and Scope Levels and Psychosocial Outcome Severity Guide).

DEFICIENCY CATEGORIZATION

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

- Facility failed to implement an effective pain management regime for a resident who sustained a fracture of the hip and was determined to not be a surgical candidate. Resident stated that pain medication was not effective, and she was in continuous pain. She indicated she had notified staff of the pain, but nothing was done. Interview of staff indicated no one had contacted the practitioner to discuss the ineffective pain relief. The staff stated that they were concerned regarding the amount of pain medication the resident was receiving and that they were concerned that she would become increasingly tolerant and addicted to the medication. They stated they were aware that the resident declined assistance with ADL's due to "pain" and felt that the resident was not having the amount of pain that she stated she had. The resident was observed on multiple occasions to,

holding her hip area, moaning and crying out, sweating, and striking out when staff attempted to move her.

An example of Severity Level 3 Noncompliance: Actual Harm that is not Immediate Jeopardy includes, but is not limited to:

- The facility failed to provide effective pain management to a resident with a diagnosis of bone cancer. Record review revealed the resident only had PRN (as needed) pain medication every six hours. According to the resident this pain regime was not effective resulting in excruciating breakthrough pain multiple times each day. The resident said that staff would tell her she had to wait, and often would not get the PRN medicine promptly when it was due. The surveyor observed the resident to be tearful and unable to participate in activities.

Examples of Severity Level 2 Noncompliance: No Actual Harm with potential for more than minimal harm that is Not Immediate Jeopardy includes, but is not limited to:

- Facility failed to provide an effective pain management treatment per the resident's choice and preference. A resident request a hot shower on the evening shift as an effective intervention for back pain. The staff member assigned to her informed her that she would not be able to be showered until later in the evening. A staff member who understood what the resident was experiencing quickly intervened and gave her a hot shower relieving her back pain.
- The facility staff failed to consistently evaluate the effectiveness of regularly scheduled pain medication on a resident. The resident was receiving the pain medication on a routine basis; however, the record did not reflect the resident's response to the administration of the pain medication. In interviews, the resident stated that her pain was being managed for the most part, but that staff did not ask her if she received relief from the medication. She stated that occasionally, she would not attend an activity due to discomfort, but this did not routinely occur. When she mentioned it to staff, they would tell her to lie down for a while and would check on her later. However, she stated that they usually did not recheck her. Staff interviewed stated they didn't have the time to go back, check, and record the resident's response, but, if she complained, they would recheck her and see if she needed anything else.

Severity Level 1 noncompliance: No actual harm with potential for minimal harm includes,

The failure of the facility to provide appropriate care and services related to pain management places the resident at risk for more than minimal harm. Therefore Severity 1 does not apply for this regulatory requirement.

F699

(Rev. 208; Issued:10-21-22; Effective: 10-21-22; Implementation:10-24-22)

§483.25(m) Trauma-informed care

The facility must ensure that residents who are trauma survivors receive culturally competent, trauma-informed care in accordance with professional standards of practice and accounting for residents' experiences and preferences in order to eliminate or mitigate triggers that may cause re-traumatization of the resident.

INTENT

The intent of this requirement is to ensure that facilities deliver care and services which, in addition to meeting professional standards, are delivered using approaches which are culturally-competent and account for experiences and preferences, and address the needs of trauma survivors by minimizing triggers and/or re-traumatization.

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>

“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 (“Trauma.” SAMHSA-HRSA Center for Integrated Health Solutions. Substance Abuse and Mental Health Services Administration. 30 Nov 2016. Accessed at: <http://www.integration.samhsa.gov/clinical-practice/trauma>).

“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. Referred to variably as “trauma-informed care” or “trauma-informed approach.” Adapted from Concept of Trauma and Guidance for a Trauma-Informed Approach:

<https://store.samhsa.gov/system/files/sma14-4884.pdf>

GUIDANCE: §483.25(m)

Background: *Increasingly diverse demographics among nursing home residents require nursing homes to provide culturally competent care. Cultural competency, which includes language, and cultural preferences, and other cultural aspects such as thoughts, communications, actions, customs, beliefs, values, and institutions of racial, ethnic, religious, or social groups, is an important aspect of person-centered care. These elements influence the beliefs surrounding health, healing, wellness and the delivery of health services and are critical to reducing health disparities. “Cultural competence has emerged as an important issue for three practical reasons. First, as the United States becomes more diverse, practitioners will increasingly see people with a broad range of perspectives on health, often influenced by their social or cultural backgrounds. Second, research has shown that provider-patient communication is linked to health outcomes.¹ And third, two landmark Institute of Medicine (IOM) reports—Crossing the Quality Chasm and Unequal Treatment—highlight the importance of patient-centered care and cultural competence in improving quality and eliminating health disparities.²”*

According to the Substance Abuse and Mental Health Services Administration (SAMHSA), seventy percent (70%) of adults in the United States have experienced some type of traumatic event, at least once in their lives. There is a direct correlation between trauma and physical health conditions such as diabetes, chronic obstructive pulmonary disease (COPD), heart disease, cancer, and high blood pressure.

While care and services must always be person-centered and honor residents’ choice and preferences, what is different about providing care and services to a trauma survivor is that these residents may have lost the ability to trust caregivers, and to feel safe in their environment. As a result, the principles of trauma-informed care must be addressed and applied purposefully.

The following principles pertaining to trauma-informed care have been adapted from SAMHSA’s Concept of Trauma and Guidance for a Trauma-Informed Approach, located at

<https://store.samhsa.gov/system/files/sma14-4884.pdf>

- *Safety – Ensuring residents have a sense of emotional and physical safety.*
- *Trustworthiness and transparency – Efforts to establish a relationship based on trust, and clear and open communication between the staff and the resident.*
- *Peer support and mutual self-help – If practicable, it may be appropriate to assist the resident in locating and arranging to attend support groups which are organized by qualified professionals. It may be possible for the group to meet in the facility.*

- *Collaboration – There is an emphasis on partnering between residents and/or his or her representative, and all staff and disciplines involved in the resident’s care in developing the plan of care. There is recognition that healing happens in relationships and in the meaningful sharing of power and decision-making.*
- *Empowerment, voice, and choice – Ensuring that resident’s choice and preferences are honored and that residents are empowered to be active participants in their care and decision-making, including recognition of, and building on resident’s strengths.*

Assessment

Facilities should use a multi-pronged approach to identifying a resident’s history of trauma as well as his or her cultural preferences. This would include asking the resident about triggers that may be stressors or may prompt recall of a previous traumatic event, as well as screening and assessment tools such as the Resident Assessment Instrument (RAI), Admission Assessment, the history and physical, the social history/assessment, and others. There are many psychosocial screening and assessment tools available at the following SAMHSA website: <https://www.integration.samhsa.gov/clinical-practice/screening-tools#TRAUMA>

Trauma

Residents of long-term care facilities may include, but are not limited to, trauma survivors such as military veterans, survivors of large-scale natural and human-caused disasters, Holocaust survivors, survivors of physical, sexual, and/or mental abuse (past or current), or other violent crime, as well as residents with a history of imprisonment, homelessness, or who have suffered the traumatic loss of a loved one.

The history and physical assessment done by the attending physician can reveal many clues to a resident’s history of trauma. Scars and other signs of physical trauma should be explored to determine the cause if the resident is comfortable/agreeable with discussing them. Numerical tattoos may be an indicator of World War II Holocaust survivors. Residents with a history of trauma may have diagnoses such as anxiety, depression, or may have substance abuse issues such as alcoholism, and/or may abuse prescription medications or street drugs. Evidence of physical and/or psychological trauma can be revealed during a comprehensive social history or assessment by the social worker.

Triggers

Facilities must identify triggers which may re-traumatize residents with a history of trauma. A trigger is a psychological stimulus that prompts recall of a previous traumatic event, even if the stimulus itself is not traumatic or frightening. For many trauma survivors, the transition to living in an institutional setting (and the associated loss of independence) can trigger profound re-traumatization. While most triggers are highly individualized, some common triggers may include:

- *Experiencing a lack of privacy or confinement in a crowded or small space;*
- *Exposure to loud noises, or bright/flashing lights;*

- *Certain sights, such as objects that are associated with those that used to abuse, and/or*
- *Sounds, smells, and even physical touch.*

Culture

As mentioned in the Background section above, the increasingly changing demographics of nursing homes has led to the need to provide culturally competent care. In addition to racial and ethnic diversity, this also includes religious preference, sexual orientation, and gender identity.

There are several tools that facilities may use in addition to the Resident Assessment Instrument (RAI) to assist them in identifying a resident's cultural preferences. Chapter 3 of the RAI gives guidance on completing Minimum Data Set (MDS) items in section A that addresses Race, Ethnicity, and Language with which the resident most closely identifies. These MDS items may be indicators of a resident's culture and may indicate further assessment is necessary to determine if there are any cultural preferences which should be honored while the resident is in the facility. The categories in this classification are socio-political constructs and should not be interpreted as being scientific or anthropological in nature. They provide demographic race/ethnicity specific health trend information. These categories are NOT used to determine eligibility for participation in any Federal program.

MDS Section A identifies whether the resident wants or needs an interpreter and the resident's preferred language. Inability to make needs known and to engage in social interaction because of a language barrier can result in isolation, depression, and unmet needs. Language barriers can interfere with accurate assessment.

Facilities must use their Facility Assessment (See F838 for additional guidance related to Facility Assessment) to identify resident populations having unique cultural characteristics, such as language (including American Sign Language), religious or cultural practices, values, and preferences. This facilitates a facility-wide and department-wide understanding of cultural differences and how to approach the provision of care and services with dignity and respect for the individual. (Also see, F675, Quality of Life, for further discussion of the impact of cultural differences on residents and staff.)

NOTE: Facilities are required to communicate effectively, both verbally and in writing, with residents in a language and manner they can understand. For additional information see F552, Right to be Informed/Make Treatment Decisions; F572, Notice of Rights and Rules; and F573, Right to Access/Purchase Copies of Records.

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. 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 Competence <https://nccc.georgetown.edu>*
- *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/clas/blueprint>*
- *Office of Minority Health “Think Cultural Health” website <https://www.thinkculturalhealth.hhs.gov>*
- *Georgetown University publication: Cultural Competence in Health Care: Is it important for people with chronic conditions <https://hpi.georgetown.edu/agingsociety/pubhtml/cultural/cultural.html>*

Care Planning to Address Past Trauma

The facility should collaborate with resident trauma survivors, and as appropriate, the resident’s family, friends, and any other health care professionals (such as psychologists, mental health professionals) to develop and implement individualized interventions. In some cases, if a facility has more than one trauma survivor, social services might consider establishing a support group that is run by a qualified professional, or allowing a support group to meet in the facility. In situations where a trauma survivor is reluctant to share his or her history, facilities are still responsible to try to identify triggers which may re-traumatize the resident, and develop care plan interventions which minimize or eliminate the effect of the trigger on the resident.

Trigger-specific interventions should identify ways to decrease the resident’s exposure to triggers which re-traumatize the resident, as well as identify ways to mitigate or decrease the effect of the trigger on the resident.

Examples of trigger-specific interventions include, but are not limited to the following:

<i>Trigger</i>	<i>Intervention</i>
<i>Showers/shower fixtures</i>	<i>Provide alternative methods for bathing such as tubs, sponge bath.</i>
<i>Confinement in small/crowded spaces</i>	<i>Offer individual or small group activities</i>

<i>Trigger</i>	<i>Intervention</i>
<i>Loud noises</i>	<i>Decrease/eliminate exposure to loud noises during holiday celebrations (July 4th, New Year's Eve); and/or decrease volume of, or eliminate overhead paging systems</i>
<i>Removal of clothing</i>	<i>Consideration should be given to methods of assistance given to resident such as:</i> <ul style="list-style-type: none"> • <i>Consistent staffing/same-sex care giver</i> • <i>Removing clothing slowly</i> • <i>Explanation of what is happening</i>
<i>Exposure to smoke or fire</i>	<ul style="list-style-type: none"> • <i>Remove from areas where smoking is permitted, or cookouts occur;</i> • <i>Provide alternative meals inside facility</i>

Additionally, trauma-specific interventions should recognize the interrelation between trauma and symptoms of trauma such as substance abuse, eating disorders, depression, and anxiety.

Trauma-specific interventions generally recognize the survivor's need to be respected, informed, connected, and hopeful regarding their own recovery. Trauma survivors may need access to support groups either in the facility or in the community, if appropriate and feasible.

Care Planning to address Cultural Preferences

When a facility admits a resident, it has determined that it can provide the individualized care and services that resident requires. Facilities must create and sustain an environment that humanizes and promotes each resident's well-being and feeling of self-worth and self-esteem. This requires nursing home leadership to establish a culture that treats each resident with respect and dignity as an individual, and addresses, supports and/or enhances his/her feelings of self-worth including personal control over choices and cultural preferences.

It is important for facilities to be aware of the impact of culture and cultural preferences on the provision of care and have an understanding of the cultural norms and practices of the individuals they care for. For example, in some cultures, it may be considered taboo to direct care at end of life; or in other cultures care must be provided by caregivers of the same sex as the resident.

In order to provide culturally competent care, staff must understand the cultural preferences of the individual and how it impacts the delivery of care. A key component is identifying how to communicate with the resident, in order to be able to identify physical concerns and issues, and for developing a trusting relationship with staff. For example, if the resident is non-English speaking, or has limited understanding of English, the facility should identify how communication will occur with the resident. The care plan should identify the language spoken and what tools are available to communicate, whether it be with a communication board or other systems, or through translators. If

communication systems are used, all staff interacting with the resident must know where those materials are kept, must understand how to use them, and consistently implement use of those methods. Staff must demonstrate proficiency in communicating with the resident to assure that critical information can be conveyed, such as a change in condition, the presence of pain, explanation of routine care, and the ability to refuse care and services. The facility must provide sufficient guidance for staff, including temporary staff, on how to communicate and deliver care for the resident. See also §483.10(c)(1), Resident Rights and §483.21(b)(3)(iii) Comprehensive Person-Centered Care Planning.

There are many aspects of cultural preferences which may impact the delivery of care, such as:

- *Food preparation and choices;*
- *Clothing preferences such as covering hair or exposed skin;*
- *Physical contact or provision of care by a person of the opposite sex; or*
- *Cultural etiquette, such as avoiding eye contact or not raising the voice.*

Additionally, facilities should consider:

- *Offering activities that are culturally relevant to resident populations within the facility;*
- *Group activities with both sexes may not be permitted or appropriate in some cultures, or the type of programming may be in conflict with his/her cultural preferences;*
- *Providing reading materials, movies, newspapers in the resident's preferred language may help orient a resident to date, times and events;*
- *Allowing the performance of religious rites at end of life to the extent possible; and*
- *Certain medications, procedures or treatments may be prohibited.*

Social services and facility administration may need to evaluate how forms, including informed consent forms, are provided in the language used by the resident. As mentioned above, this is a facility-wide opportunity to provide a culturally diverse environment, respecting and treating each resident with dignity. Assisting the resident and his/her representative with daily schedules, developed with input by the resident/representative, ahead of time may alleviate fear and frustration.

*Resident-specific approaches must be developed and included in the resident's care plan. These interventions must be provided consistently, and supervising staff should monitor the delivery of care and staff interactions with the resident to assure they are implemented as written. Using consistent staff, to the extent possible, will assist the resident in feeling more comfort in the facility. If concerns related to culturally competent and/or trauma-informed **care planning** are identified, see additional guidance at §483.21(b) in F656.*

Monitoring Delivery of Care and Services

As required with any care plan interventions, facilities must monitor the effects of their approaches to ensure they are implemented as intended, and are having the desired effect to achieve the measurable objectives and the resident's goals for care. For residents with a history of trauma in particular, facilities must evaluate whether the interventions have been able to mitigate (or reduce) the impact of identified triggers on the resident that may cause re-traumatization. It is critical to involve the resident and/or his or her family or representative in this evaluation to ensure clear and open discussion and better understand if interventions must be modified.

It may be necessary to engage the services of an interpreter to monitor or evaluate the effect of cultural interventions for non-English speaking residents. As noted above, it is critical to involve the resident and/or his or her family in evaluating the effectiveness of cultural interventions in achieving measurable objectives and resident goals.

Surveyors should refer to the following when investigating concerns and citing noncompliance 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)*

KEY ELEMENTS OF NONCOMPLIANCE

To cite deficient practice at F699, the surveyor's investigation will generally show that the facility failed to do any one of the following:

- Identify cultural preferences of residents who are trauma survivors;*
- Identify a resident's past history of trauma, and/or triggers which may cause re-traumatization;*
- Consistently use approaches that are culturally competent and/or are trauma-informed*

INVESTIGATIVE SUMMARY

Use the General Critical Element (CE) Pathway along with the above interpretive guideline when determining if the facility meets the requirements to provide culturally competent, trauma-informed care in accordance with professional standards of practice and accounting for residents' experiences and preferences in order to eliminate or mitigate triggers that may cause re-traumatization of the resident.

DEFICIENCY CATEGORIZATION

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

A resident was admitted with a history of sexual abuse by a male and a diagnosis of post-traumatic stress disorder. The resident requested only female staff provide perineal care due to her severe trauma. A male staff person answered the resident's call light for assistance to the bathroom and insisted on performing perineal care as he was the only staff member available at the time. She refused his assistance and began to get visibly upset and requested that a female staff member be called in. The resident stated that the male staff member insisted on performing perineal hygiene after she had toileted despite the residents past trauma. After returning her to her bed, she was crying and distraught and stated that she was afraid to request assistance with perineal care as he might return. She stated she cried all night and that she had profuse sweating, fearing that someone was outside her door, waiting to come in if she fell asleep. Eventually the resident fell asleep but awakened screaming, kicking and throwing objects, re-living her previous sexual assault. She told staff who came into her room that she was fearful for her life, felt dirty and demeaned, that she wasn't respected, and there was no reason to go on living.

An example of Severity Level 3 Noncompliance: Actual Harm that is not Immediate Jeopardy includes, but is not limited to:

Residents were gathered to watch July 4th fireworks on television. A resident with a known history of surviving a mass shooting several years ago was placed in the activity room to watch the fireworks. When the show began, the resident became tearful and frightened when he heard the sound of the fireworks which resembled the sound of gun shots. The facility staff noticed that the resident was tearful and appeared frightened. When asked what was wrong, the resident shared that he was having flashbacks from the mass shooting he survived years ago. The staff member rubbed the resident's back and said "it will be ok, the show is only 30 minutes long." The resident remained in the activity room for the duration of the fireworks and continued to be tearful. In the following weeks, the resident decreased his attendance at activities that he previously enjoyed.

An example of Severity Level 2 Noncompliance: No Actual Harm with potential for more than minimal harm that is not Immediate Jeopardy includes, but is not limited to:

Facility staff escorted residents to a local baseball game. One of the residents was a survivor of a refugee camp and is not comfortable in highly populated areas. Prior to leaving for the game, facility staff failed to consider the resident's discomfort with crowded areas due to his time in a refugee camp. Upon arriving to the baseball game, there were hundreds of fans that came to watch the game. While watching the game, the resident informed one of the facility staff members that he was not enjoying himself because he was feeling anxious in the stadium with so many people around him and often has panic attacks when he is in crowded areas too long. The facility staff member immediately escorted the resident out of the stadium and onto the bus where his anxiety resolved.

An example of Severity Level 1 noncompliance: No actual harm with potential for minimal harm:

Because of the potential for psychosocial harm, noncompliance at F699 should generally not be cited at severity level 1.

F700

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§483.25(n) Bed Rails.

The facility must attempt to use appropriate alternatives prior to installing a side or bed rail. If a bed or side rail is used, the facility must ensure correct installation, use, and maintenance of bed rails, including but not limited to the following elements.

§483.25(n)(1) Assess the resident for risk of entrapment from bed rails prior to installation.

§483.25(n)(2) Review the risks and benefits of bed rails with the resident or resident representative and obtain informed consent prior to installation.

§483.25(n)(3) Ensure that the bed's dimensions are appropriate for the resident's size and weight.

§483.25(n)(4) Follow the manufacturers' recommendations and specifications for installing and maintaining bed rails.

INTENT §483.25(n)

The intent of this requirement is to ensure that prior to the installation *or use* of bed rails, the facility attempts to use alternatives. If the *attempted* alternatives were not adequate to meet the resident's needs, the resident is assessed for the use of bed rails, which includes a review of risks including entrapment; and informed consent is obtained from the resident or if applicable, the resident representative. The facility must ensure the bed is appropriate for the resident and that bed rails are properly installed and maintained.

DEFINITIONS §483.25(n)

"Entrapment" is an event in which a resident is caught, trapped, or entangled in the space in or about the bed rail.

"Bed rails" are adjustable metal or rigid plastic bars that attach to the bed. They are available in a variety of types, shapes, and sizes ranging from full to one-half, one-quarter, or one-eighth lengths. Also, some bed rails are not designed as part of the bed by the manufacturer and may be installed on or used along the side of a bed.

Examples of bed rails include, but are not limited to:

- Side rails, bed side rails, and safety rails; and

- Grab bars and assist bars.

GUIDANCE §483.25(n)

Even when bed rails are properly designed to reduce the risk of entrapment or falls, are compatible with the bed and mattress, and are used appropriately, they can present a hazard to certain individuals, particularly to people with physical limitations or altered mental status, such as dementia or delirium.

Resident Assessment

After a facility has *first* attempted *to use appropriate* alternatives to bed rails and determined that these alternatives do not meet the resident's needs, the facility must assess the resident for the risks of entrapment and *review* possible *risks and* benefits of bed rails *prior to installation or use*. In determining whether to use bed rails to meet the needs of a resident, the following components of the resident assessment should be considered including, but not limited to:

- Medical diagnosis, conditions, symptoms, and/or behavioral symptoms;
- Size and weight;
- Sleep habits;
- Medication(s);
- Acute medical or surgical interventions;
- Underlying medical conditions;
- Existence of delirium;
- Ability to toilet self safely;
- Cognition;
- Communication;
- Mobility (in and out of bed); *and*
- Risk of falling.

In addition, the resident assessment must include an evaluation of the alternatives that were attempted *prior to the installation or use of a bed rail* and how these alternatives failed to meet the resident's assessed needs.

The facility must also assess the resident's risk from using bed rails. The following includes *examples of the* potential risks *with* the use of bed rails, as identified by the Food and Drug Administration's Hospital Bed Safety Workgroup Clinical Guidance For the Assessment and Implementation of Bed Rails In Hospitals, Long Term Care Facilities, and Home Care Settings (April 2003), and *that* have been adapted for surveyor guidance:

- Accident hazards
 - The resident could attempt to climb over, around, between, or through the rails, or over the foot board,
 - A resident or part of his/her body could be caught between rails, the openings of the rails, or between the bed rails and mattress.
- Barrier to residents from safely getting out of bed

- A resident could crawl over rails and fall from greater heights increasing the risk for serious injury
- A resident could attempt to get out of bed over the foot board
- Physical restraint
 - Hinders residents from independently getting out of bed thereby confining them to their beds
 - Creates a barrier to performing routine activities such as going to the bathroom or retrieving items in his/her room
- Other potential negative physical outcomes
 - Decline in resident function, such as muscle functioning/balance
 - Skin integrity issues
- Decline in other areas of activities of daily living such as using the bathroom, continence, eating, hydration, walking, and mobility
- Other potential negative psychosocial outcomes
 - Creates an undignified self-image and alter the resident's self-esteem
 - Contributes to feelings of isolation
 - Induces agitation or anxiety

These potential risks can be exacerbated by improper match of the bed rail to bed frame, improper installation and maintenance, and use with other devices or supports that remain when the bed rail is removed.

Entrapment may occur when a resident is caught between the mattress and bed rail or in the bed rail itself. Although not all bed rails create a risk for entrapment, injury may still occur *and is varied* depending on the resident. Residents most at risk for entrapment are those who are frail or elderly or those who have conditions such as agitation, delirium, confusion, pain, uncontrolled body movement, hypoxia, fecal impaction, acute urinary retention, etc. that may cause them to move about the bed or try to exit from the bed. The untimeliness of assistance using the bathroom and inappropriate positioning or other care-related activities can contribute to the risk of entrapment.

Informed Consent

- After *appropriate* alternatives have been attempted and prior to installation, the facility must obtain informed consent from the resident or the resident representative for the use of bed rails. The facility should maintain evidence that it has provided sufficient information so that the resident or resident representative could make an informed decision. *Information that the facility should provide to the resident, or resident representative include, but are not limited to:*
 - What assessed medical needs would be addressed by the use of bed rails;
 - The resident's benefits from the use of bed rails and the likelihood of these benefits;
 - The resident's risks from the use of bed rails and how these risks will be mitigated; and
 - Alternatives attempted that failed to meet the resident's needs and alternatives considered but not attempted because they were considered to be inappropriate.

The information should be presented to the resident or the resident representative, so that it could be understood and that consent can be given voluntarily, free from coercion.

Appropriate Alternatives

Facilities must attempt to use appropriate alternatives prior to installing or using bed rails. CMS encourages facilities to refer to published information from recognized authorities such as the Food and Drug Administration, which has identified the following alternatives to bed rail use: “Alternatives include: roll guards, foam bumpers, lowering the bed and using concave mattresses that can help reduce rolling off the bed.” This and more information may be found at

<https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/ConsumerProducts/BedRailSafety/ucm362843.htm>. This webpage was last updated in December, 2017.

See also, Clinical Guidance for Assessment and Implementation of Bed Rails in Hospitals, Long Term Care Facilities, and Home Care Settings; <https://www.fda.gov/downloads/HospitalBeds/UCM397178.pdf>.

Recommendations for Health Care Providers about bed rails;

<https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/ConsumerProducts/BedRailSafety/ucm362848.htm>

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

- purpose for which the bed rail was intended and evidence that alternatives were tried and were not successful*
- assessment of the resident, the bed, the mattress, and rail for entrapment risk (which would include ensuring bed dimensions are appropriate for resident size/weight), and*
- risks and benefits were reviewed with the resident or resident representative, and informed consent was given before installation or use.*

Installation and Maintenance of Bed Rails

Assuring the correct installation and maintenance of bed rails is an essential component in reducing the risk of injury resulting from entrapment or falls. The FDA and the United States Consumer Product Safety Commission (CPSC) has recommended the following initial and ongoing actions to prevent deaths and injuries from entrapment and/or falls from bed rails:

- Before bed rails are installed, the facility should:

- Check with the manufacturer(s) to make sure the bed rails, mattress, and bed frame are compatible, since most bed rails and mattresses are purchased separately from the bed frame.

NOTE: The FDA has published (1) the Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment as a resource to reduce entrapments resulting from hospital beds and (2) Practice Hospital Bed Safety as to the proper dimensions and distance of various parts of the beds (i.e., distance between bed frames and mattresses, bed rails and mattresses, etc.)

- Rails should be selected and placed to discourage climbing over rails, which could lead to falling over bed rails.
- When installing and using bed rails, the facility should:
 - Ensure that the bed's dimensions are appropriate for the resident.
 - Confirm that the bed rails to be installed are appropriate for the size and weight of the resident using the bed.
 - Install bed rails using the manufacturer's instructions *and specifications* to ensure a proper fit.
 - Inspect and regularly check the mattress and bed rails for areas of possible entrapment.
 - Regardless of mattress width, length, and/or depth, the bed frame, bed rail and mattress should leave no gap wide enough to entrap a resident's head or body. Gaps can be created by movement or compression of the mattress which may be caused by resident weight, resident movement or bed position, or by using a specialty mattress, such as an air mattress, mattress pad or water bed.
 - Check bed rails regularly to make sure they are still installed correctly as rails may shift or loosen over time.

In addition, ongoing precautions may include following manufacturer equipment alerts and recalls and increasing resident supervision.

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

Facilities must also conduct routine preventive maintenance of beds and bed rails to ensure they meet current safety standards and are not in need of repair.

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

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

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

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

Ongoing Monitoring and Supervision

Assuring the correct use of an installed bed rail and maintenance of bed rails is an essential component in reducing the risk of injury. After the installation of bed rails, it is expected that the facility will continue to provide necessary treatment and care *to the resident* in accordance with professional standards of practice and the resident's choices. This should be evidenced in the resident's records, *including their care plan*, including, *but not limited to*, the following *information*:

- The type of specific direct monitoring and supervision provided during the use of the bed rails, including documentation of the monitoring;
- The identification of how needs will be met during use of the bed rails, such as for re-positioning, hydration, meals, use of the bathroom and hygiene;
- Ongoing assessment to assure that the bed rail is used to meet the resident's needs;
- Ongoing evaluation of risks;
- The identification of who may determine when the bed rail will be discontinued; and
- The identification and interventions to address any residual effects of the bed rail (e.g., generalized weakness, skin breakdown).

KEY ELEMENTS OF NONCOMPLIANCE §483.25(n)

To cite deficient practice at F700, the surveyor's investigation will generally show that the facility failed to do one or more of the following:

- Identify and use appropriate alternative(s) prior to installing or *using* a *side or* bed rail;
- Assess the resident for risk of entrapment prior to installing or *using* a bed rail;
- Assess the risk versus benefits of using a bed rail and review them with the resident or the resident's representative;
- Obtain informed consent for the installation and use of bed rails prior to *use*.
- Ensure appropriate dimensions of the bed based on the resident's size and weight;
- Ensure correct installation of bed rails, including adherence to manufacturer's recommendations and/or specifications;
- Ensure correct use of an installed bed or side rail; and
- Ensure scheduled maintenance of any bed rail in use according to *the* manufacturer's recommendations and specifications.

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

INVESTIGATIVE PROTOCOL §483.25(n)

Use this protocol for:

- A sampled resident who has MDS data that indicates a bed/side rail is used;
- Surveyor observation of the use of a bed/side rail for a resident; and/or
- An allegation of inappropriate use of a bed/side rail received by the State Survey Agency.

PROCEDURES §483.25(n)

Briefly review the assessment, care plan, and orders of the resident to identify facility interventions and to guide observations to be made. Corroborate observations by interview and record review.

Observation- Resident

During observations of a resident who has bed/side rails, determine:

- What type of bed rail is installed *or used* and for how long the bed rail has been in use;
- If the bed rail in good working order;
- Frequency of use of the bed rail;
- Any physical or psychosocial reaction to the bed rail, such as attempts to release/remove the bed rail, verbalizing anger/anxiety;
- Who *raises and lowers* the bed rail and how often monitoring is provided;
- How the resident is positioned in the bed relative to the bed rails and how the resident moves in bed;
- How the resident requests staff assistance (e.g., access to the call light);

- Whether the resident is toileted, ambulated or provided exercises or range of motion when the bed rails are released, who released the bed rails and for how long;

NOTE: A resident may have a device in place that the facility has stated can be removed by the resident. For safety reasons, do not request that the resident remove the bed rails, but rather request that staff ask the resident to demonstrate how he/she releases the bed rails.

Interview-Resident or Resident Representative

Interview the resident, or if applicable, the resident representative, to the degree possible to identify:

- Who requested the bed rail to be installed *or used*,
- Prior to the use of the bed rail, whether staff provided information regarding how the bed rail would address a resident need, the risks and benefits, and alternatives to bed rails, when and how long the bed rails were going to be used;
- Whether the interdisciplinary team provided interventions for monitoring and release of the bed rails for activities, such as use of the bathroom, walking and range of motion;
- Whether staff discussed mobility issues with the resident, or resident's representative, when the bed rail is in use and/or other impacts on activities of daily living and involvement in activities; and
- How the resident can request staff assistance when the bed rail is in use.

Interviews-Staff

Interview direct care and licensed nursing staff on various shifts who provide care to the resident to determine:

- Knowledge of specific interventions related to the use of the bed rails for the resident, including:
 - When use of the bed rail was initiated;
 - The rationale for selecting the bed rail for use;
 - Identifying the benefits and risks of using the bed rail;
- What is the resident's functional ability, such as bed mobility and ability to transfer between positions, to and from bed or chair, to toilet and to ability to stand;
- Whether there have been any physical and/or psychosocial changes related to the use of the bed rail, such as increased incontinence, decline in ADLs or ROM, increased confusion, agitation, and depression;
- Whether other interventions have been attempted to minimize or eliminate the use of the bed rails; and
- Whether there are facility guidelines/protocols for the use of bed rails.

Interview the charge nurse, to gather the following additional information:

- How the implementation of the use of bed rails is monitored and who is responsible for the monitoring;
- Who evaluates and assesses the resident to determine the ongoing need for bed rails;
- Whether bed rail use should be gradually decreased; and
- How the modifications for the interventions are evaluated for effectiveness in discontinuing the use of the bed rails.

Record Review

Review the MDS, assessments, physician orders, therapy and nursing notes and other progress notes that may have assessment information related to use of the bed rail. Determine whether identified decline can be attributed to a disease progression or use of bed rails. Determine whether the assessment information accurately and comprehensively reflects the status of the resident for:

- The identification of specific medical symptom(s) for which the bed rail is used;
- Functional ability, including strength and balance (such as bed mobility and ability to transfer between positions, to and from bed or chair, and to stand and the ability to toilet);
- Identification of the resident's risks such as physical/functional decline and psychosocial changes, and benefits, if any, due to the use of the bed rails;
- Attempts at using alternatives to bed rails, including how the alternatives did not meet the resident's medical or safety need or were inappropriate;
- Identification of any injuries, or potential injuries, that occurred during the use of bed rails.

When the interdisciplinary team has determined that a resident may benefit from the use of a device for mobility or transfer, whether the assessment includes a review of the resident's:

- Bed mobility; and
- Ability to transfer between positions, to and from bed or chair, to stand and the ability to toilet.

Review the resident's care plan to determine if it is consistent with the resident's specific conditions, risks, needs, behaviors, preferences, current professional standards of practice, and included measurable objectives and timetables, with specific interventions/services for use of the bed rail. The care plan may include:

- Which medical need would be met through the use of bed rails;
- How often the bed rail is applied, duration of use, and the circumstances for when it is to be used;

- How monitoring is provided, and when and how often the bed rail is to be released and assistance provided for use of the bathroom, walking and range of motion;
- What the resident's functional ability is, such as bed mobility and ability to transfer between positions, to and from bed or chair, and to stand and toilet and staff required for each function that requires assistance;
- Identification of interventions to address any potential complications such as physical and/or psychosocial changes related to the use of the bed rails, such as increased incontinence, decline in ADLs or ROM, increased confusion, agitation, and depression;
- Identification of interventions to minimize or eliminate the use of the bed rails; and
- Who monitors for the implementation of the use of the bed rails, and who evaluates and assesses the resident to determine the ongoing need for bed rails, whether the bed rail use should be gradually decreased, and how the modifications for the interventions are evaluated for effectiveness in discontinuing the use of the bed rail.

DEFICIENCY CATEGORIZATION §483.25(n)

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

- A facility failed to attempt to use alternatives to bed rails and assess a resident for risk of entrapment. The resident was assessed to be at risk of falls when she made repeated attempts to self-transfer off of her bed. All of the falls occurred when a half side rail was in use. According to a facility accident report, the resident was found on the floor with her back against the bed, holding onto one of the half side rails with both hands, with her neck wedged between the half side rails. The resident was able to remove herself from between the mattress and the bed rail, and did not sustain any injuries from the fall. After this incident, the facility performed a bed rail assessment, which did not indicate the risks/benefits of using bed rails. However, no changes were made to the resident's care plan, nor was there any documentation that the facility considered discontinuing use of the bed rails. Nine months later, the resident was found dead on the floor next to her bed, with her head wedged between the half side rail and the mattress. The resident's death certificate listed the cause to be asphyxiation-positional, extrinsic compression of the neck, and neck trapped under the bed rail.
- The facility failed to assess the resident for use of a bed rail, and failed to ensure that the bed rails did not pose a risk of entrapment or injury from falls. A moderately cognitively impaired resident was admitted to the facility who required extensive assistance with bed mobility and transfer, and was not ambulatory. The nursing assessment completed on admission indicated that the resident was at high risk for falls and full bed rails were used on all open sides of the bed. No assessment related to the use of bed rails was completed. A facility investigation report revealed that the resident crawled to the foot of his bed with

the full bed rails in a raised position, tried to stand and ambulate, and fell off the right side of the bed. The resident sustained a femoral neck fracture and was hospitalized.

- A facility failed to attempt to use alternatives to bed rails and assess a resident for risk of entrapment. A bed rail assessment indicated that two half side rails would be used for the resident to promote independence. There was no evidence that the facility evaluated risks associated with bed rail use when the facility changed the bed mattress to an air mattress. A facility accident report indicated that a nurse aide discovered the resident on the floor, with his/her head positioned between the side rail and the air mattress. The resident had visible bruising to the neck, had no pulse, or blood pressure.

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

An example of noncompliance that demonstrates severity at level three includes, but is not limited to:

- A facility failed to ensure the resident's bed dimensions were appropriate for the resident's size and weight. An extremely obese resident fell out of bed and sustained an injury while using the bed rail as an enabler to turn on his side. The bed was narrow and the bed rail could not sustain his weight and broke. The bed was meant to sustain the size and weight of a smaller person per manufacturer's directions.

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

An example of noncompliance that demonstrates severity at level two includes, but is not limited to:

- The facility failed to inform a resident/representative of the risks and benefits of using side rails, prior to installing *or using* them on the resident's bed. The resident was cognitively impaired and was unable to comprehend, however, the staff did not contact the resident's representative to provide the information.

Examples of Severity Level 1 Noncompliance No Actual Harm with Potential for Minimal Harm include, but are not limited to: Facility failed to have a schedule for routine maintenance of its four beds with bed rails, which were newly installed two years ago. There is no evidence of incidents or injuries in those two years, the relevant resident care plans appear appropriate regarding bedrail usage, and the facility provides evidence of checks by staff on the impacted residents and appropriate use and installation of bed rails.

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

Other resources which may be useful:

Falls

National Council on Aging National Falls Prevention Resource Center at
<http://www.ncoa.org/center-for-healthy-aging/falls-resource-center>

Centers for Disease Control and Prevention at
<http://www.cdc.gov/homeandrecreationalafety/falls/>

World Health Organization Fall Prevention in Older Age at
http://www.who.int/ageing/projects/falls_prevention_older_age/en/

National Institute of Health- Senior Health at
<http://nihseniorhealth.gov/falls/aboutfalls/01.html>

Wandering and Elopement Resources

National Council of Certified Dementia Practitioners at <http://www.nccdp.org>

F712

(Rev. 208; Issued:10-21-22; Effective: 10-21-22; Implementation:10-24-22)

§483.30(c) Frequency of physician visits.

§483.30(c)(1) The resident must be seen by a physician at least once every 30 days for the first 90 days after admission, and at least once every 60 *days* thereafter.

§483.30(c)(2) A physician visit is considered timely if it occurs not later than 10 days after the date the visit was required.

§483.30(c)(3) Except as provided in paragraphs (c)(4) and (f) of this section, all require physician visits must be made by the physician personally.

DEFINITIONS §483.30(c)

Must be seen, for purposes of the visits required by §483.30(c)(1), means that the physician or NPP must make actual face-to-face contact with the resident, and at the same physical location, not via a telehealth arrangement. There is no requirement for this type of contact at the time of admission, since the decision to admit an individual to a nursing facility (whether from a hospital or from the individual's own residence) generally involves physician contact during the period immediately preceding the admission.

“Non-physician practitioner (NPP)” means a nurse practitioner (NP), clinical nurse specialist (CNS) or physician assistant (PA).

GUIDANCE §483.30(c)

The timing of physician visits is based on the admission date of the resident.

In a SNF, the first physician visit (this includes the initial comprehensive visit) must be conducted within the first 30 days after admission, and then at 30 day intervals up until 90 days after the admission date. After the first 90 days, visits must be conducted at least once every 60 days thereafter.

Permitting up to 10 days’ slippage of a due date will not affect the next due date. However, do not specifically look at the timetables for physician visits unless there is indication of inadequate medical care. The regulation states that the physician (or his/her delegate) must visit the resident **at least** every 30 or 60 days. There is no provision for physicians to use discretion in visiting at intervals longer than those specified at §483.30(c), F712. Although the physician may not delegate the responsibility for conducting the initial visit in a SNF, NPPs may perform other medically necessary visits prior to and after the physician’s initial visit, as allowed by State law.

After the initial physician visit in SNFs, where States allow their use, an NPP may make every other required visit. (See §483.30(e), F714 Physician delegation of tasks in SNFs.) These alternate visits, as well as medically necessary visits, may be performed and signed by the NPP. (Physician co-signature is not required, unless required by State law).

In a NF, the physician visit requirement may be satisfied in accordance with State law by an NPP who is not an employee of the facility but who is working in collaboration with a physician and who is licensed by the State and performing within the state’s scope of practice. (See §483.30(f)).

In a NF, medically necessary visits performed by NPPs employed by the facility, may not take the place of physician required visits, nor may the visit count towards meeting the physician visit schedule prescribed at §483.20(c)(1).

In SNFs and NFs, facility policy that allows NPPs to conduct required visits, and/or allows a 10-day slippage in the time of the required visit, does not relieve the physician of the obligation to visit a resident personally when the resident’s medical condition makes that visit necessary.

Table 1: Authority for Non-Physician Practitioners to Perform Visits, Sign Orders and Sign Medicare Part A Certifications/Re-certifications when Permitted by the State

	Initial Comprehensive Visit	Admission Orders*	Other Required Visits & Orders[^]	Other Medically Necessary Visits & Orders⁺	Certification/Recertification[±]
SNFs					
PA, NP & CNS employed by the facility	May not perform	<i>May not provide</i>	May perform alternate visits <i>and sign</i>	May perform and sign	May not sign
PA, NP & CNS not a facility employee	May not perform	<i>May not provide</i>	May perform alternate visits <i>and sign</i>	May perform and sign	May sign <i>as permitted under State laws.</i>
NFs					
PA, NP, & CNS employed by the facility	May not perform	<i>May not provide</i>	May not perform <i>or sign</i>	May perform and sign	Not applicable
PA, NP, & CNS not a facility employee	May perform	<i>May provide*</i>	May perform <i>and sign</i>	May perform and sign	Not applicable

*A NPP may provide admission orders if a physician personally approved in writing a recommendation for admission to the facility prior to *the resident's* admission. For additional requirements on physician recommendation for admission and admission orders, see §483.30(a), F710.

[^] Other required visits are the physician visits required by §483.30(c)(1) other than the initial comprehensive visit.

⁺ Medically necessary visits are independent of required *physician* visits §483.30(c)(1) and may be performed prior to the initial comprehensive visit *as permitted under state laws.*

[±]Though not part of a compliance determination for this section, this *column* is provided for clarification and relates specifically to coverage of a Part A Medicare stay *requirements*, which can take place only in a Medicare-certified SNF.

In a facility where beds are dually-certified under Medicare and Medicaid, the facility must determine how the particular resident stay is being paid in order to identify whether physician delegation of tasks is permissible and if an NPP may perform the tasks. For example:

- For residents in a Part A Medicare stay, the NPP must follow the requirements for physician services in a SNF. This includes, at the option of a physician, required physician visits alternated between personal visits by the physician and visits by an NPP after the physician makes the initial comprehensive visit; and
- For residents in a Medicaid stay, the NPP must follow the requirements for physician services in a NF. An NPP who is not employed by the facility and is working in collaboration with a physician may perform any required physician task for a resident in a Medicaid-stay, at the option of the State. (NPPs employed by the facility may not perform required physician visits but may perform other medically necessary visits)

It is expected that visits will occur at the facility rather than the doctor's office unless office equipment is needed or a resident specifically requests an office visit. If the facility has established policy that residents leave the grounds for medical care, the resident does not object, and this policy does not infringe on his/her rights including the right to privacy, there is no prohibition to this practice. The facility should inform the resident of this practice, in accordance with §483.10(g)(16), F581, Notice of rights and services.

Certifications/Re-certifications in SNFs: Under 42 CFR §424.20, certifications and re-certifications are required to verify that a resident requires daily skilled nursing care or rehabilitation services. NPs, CNSs, and PAs who are not employed by the facility and who are working in collaboration with a physician may sign the required initial certification and re- certifications when permitted under the scope of practice for the State. 42 CFR §424.20(e)(2).

PROBES §483.30(c)

- Does the scheduling and frequency of physician visits relate to any identified quality of care problems?
- If the resident is admitted under a SNF stay, did the physician conduct the initial comprehensive visit, in-person, within the first 30 days?
- If the resident is admitted under a NF stay, did the physician or an NPP who is not employed by the facility but who is working in collaboration with a physician conduct the initial comprehensive visit, in-person, within the first 30 days?
- Are physician visits conducted at the required intervals, with no more than 10 days slippage from the due date?

- In a SNF, if the physician delegates required visits to an NPP, does the physician personally conduct alternate visits with the NPP as required?
- Does the resident or resident representative report meeting with the physician? If so, how often?

POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION

If the failure of the physician to visit the resident at the required intervals resulted in a negative outcome to the resident, also investigate compliance with §483.30(a), F710, Resident's care supervised by a physician.

DEFICIENCY CATEGORIZATION

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

- The facility failed to ensure the attending physician conducted required visits for several consecutive months in the facility. The physician responded to phone calls and provided verbal orders during this time-frame, however did not visit and make face-to-face contact with the resident, who experienced a significant negative change in status. No other physicians or NPPs visited the resident. This placed the resident at risk for serious harm or death.

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

- A resident newly admitted to the facility and determined to be at high risk of developing a pressure ulcer/injury, developed an unstageable pressure ulcer during the first 30 days. While the physician was consulted by telephone, the facility failed to ensure the physician conducted an initial comprehensive visit for over 40 days, contributing to the decline in the resident's skin status.

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

- The facility failed to ensure the physician *personally* conducted an initial comprehensive visit within the first 30 days after admission, for a resident under a Medicare Part A stay.

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

- The facility failed to ensure that the attending physician alternated required monthly visits with the Nurse Practitioner (*NP*) as required for a resident under a SNF stay. A review of the Progress Notes revealed that notes were written, signed and dated by the NP for several consecutive visits, and all of the resident's needs were met. No documentation was found to indicate that the attending physician had visited and examined the resident at least once every

30 days for the first 90 days after admission or at least once every 60 days thereafter during this time.

F725

(Rev. 208; Issued:10-21-22; Effective: 10-21-22; Implementation:10-24-22)

§483.35 Nursing Services

The facility must have sufficient nursing staff with the appropriate competencies and skills sets to provide nursing and related services to assure resident safety and attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident, as determined by resident assessments and individual plans of care and considering the number, acuity and diagnoses of the facility's resident population in accordance with the facility assessment required at §483.70(e).

§483.35(a) Sufficient Staff.

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

- (i) Except when waived under paragraph (e) of this section, licensed nurses; and**
- (ii) Other nursing personnel, including but not limited to nurse aides.**

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

INTENT §483.35(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(f) *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, §483.70(e) an assessment of the resident population is the foundation of the facility assessment and determination of the level of sufficient staff needed. It must include an evaluation of diseases, conditions, physical 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(q)). 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 §483.70(e). Does the type and level of the staff onsite reflect the expectations described in the facility assessment?
- Does the workload or assignments of the nursing staff allow them time to participate in team meetings, care planning meetings, attend training, spend time caring for residents and take time for breaks including meal breaks?
- *Are 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.*

F727

(Rev. 208; Issued:10-21-22; Effective: 10-21-22; Implementation:10-24-22)

§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, §483.70(e), 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(q)). 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.*

F729

(Rev. 208; Issued:10-21-22; Effective: 10-21-22; Implementation:10-24-22)

§483.35(d)(4) Registry verification.

Before allowing an individual to serve as a nurse aide, a facility must receive registry verification that the individual has met competency evaluation requirements unless—

- (i) The individual is a full-time employee in a training and competency evaluation program approved by the State; or**
- (ii) The individual can prove that he or she has recently successfully completed a training and competency evaluation program or competency evaluation program approved by the State and has not yet been included in the registry. Facilities must follow up to ensure that such an individual actually becomes registered.**

§483.35(d)(5) Multi-State registry verification.

Before allowing an individual to serve as a nurse aide, a facility must seek information from every State registry established under sections 1819(e)(2)(A) or 1919(e)(2)(A) of the Act that the facility believes will include information on the individual.

§483.35(d)(6) Required retraining.

If, since an individual's most recent completion of a training and competency evaluation program, there has been a continuous period of 24 consecutive months during none of which the individual provided nursing or nursing-related services for monetary compensation, the individual must complete a new training and competency evaluation program or a new competency evaluation program.

GUIDANCE §§483.35(d)(4)-(6)

If the nurse aide provides documentation to verify that he or she performed nursing or nursing-related services for monetary compensation (including providing assistance with activities of daily living (ADL) care) for at least one documented day (e.g., 8 consecutive hours) during the previous 24 months, he/she is not required to take a new nurse aide training and competency evaluation program or a new competency evaluation program (NATCEP/CEP). It is not required that these services be provided in a nursing home setting so long as the nurse aide was performing nursing or nursing-related services, including assisting with ADLs, *for monetary compensation*. The State is required to remove the individual's name from the registry if the services are not provided for monetary compensation during the 24-month period.

PROCEDURE

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

- Review the nurse aide personnel folder to determine if the facility received registry verification that the individual has met competency evaluation requirements before the employee's start date unless an exception applies as noted in §483.35(d)(4).*
- Review the nurse aide personnel folder to determine if the facility verified information from every State registry that the facility believes will include information concerning that individual before the employee's start date.*
- If records reveal a nurse aide has not provided nursing related services for monetary compensation over a 24-month period, did the individual complete a new training and competency evaluation program?*

F732

(Rev. 208; Issued:10-21-22; Effective: 10-21-22; Implementation:10-24-22)

§483.35(g) Nurse Staffing Information.

§483.35(g)(1) Data requirements. The facility must post the following information on a daily basis:

- (i) Facility name.
- (ii) The current date.
- (iii) The total number and the actual hours worked by the following categories of licensed and unlicensed nursing staff directly responsible for resident care per shift:
 - (A) Registered nurses.
 - (B) Licensed practical nurses or licensed vocational nurses (as defined under State law).
 - (C) Certified nurse aides.
- (iv) Resident census.

§483.35(g)(2) Posting requirements.

- (i) The facility must post the nurse staffing data specified in paragraph (g)(1) of this section on a daily basis at the beginning of each shift.
- (ii) Data must be posted as follows:
 - (A) Clear and readable format.
 - (B) In a prominent place readily accessible to residents and visitors.

§483.35(g)(3) Public access to posted nurse staffing data. The facility must, upon oral or written request, make nurse staffing data available to the public for review at a cost not to exceed the community standard.

§483.35(g)(4) Facility data retention requirements. The facility must maintain the posted daily nurse staffing data for a minimum of 18 months, or as required by State law, whichever is greater.

INTENT §483.35(g)

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

GUIDANCE §483.35(g)

The facility's *staffing data* "document" may be a form or spreadsheet, as long as all the required information is displayed clearly and in a visible place. The information should be displayed in a prominent place *that is readily* accessible to residents and visitors and presented in a clear and readable format. This information posted must be up-to-date and current.

The facility is required to list the total number of staff and the actual hours worked by the staff to meet this regulatory requirement. The information should reflect staff absences on that shift due to call-outs and illness.

Staffing must include all nursing staff who are paid by the facility (including contract staff). The nursing home is not *required to* include in the posting *the data for* staff *who are* paid for through other sources; examples include hospice staff covered by the hospice benefit, or individuals hired by families to provide companionship or assistance to a specific resident.

Probes:

PROCEDURES AND PROBES §483.35(g)

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

- *The facility posts the following information on a daily basis*
 1. *Facility name*
 2. *The current date*
 3. *The total number and actual hours worked by the following categories of licensed and unlicensed nursing staff directly responsible for resident care per shift: registered nurses, licensed practical nurses or licensed vocational nurses, and certified nurse aides.*
 4. *Resident census*
- *The facility must post the nurse staffing data mentioned above on a daily basis at the beginning of each shift.*
- *The data must be posted in a clear and readable format and in a prominent place readily accessible to residents and visitors.*
- *The facility must upon oral or written request make nurse staffing data available to the public for review at a cost not to exceed the community standard.*
- *The facility must maintain the posted daily nurse staffing data for a minimum of 18 months, or as required by State law, whichever is greater.*

KEY ELEMENTS OF NONCOMPLIANCE

To cite deficient practice at F732, the surveyor's investigation will generally show that the facility failed to do any one of the following:

- Ensure staffing information was posted in a prominent place readily accessible to residents and visitors; **or**
- Ensure staffing information was accurate and current; **or**
- Ensure staffing information was complete and was not missing information (e.g. specific units were not reflected on the posting); **or**
- *Make daily staffing available to the public for review upon request: **or***

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

F740

(Rev. 208; Issued:10-21-22; Effective: 10-21-22; Implementation:10-24-22)

§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 §483.70(e) (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/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Downloads/Survey-Resources.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/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Downloads/Survey-Resources.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 March 2, 2021. <https://www.nimh.nih.gov/index.shtml>. This website provides resources for the understanding and treatment of mental illnesses.*

- *National Long-term Care Ombudsman Resource Center. Accessed March 2, 2021. <https://ltombudsman.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 March 2, 2021. <https://www.nimh.nih.gov/health/publications/schizophrenia/index.shtml>.*
This booklet describes symptoms, causes, and treatments for schizophrenia with information on ways to get help and cope effectively.
- *NIMH. "Bipolar Disorder." Accessed March 2, 2021. <https://www.nimh.nih.gov/health/publications/bipolar-disorder/index.shtml>.*
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 March 2, 2021. <https://www.nimh.nih.gov/health/publications/ptsd-listing.shtml>.*
This is a list of publications related to post-traumatic stress disorder.
- *NIMH. "Anxiety Disorders." Accessed March 2, 2021. <https://www.nimh.nih.gov/health/publications/anxiety-disorders-listing.shtml>.*
This is a list of publications related to anxiety disorders.
- *NIMH. "Depression." Accessed March 2, 2021. <https://www.nimh.nih.gov/health/publications/depression-listing.shtml>.*
This is a list of publications related to depression.
- *NIMH. "Generalized Anxiety Disorder (GAD)." Accessed March 2, 2021. <https://www.nimh.nih.gov/health/publications/generalized-anxiety-disorder-listing.shtml>.*
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. 208; Issued:10-21-22; Effective: 10-21-22; Implementation:10-24-22)

§483.40(a) The facility must have sufficient staff who provide direct services to residents with the appropriate competencies and skills sets to provide nursing and related services to assure resident safety and attain or maintain the highest practicable physical, mental and psychosocial well-being of each resident, as determined by resident assessments and individual plans of care and considering the number, acuity and diagnoses of the facility's resident population in accordance with §483.70(e). These competencies and skills sets include, but are not limited to, knowledge of and appropriate training and supervision for:

§483.40(a)(1) Caring for residents with mental and psychosocial disorders, as well as residents with a history of trauma and/or post-traumatic stress disorder, that have been identified in the facility assessment conducted pursuant to §483.70(e), and [as linked to history of trauma and/or post-traumatic stress disorder, will be implemented beginning November 28, 2019 (Phase 3)]

§483.40(a)(2) Implementing non-pharmacological interventions.

INTENT §483.40(a), (a)(1) & (a)(2)

The intent of this requirement is to ensure that the facility has sufficient staff members who possess the basic competencies and skills sets to meet the behavioral health needs of residents for whom the facility has assessed and developed care plans. The facility must consider the acuity of the population and its assessment in accordance with §483.70(e). This includes residents with mental disorders, psychosocial disorders, or substance use disorders (*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 March 2, 2021. <https://www.nimh.nih.gov/health/topics/post-traumatic-stress-disorder-ptsd/index.shtml>.

"Non-pharmacological intervention" refers to approaches to care that do not involve medications, generally directed towards stabilizing and/or improving a resident's mental, physical, and psychosocial well-being.

GUIDANCE §483.40(a), (a)(1) & (a)(2)

Sufficient Staff to Provide Behavioral Health Care and Services

The facility must address in its facility assessment under §483.70(e) (F838), the behavioral health needs that can be met and the numbers and types of staff needed to meet these needs.

If a resident qualifies for specialized Level II services under PASARR, please refer to §483.20(k) (F645). If the resident does not qualify for specialized services under PASARR, but requires more intensive behavioral health services (e.g., individual counseling), the facility must demonstrate reasonable attempts to provide for and/or arrange for such services. This would include ensuring that the types of service(s) needed is clearly identified based on the individual assessment, care plan and strategies to arrange such services.

Facilities must have sufficient direct care staff (nurse aides and licensed nurses) with knowledge of behavioral health care and services in accordance with the care plans for all residents, including those with mental or psychosocial disorders, *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 §483.70(e) (F838), the facility's assessment must include an evaluation of staff competencies that are necessary to provide the level and types of care needed for the resident population. The facility must have a process for evaluating these competencies.

If sufficient and/or competent staffing concerns are present during the surveyor's investigation or while completing the Sufficient and Competent Staffing Facility Task, refer to the Behavioral and Emotional Status (CMS-20067) Critical Element Pathway.

KEY ELEMENTS OF NONCOMPLIANCE §483.40(a), (a)(1) & (a)(2)

To cite deficient practice at F741, the surveyor's investigation will generally show that the facility failed to:

- Rule out underlying causes for the resident's behavioral health care needs through assessment, diagnosis, and treatment by qualified professionals, such as physicians, including psychiatrists or neurologists;
- Identify competencies and skills sets needed in the facility to work effectively with residents with mental disorders and other behavioral health needs;
- *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 *at the CMS Nursing Homes Survey Resources website that can be accessed by visiting <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Downloads/Survey-Resources.zip>.*

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§483.40(b) Based on the comprehensive assessment of a resident, the facility must ensure that—

§483.40(b)(1)

A resident who displays or is diagnosed with mental disorder or psychosocial adjustment difficulty, or who has a history of trauma and/or post-traumatic stress disorder, receives appropriate treatment and services to correct the assessed problem or to attain the highest practicable mental and psychosocial well-being;

DEFINITIONS §483.40(b) & §483.40(b)(1)

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

“**Mental *disorder* and psychosocial adjustment difficulty**” refers to the development of emotional and/or behavioral symptoms in response to an identifiable stressor(s) that has not been the resident’s typical response to stressors in the past or an inability to adjust to stressors as evidenced by chronic emotional and/or behavioral symptoms. (Adapted from Diagnostic and Statistical Manual of Mental Disorders - Fifth edition. 2013, American Psychiatric Association.).

INTENT §483.40(b) & §483.40(b)(1)

The intent of this regulation is to ensure that a resident who upon admission, was assessed and displayed or was diagnosed with a mental or psychosocial adjustment difficulty or a history of trauma and/or post-traumatic stress disorder (PTSD), receives the appropriate treatment and services to correct the initial assessed problem or to attain the highest practicable mental and psychosocial well-being. Residents who were admitted to the nursing home with a mental or psychosocial adjustment difficulty, or who have a history of trauma and/or PTSD, must receive appropriate person-centered and individualized treatment and services to meet their assessed needs.

GUIDANCE §483.40(b) & §483.40(b)(1)

Residents who experience mental or psychosocial adjustment difficulty, or who have a history of trauma and/or post-traumatic stress disorder (PTSD) require specialized care and services to meet their individual needs. The facility must ensure that an interdisciplinary team (IDT), which includes the resident, the resident’s family and/or representative, whenever possible, develops and implements approaches to care that are both clinically appropriate and person-centered. Expressions or indications of distress, lack of improvement or decline in resident functioning should be documented in the resident’s record and steps taken to determine the underlying cause of the negative outcome.

For additional information regarding non-pharmacological interventions, see §483.40(a)(2) (F741), Implementing non-pharmacological interventions.

What is appropriate treatment and services to correct the assessed problem or to attain the highest practicable mental and psychosocial well-being?

The facility must provide the “appropriate treatment and services” to correct the assessed problem or to attain the highest practicable mental and psychosocial well-being. The determination of what is “appropriate” is person-centered and would be based on the individualized assessment and comprehensive care plan. To the extent that the care plan identifies particular treatment and services, the facility must make reasonable attempts to provide these services directly or assist residents with accessing such services.

A facility must determine through its facility assessment what types of behavioral health services it may be able to provide. Some examples of treatment and services for psychosocial adjustment difficulties may include providing residents with opportunities for autonomy; arrangements to keep residents in touch with their communities, cultural heritage, former lifestyle, and religious practices; and maintaining contact with friends and family. The coping skills of a person with a history of trauma or PTSD will vary, so assessment of symptoms and implementation of care strategies should be highly individualized. Facilities should use evidence-based interventions, if possible.

Background on Trauma and PTSD

A close relationship exists between mental and psychosocial adjustment difficulties, histories of trauma, and PTSD.

- Adjustment difficulties:
 - Occur within 3 months of the onset of a stressor and last no longer than 6 months after the stressor or its consequences have ended;
 - Are characterized by distress that is out of proportion to the severity or intensity of the stressor, taking into account external context and cultural factors, and/or a significant impairment in social, occupational, or other important areas of functioning;
 - May be related to a single event or involve multiple stressors and may be recurrent or continuous;
 - May cause a depressed mood, anxiety, and/or aggression;
 - May be diagnosed following the death of a loved one when the intensity, quality, or persistence of grief exceeds what normally might be expected; and
 - Can occur for individuals with or without PTSD or a history of trauma.
- History of trauma:
 - Involves psychological distress, following a traumatic or stressful event, that is often variable;
 - May be connected to feelings of anxiety and/or fear;
 - Often involves expressions of anger or aggressiveness; and
 - Some individuals who experience trauma will develop PTSD.
- PTSD:
 - Involves the development of symptoms following exposure to one or more traumatic, life-threatening events;

- Usually develops within the first 3 months after the trauma occurs, although there may be a delay in months or even years;
- Symptoms may include, but are not limited to, the re-experiencing or re-living of the stressful event (e.g., flashbacks or disturbing dreams), emotional and behavioral expressions of distress (e.g., outbursts of anger, irritability, or hostility), extreme discontentment or inability to experience pleasure, as well as dissociation (e.g., detachment from reality, avoidance, or social withdrawal), hyperarousal (e.g., increased startle response or difficulty sleeping); and
- May be severe or long-lasting when the stressor is interpersonal and intentional (e.g., torture or sexual violence).

(Adapted from American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders, Fifth edition. Arlington, VA: American Psychiatric Association Publishing, 2013.)

Although PTSD is commonly viewed as a disorder experienced only by military veterans, it is not exclusively a consequence of combat or war zone exposure. Individuals who have been physically or sexually assaulted or who experienced a terrorist attack or natural disaster, among other things may also be affected by PTSD. Additionally, some older nursing home residents may have lived through a time of genocide and witnessed or been subjected to the intentional and systematic destruction of a racial, political, or cultural group such as that which occurred during the Holocaust in World War II.

Moving from the community into a long-term care facility, for an individual with a history of trauma or PTSD, can be a very difficult transition and cause worsening or reemergence of symptoms. Additionally, the structured environment of the nursing home can trigger memories of traumatic events and coping with these memories may be more difficult for older adults.

KEY ELEMENTS OF NONCOMPLIANCE §483.40(b) & §483.40(b)(1)

To cite deficient practice at F742, the surveyor's investigation will generally show that the facility failed to:

- Assess the resident's expressions or indications of distress to determine if services were needed;
- Provide services and individualized care approaches that address the assessed needs of the resident and are within the scope of the resources in the facility assessment;
- Develop an individualized care plan that addresses the assessed emotional and psychosocial needs of the resident;
- Assure that staff consistently implement the care approaches delineated in the care plan;
- Monitor and provide ongoing assessment as to whether the care approaches are meeting the emotional and psychosocial needs of the resident; or

- Review and revise care plans that have not been effective and/or when the resident has a change in condition and accurately document all of these actions in the resident's medical record.

NOTE: For behavioral health care concerns that do not pertain to residents who display or are diagnosed with a mental disorder or psychosocial adjustment difficulty, or who have a history of trauma and/or post-traumatic stress disorder, review regulatory requirements at §483.40 (F740), Behavioral Health Services.

INVESTIGATIVE PROTOCOL §483.40(b) & §483.40(b)(1)

Objectives

The objectives of this protocol are to determine, based on the comprehensive assessment of a resident, that the facility ensured that the resident who displays or is diagnosed with a mental or psychosocial adjustment difficulty, or who has a history of trauma and/or PTSD receives the care and services necessary to reach and maintain the highest level of mental and psychosocial functioning.

Procedures

In order to guide observations, briefly review the comprehensive assessment and interdisciplinary care plan.

Observations

Observe for manifestations related to mental and psychosocial adjustment difficulties, a history of trauma and/or PTSD which may, over a period of time, include:

- Impaired verbal communication without physiological cause;
- Social isolation and withdrawal inconsistent with the resident's usual demeanor;
- Sleep pattern disturbance (e.g., disruptive change in sleep/rest pattern as related to one's biological and emotional needs);
- Deviation from past spiritual beliefs or rituals (alterations in one's belief system);
- Inability to control behavior, anger, and the potential for physical harm to oneself or others; and
- Stereotyped response to any stressor (i.e., the same characteristic response, regardless of the stimulus).

NOTE: Observe staff interactions with the resident in formal and informal situations and determine whether or not they implement interventions in accordance with the care plan.

Interviews

Resident/Resident Representative

Interview the resident, resident's family, or representative(s), to the degree possible, to determine:

- Awareness of the current condition(s) or history of the condition(s) or diagnosis/diagnoses;
- Participation in the development of a person-centered care plan;

- Whether or not resident choices and preferences are considered; and
- Validity of observations and data collection.

Staff Interviews

Interview IDT member(s) as necessary to determine:

- Whether or not care provided is consistent with the care plan; and
- That staff are knowledgeable about how to support the resident when they are expressing or indicating feelings of distress;

Additionally, speaking to staff on various shifts can help to determine:

- Staff knowledge of facility-specific guidelines and protocols related to the treatment of mental disorders and psychosocial adjustment difficulties, history of trauma, and PTSD;
- Whether certified nurse aides (CNA) know how, what, when, and to whom to report changes in condition;
- How facility staff monitor care plan implementation, and changes in condition; and
- How changes in both the care plan and the resident's condition are communicated to the staff.

Record Review

- Identify if the resident triggers Care Area Assessments (CAA) for activities, mood state, psychosocial well-being, and psychotropic drug use.
 - Consider whether the CAA process was used to assess the causal factors for decline, potential for decline, or lack of improvement.
- Review the resident's care plan for interventions to address the assessed problem.
- How are mental and psychosocial adjustment difficulties, a history of trauma, and/or PTSD addressed in the care plan?
 - Does it describe the expressions or indications of distress that the resident has experienced because of the assessed problem?
 - Does it describe the programs and activities that have been implemented to assist the resident in reaching and maintaining the highest level of mental and psychosocial functioning?
 - Is the care plan written in measurable language that allows assessment of its effectiveness?
- Are the data to be collected to evaluate the effectiveness of the care plan identified?
- Are the data collection done according to the care plan?
- Is there an assessment of the resident's usual and customary routines and preferences?
 - Are accommodations made by the facility to support the resident by incorporating these routines and preferences in the care plan?
- Does record review indicate that the care and services outlined in the care plan are effective in decreasing the resident's expressions or indications of distress?

- If the data collected indicate that expressions or indications of distress are unchanged in frequency or severity over two or more assessment periods, is the plan reassessed and intervention approaches revised to support the resident in attaining the highest practicable mental and psychosocial well-being?

NOTE: Clinical conditions that may produce apathy, malaise, and decreased energy levels that can be mistaken for depression associated with mental or psychosocial adjustment difficulty may include, but are not limited to:

- Metabolic or endocrine disorders (e.g., Cushing's disease, diabetes/hypoglycemia, hypothyroidism);
- Central nervous system disorders (e.g., tumors and other mass lesions, Parkinson's disease, multiple sclerosis, Alzheimer's disease);
- Miscellaneous conditions (e.g., pernicious anemia, pancreatic disease, malignancy, infections, congestive heart failure, hypotension, dehydration, circadian rhythm disruption);
- Over-medication for treatment of other conditions; and
- Use of restraints.

DEFICIENCY CATEGORIZATION §483.40(b) & §483.40(b)(1)

An example of Severity Level 4 Non-compliance: Immediate Jeopardy to Resident Health or Safety includes, but is not limited to:

- A surveyor observed a resident, who was crying and exhibiting signs of distress, lying in bed in her room. During an interview, the resident told the surveyor that she had lost all hope, felt betrayed by her family and her faith, and was ready to die. The resident shared that her children sold her house before she came to the nursing home, but that she had planned to go back there to live once her health improved. The resident added that she had lived in that house for 55 years, raising her children and enjoying life. Record review showed that upon admission, the resident indicated her goal was to return home, but also that her house had been sold by her family.

Facility progress notes documented increased anxiety and depressive mood, as well as isolation from activities she had previously enjoyed, including attendance at religious services. Additionally, the resident had stopped eating or drinking. She was receiving IV fluids and the insertion of a feeding tube was being considered.

An interview with the Care Plan Coordinator confirmed that the facility failed to develop an individualized care plan that addressed the assessed emotional and psychosocial needs of the resident. During an interview with the social worker, she indicated that she had been aware the house sold, but did not realize the resident was so distraught about it.

The facility failed to acknowledge and assess the underlying causes of the resident's expressions of distress or develop and implement a care plan that

addressed this distress. This resulted in the deterioration of the resident's physical, mental, and psychosocial well-being.

An example of Severity Level 3 Non-compliance Actual Harm that is not Immediate Jeopardy includes, but is not limited to:

- The facility determined that a resident's resistance to receiving staff assistance in the shower was a result of a traumatic event that occurred at home years ago when a home health aide left her in the shower unattended and she fell, fracturing her hip. The resident has never been able to return home since the event and is distrustful of the nursing home staff. Interventions listed on the care plan specified that she is to be assisted by two staff members in the shower. The resident is to be approached in an unhurried manner, with calm voices and soft lighting.

The surveyor observed the resident in the shower with only one certified nurse aide (CNA) in attendance and harsh lighting. During the shower the resident demonstrated anxiety and fear. She was yelling, crying, restless, and tried to get out of the shower chair many times during care. When observed 30 minutes after her shower, the resident was no longer yelling, however she still appeared fearful and her crying was just beginning to resolve.

An interview with the CNA and director of nursing confirmed that the care plan interventions had not been followed.

The facility failed to ensure that a resident, who has a history of trauma, received the appropriate treatment and services to reduce her anxiety and fear in the shower. Care planned interventions were not implemented, leading to increased expressions of distress by the resident and a decline in her mental and psychosocial well-being.

An example of Severity Level 2 Non-compliance: No Actual Harm with Likelihood for More Than Minimal Harm that is Not Immediate Jeopardy includes, but is not limited to:

- A surveyor heard a resident yelling for help. Facility staff and the surveyor followed the sound to the resident's room where they found her lying in bed in a darkened room, clinging tightly to her wallet and blanket. The staff turned on the lights to assist in calming her down.

During an interview later that day, the resident shared that she had been robbed at knife point in her own home prior to being admitted to the nursing home last year. She also mentioned that, although she felt secure in the nursing home, she still had nightmares sometimes and the nurses are supposed to leave her bathroom light on at night. The resident also asked to be moved to a room closer to the nursing station, but that had not happened yet.

Record review of the resident's assessment and care plan documented that the resident did have care planned interventions regarding her increased need for reassurance, due to the robbery prior to admission. Interventions included leaving the resident's bathroom light on at night.

Interviews with facility staff confirmed that they sometimes forget to leave the bathroom light on at night for the resident. Additionally, the social worker confirmed that the possibility of a room closer to the nursing station had not yet been investigated.

The facility failed to implement person-centered, non-pharmacological approaches to care for a resident, with a history of trauma, causing the resident increased distress and fear.

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

Severity Level 1 does not apply for this regulatory requirement because any facility practice that results in a reduction of psychosocial well-being diminishes the resident's quality of life. Because more than minimal harm is likely, any deficiency for this requirement is at least a Severity Level 2. For additional guidance, see also the Psychosocial Outcome Severity Guide *at the CMS Nursing Homes Survey Resources website that can be accessed by visiting <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Downloads/Survey-Resources.zip>.*

F743

(Rev. 208; Issued:10-21-22; Effective: 10-21-22; Implementation:10-24-22)

§483.40(b)(2) A resident whose assessment did not reveal or who does not have a diagnosis of a mental or psychosocial adjustment difficulty or a documented history of trauma and/or post- traumatic stress disorder does not display a pattern of decreased social interaction and/or increased withdrawn, angry, or depressive behaviors, unless the resident's clinical condition demonstrates that development of such a pattern was unavoidable; and

INTENT §483.40(b)(2)

The intent of this regulation is to ensure that a resident who, upon admission was not assessed or diagnosed with a mental or psychosocial adjustment difficulty or a documented history of trauma and/or post-traumatic stress disorder (PTSD), does not develop patterns of decreased social interaction and/or increased withdrawn, angry, or depressive behaviors while residing in the facility. However, after admission, if the resident is diagnosed with a condition that typically manifests a similar pattern of behaviors, documentation must validate why the pattern was unavoidable (e.g., symptoms did not initially manifest, family was unaware of previous trauma or were unavailable for interview, etc.). Development of an unavoidable pattern of behaviors refers to a situation where the interdisciplinary team, including the resident, their family, and/or resident representative, has completed comprehensive assessments, developed and implemented

individualized, person-centered approaches to care through the care-planning process, revised care plans accordingly, and behavioral patterns still manifest.

GUIDANCE §483.40(b)(2)

Nursing home admission can be a stressful experience for a resident, his/her family, and/or representative. Behavioral health is an integral part of a resident's assessment process and care plan development. The assessment and care plan should include goals that are person-centered and individualized to reflect and maximize the resident's dignity, autonomy, privacy, socialization, independence, choice, and safety.

Facility staff must:

- Monitor the resident closely for expressions or indications of distress;
- Assess and plan care for concerns identified in the resident's assessment;
- Accurately document the changes, including the frequency of occurrence and potential triggers in the resident's record;
- Share concerns with the interdisciplinary team (IDT) to determine underlying causes, including differential diagnosis;
- Ensure appropriate follow-up assessment, if needed; and
- Discuss potential modifications to the care plan.

For additional information regarding non-pharmacological interventions, see §483.40(a)(2) (F741), Implementing non-pharmacological interventions.

KEY ELEMENTS OF NONCOMPLIANCE §483.40(b)(2)

To cite deficient practice at F743, the surveyor's investigation will generally show the facility failed to:

- Identify that a resident developed decreased social interaction and/or increased withdrawn, angry, or depressive behaviors, and may have made verbalizations indicating these;
- Evaluate whether the resident's distress was attributable to their clinical condition and demonstrate that the change in behavior was unavoidable;
- Ensure an accurate diagnosis of a mental disorder or psychosocial adjustment difficulty, or PTSD was made by a qualified professional;
- Adequately assess and/or develop care plans for services and individualized care approaches that support the needs of residents who develop these patterns;
- Provide services with an individualized care approach that support the needs of residents with these indicators;
- Provide staff with training opportunities related to the person-centered care approaches that have been developed and implemented;
- Assure that staff consistently implement the approaches delineated in the care plan;
- Monitor and provide ongoing assessment as to whether the care approaches are meeting the needs of the resident; or

- Review and revise care planned interventions and accurately document the reason for revision in the resident's medical record.

INVESTIGATIVE PROTOCOL §483.40(b)(2)

Objectives

The objective of this protocol is to determine whether or not the facility meets the regulatory requirements for a resident who has displayed a pattern of decreased social interaction and/or increased withdrawn, angry, or depressive expressions or indications of distress.

Procedures

Briefly review the comprehensive assessment and interdisciplinary care plan to guide observations.

Observations

Observe residents who appear to be isolated, withdrawn, angry, or have other expressions or indications of mental or psychosocial difficulties, a history of trauma and/or PTSD. Additionally, observations may include, but are not limited to:

- Staff and resident interactions;
- Demonstration of the staff's understanding, responsiveness, and proactive care for residents' needs; and
- Implementation of care plan interventions by staff.

Interviews

Resident/Resident Representative

Interview the resident, resident's family, or representative(s), to the degree possible, to determine:

- The level of social interaction and distress that was present upon admission;
- Whether social interaction has diminished or increased since admission;
- If withdrawal, anger, and depressive expressions or indications of distress have increased without a change in the resident's clinical condition;
- Participation in the development of a person-centered care plan; and
- Whether or not resident choices and preferences are considered.

Staff Interviews

In the case where staff members have noted changes in a resident's social interactions and behaviors after admission to the facility, and the care plan does not reflect these changes, the surveyor must:

Interview IDT member(s) as necessary to determine:

- Whether or not facility staff are aware of changes in the resident's social interactions and/or behavior;

- That staff are knowledgeable about how to support the resident when they are expressing or indicating feelings of distress;
- Whether or not facility staff, including the resident, their family, and/or resident representative have reviewed the resident's care plan and revised it as necessary, to reflect the resident's current needs and goals.

Additionally, speaking to staff on various shifts can help to determine:

- Their knowledge of facility-specific guidelines and protocols related to the treatment of mental disorders and psychosocial adjustment difficulties, history of trauma, and PTSD;
- Whether certified nurse aides know how, what, when, and to whom to report changes in condition, including changes in a resident's social interactions and behaviors (e.g., residents who have begun to withdraw, express anger, and/or depression);
- How facility staff monitor the implementation of the care plan, and respond to changes in the resident's social interactions and behaviors; and
- How changes in both the care plan and the resident's condition are communicated to the staff.

Record Review

- Determine whether or not upon admission, the resident had a diagnosis of or displayed a mental or psychosocial adjustment difficulty or a documented history of trauma and/or PTSD.
- Review the resident's medical record for documentation related to a pattern of decreased social interaction and/or increased withdrawn, angry, or depressive expressions or indications of distress. Review nursing, social service, mental health notes, or other discipline notes for description of the distress.
- Review the Resident Assessment Instrument (RAI) and identify if the Minimum Data Set (MDS) captures and was used to assess the resident's conditions. Look to see that the resident Care Area Assessments (CAA) for activities, mood state, psychosocial well-being, and psychotropic drug use trigger for any reason in the absence of related diagnoses or difficulties, or history of trauma and/or PTSD.
- Consider whether the CAA process was used to identify and assess the reason and causal factors for decline, potential for decline, or lack of improvement.
- Is there an assessment of the resident's usual and customary routines and preferences?
 - Are accommodations made by the facility to support the resident by incorporating these routines and preferences in the care plan?
- Review the resident's care plan to determine if interventions are in place to alleviate the assessed distress.
 - Does it thoroughly describe the distress from a person-centered perspective?
 - Does it describe the programs and activities that have been implemented to assist the resident in reaching and maintaining the highest level of mental and psychosocial functioning?

- Is the care plan written in measurable language that allows assessment of its effectiveness?
- Does the record review indicate that the care and services outlined in the care plan are effective?

DEFICIENCY CATEGORIZATION §483.40(b)(2)

An example of Severity Level 4 Non-compliance: Immediate Jeopardy to Resident Health or Safety includes, but is not limited to:

- The facility failed to identify signs of distress exhibited by a resident who, according to the medical record, for the past month had begun rising from bed mid-morning and returning to bed immediately after dinner. This was a departure from her previous morning and night sleep patterns. Upon interview, staff communicated that as people age, they grow tired more easily and require more sleep. The staff also noted that the resident was often very tearful and seemed depressed, but again they felt that this was normal for older adults. Even though she experienced a significant weight loss and did not want to speak to a social worker when approached about these noted changes, the staff honored her wish to be left in bed. During the resident interview, she stated that she was tired and just wanted to sleep. She informed the surveyor that the last of her friends had just died, leaving her with no other childhood contacts or meaningful social relationships other than her family. She began crying and stated that she often cried, but tried not to in front of the staff because she was too proud. She felt that by sleeping a lot, she wouldn't have to face the fact that she also would die soon.

The facility's failure to identify that the resident was in distress and needed a mental health assessment caused a delay in receiving appropriate services and a deterioration in the resident's psychosocial well-being.

An example of Severity Level 3: Actual Harm that is not Immediate Jeopardy includes, but is not limited to:

- During the tour of the facility, the surveyor noticed a resident sitting by the front door of the facility wringing his hands and staring out the window. While engaged in conversation, he stated that he was afraid that he would miss his group again. He had to come to the nursing home after his wife's death and was having a hard time adjusting to the change. He stated that he joined a grief support group that he was finding helpful, but had not been able to attend for a few weeks. He was unable to sleep at night because of the worry about missing the group sessions.

His care plan indicated that the only intervention to address his grief was participation in a weekly support group meeting at the senior center. His goal was to attend group sessions, so he could better cope with the multiple losses he had experienced. An interview with the facility administrator revealed that the resident had been unable to attend group sessions for six weeks because the

facility's only van was in the shop. During those weeks, the facility failed to provide alternative interventions and address the distress caused by the missed meetings. The resident's medical record reflected that in the past month, he appeared more anxious, depressed, and angry and staff described him as "not his pleasant self."

The resident suffered a decline as a direct result of being unable to attend his weekly support group meetings and the facility did not seek any alternatives when transportation was unavailable.

An example of Severity Level 2: No Actual Harm with Likelihood for More Than Minimal Harm that is Not Immediate Jeopardy includes, but is not limited to:

- After falling at home and fracturing her femur, a resident was admitted to the skilled nursing facility for rehabilitation services. She had no history of mental or psychosocial adjustment difficulty, trauma (other than the fall), and/or PTSD. When she was first admitted she was very involved in facility events and activities, and participated enthusiastically in therapy. During observation of the breakfast meal, the surveyor noticed that the resident appears quite tired and asked the physical therapist if therapy could be postponed until later in the afternoon so she could go back to bed. When questioned, the resident stated that she has not had a good night's sleep since admission, due to the woman in the next room yelling most of the night. The resident also stated that she does not want to complain since she knows that the woman yelling has dementia. However, it is getting harder for her to get enough rest and she finds herself feeling irritable and depressed from her lack of sleep. The physical therapist reported that the resident has not been progressing as well as she was when she was first admitted and when she attends therapy, she tires and becomes frustrated easily.

The resident's lack of rest and feeling of sadness stemmed from the staff's inability to realize that the distress of another resident was affecting other residents. The resident's sleep pattern had already been disrupted for several nights and she was too tired to participate in therapy. If the situation continues, it could lead to a decline in the resident's clinical condition.

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/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Downloads/Survey-Resources.zip>.*

F744

(Rev. 208; Issued:10-21-22; Effective: 10-21-22; Implementation:10-24-22)

§483.40(b)(3) A resident who displays or is diagnosed with dementia, receives the appropriate treatment and services to attain or maintain his or her highest practicable physical, mental, and psychosocial well-being.

DEFINITIONS §483.40(b)(3)

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

“Dementia” is a general term to describe a group of symptoms related to loss of memory, judgment, language, complex motor skills, and other intellectual function, caused by the permanent damage or death of the brain's nerve cells, or neurons. However, dementia is not a specific disease. There are many types and causes of dementia with varying symptomology and rates of progression. (Adapted from: “About Dementia.” Alzheimer’s Foundation of America. 30

Nov 2016. Accessed at: <https://www.alzfdn.org/AboutDementia/definition.html>)

“Highest practicable physical, mental, and psychosocial well-being” is defined as the highest possible level of functioning and well-being, limited by the individual’s recognized pathology and normal aging process. Highest practicable is determined through the comprehensive resident assessment and by recognizing and competently and thoroughly addressing the physical, mental or psychosocial needs of the individual.

GUIDANCE §483.40(b)(3)

Providing care for residents living with dementia is an integral part of the person-centered environment, which is necessary to support a high quality of life with meaningful relationships and engagement. Fundamental principles of care for persons living with dementia involve an interdisciplinary approach that focuses holistically on the needs of the resident living with dementia, as well as the needs of the other residents in the nursing home. Additionally, it includes qualified staff that demonstrate the competencies and skills to support residents through the implementation of individualized approaches to care (including direct care and activities) that are directed toward understanding, preventing, relieving, and/or accommodating a resident’s distress or loss of abilities.

If there are staffing concerns related to the provision of behavioral health services, refer to §483.40(a) (F741), Sufficient and Competent Staff.

The facility must provide dementia treatment and services which may include, but are not limited to, the following:

- Ensuring adequate medical care, diagnosis, and supports based on diagnosis;
- Ensuring that the necessary care and services are person-centered and reflect the resident’s goals, while maximizing the resident’s dignity, autonomy, privacy, socialization, independence, choice, and safety; and

- Utilizing individualized, non-pharmacological approaches to care (e.g., purposeful and meaningful activities). Meaningful activities are those that address the resident's customary routines, interests, preferences, and choices to enhance the resident's well-being.

It is expected that a facility's approach to care for a resident living with dementia follows a systematic care process. In order to ensure that residents' individualized dementia care needs are met, the facility is expected to assess, develop, and implement care plans through an interdisciplinary team (IDT) approach that includes the resident, their family, and/or resident representative, to the extent possible. Care plan goals must be achievable and the facility must provide those resources necessary for an individual resident to be successful in reaching those goals. Surveyors must determine whether the failure to attain or maintain the highest practicable physical, mental, and psychosocial well-being (in accordance with the comprehensive assessment and care plan) was avoidable or unavoidable. An unavoidable facility failure refers to a situation where the IDT has completed comprehensive assessments, developed and implemented individualized, person-centered approaches to care through the care-planning process, revised care plans accordingly, and residents are unable to attain or maintain their highest practicable physical, mental, and psychosocial well-being.

Residents living with dementia require specialized services and supports, (e.g., specialized activities, nutrition, and environmental modifications) that vary, based on the individual's abilities and challenges related to their condition. Dementia causes significant intellectual functioning impairments that interfere with life, including activities and relationships. People living with dementia may lose their ability to communicate, solve problems, and cope with stressors. They may also experience fear, confusion, sadness, and agitation. While memory loss is a common indication of dementia, memory loss by itself does not mean that a person has dementia.

Although it is common in very elderly individuals, dementia is not a normal part of the aging process. There are several diseases that can cause symptoms of dementia (e.g., Alzheimer's disease, vascular dementia, Lewy body dementia). Other conditions can also cause dementia or dementia-like symptoms (including, e.g., reactions to medications, metabolic problems and endocrine abnormalities, nutritional deficiencies, and heart and lung problems).

Some individuals living with dementia may have co-existing symptoms, such as paranoia, delusions or hallucinations or psychiatric conditions, such as depression or bipolar affective disorder. Progressive dementia may exacerbate these symptoms and conditions.

Behavioral or psychological expressions are occasionally related to the brain disease in dementia; however, they may also be caused or exacerbated by environmental triggers. Such expressions or indications of distress often represent a person's attempt to communicate an unmet need, discomfort, or thoughts that they can no longer articulate.

Medications may be unnecessary and are likely to cause harm when given without a clinical indication, at too high of a dose, for too long after the resident's distress has been resolved, or if the medications are not monitored. However, medications may be effective when the underlying cause of a resident's distress has been determined and non-pharmacologic approaches to care have been ineffective or for expressions of distress that have worsened. All approaches to care, non-pharmacological and pharmacological, need to be person-centered, monitored for efficacy, risks, benefits, and harm, and revised as necessary.

If there are concerns about medication use in dementia, refer to §483.45(d) (F757), Unnecessary Drugs and §483.45(e) (F758), Psychotropic Drugs.

KEY ELEMENTS OF NONCOMPLIANCE §483.40(b)(3)

To cite deficient practice at F744, the surveyor's investigation will generally show that the facility failed to:

- Assess resident treatment and service needs through the Resident Assessment Instrument (RAI) process;
- Identify, address, and/or obtain necessary services for the dementia care needs of residents;
- Develop and implement person-centered care plans that include and support the dementia care needs, identified in the comprehensive assessment;
- Develop individualized interventions related to the resident's symptomology and rate of progression (e.g., providing verbal, behavioral, or environmental prompts to assist a resident with dementia in the completion of specific tasks);
- Review and revise care plans that have not been effective and/or when the resident has a change in condition;
- Modify the environment to accommodate resident care needs; or
- Achieve expected improvements or maintain the expected stable rate of decline.

Investigating Concerns Related to Dementia Care Treatment and Services

Use the Dementia Care Critical Element Pathway (CMS-20133), along with guidance, when determining if the facility meets the requirements pertaining to the treatment and services for a resident who displays or is diagnosed with dementia. Treatment and services must meet the resident's highest practicable physical, mental, and psychosocial well-being.

Review, as needed, all appropriate resident assessments, associated care planning and care plan revisions, along with physician's orders to identify initial concerns and guide the investigation. Review the Minimum Data Set (MDS) and other supporting documentation to help determine if the facility is in compliance. Observe for evidence that dementia care needs are met and related services are provided. Staff are expected to assess and provide appropriate care for residents with dementia. Interview the resident, their family, and/or representative(s) and the IDT, as needed to gather information about dementia care in the nursing home. Corroborate the information obtained and any concerns noted during the survey, by building upon the investigation through additional

observations, interviews, and record review. In determining compliance, additionally refer to the Psychosocial Severity Outcome Guide.

DEFICIENCY CATEGORIZATION §483.40(b)(3)

An example of Severity Level 4: Immediate Jeopardy to Resident Health or Safety includes, but is not limited to:

- Based upon a comprehensive assessment by a qualified professional, it was identified that a resident living with dementia required close supervision to prevent injury. The resident's care plan indicated that the facility had developed individualized interventions to support him. However, documentation in the resident's record provided information about an incident that had occurred recently as a result of lack of supervision. When left alone in the bathroom, the resident sustained second degree burns to his hand from hot water, requiring treatment at the emergency room. Following the incident, no revisions were made to the resident's care plan.

The facility failed to implement individualized interventions, as well as revise the care plan accordingly, to address the resident's dementia care needs, resulting in injury, as evidenced by observation, record review, and/or interview.

An example of Severity Level 3: Actual Harm that is not Immediate Jeopardy includes, but is not limited to:

- The care plan for a resident with an identified diagnosis of dementia included the need for close supervision to prevent the resident from wandering into the rooms of other residents. However, the review of the care plan indicated that the facility had failed to develop person-centered interventions to prevent the resident from wandering. The record review also provided information about a resident-to-resident altercation that had occurred a week prior to the survey. The altercation involved a sweater that was removed from the room of another resident, who slapped and scratched the resident living with dementia, because she refused to return the garment. The resident received minor lacerations and bruising, which was cared for by the direct care staff at the nursing home. The care plan was revised to reflect the need to closely supervise.

During the survey, the resident was observed wandering in and out of resident rooms. When questioned, direct care staff were unaware that the resident required close supervision.

The facility failed to develop and implement interventions to address the resident's dementia care needs, resulting in the resident's inability to achieve her highest level of functioning.

An Example of Severity Level 2: No Actual Harm with Likelihood for More Than Minimal Harm that is Not Immediate Jeopardy

- A resident was observed standing in her doorway asking what day of the week it was. Two staff members were within hearing distance, but did not reply to the resident. The surveyor also noticed that there was no calendar in the resident's room.

Review of the resident's record showed that she had a diagnosis of dementia. The care plan noted that the resident has a tendency to forget what day of the week it is and can become anxious when not reminded. Interventions include that staff are to ensure that a current calendar is on her bedroom wall and remind the resident what day it is when she wakes up each morning and when facility staff are asked.

The facility failed to support the resident and implement care planned interventions to reduce her confusion, which had the potential to cause the resident anxiety.

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

Severity Level 1 does not apply for this regulatory requirement because any facility practice that results in a reduction of psychosocial well-being diminishes the resident's quality of life. Because more than minimal harm is likely, any deficiency for this requirement is at least a Severity Level 2. For additional guidance, see also the Psychosocial Outcome Severity Guide *at the CMS Nursing Homes Survey Resources website that can be accessed by visiting <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Downloads/Survey-Resources.zip>.*

NOTE: If there are indications that a resident is in a secured/locked area without a clinical justification and/or placement is against the will of the resident, their family, and/or resident representative, review regulatory requirements at §483.12 and §483.12(a) (F603), Involuntary Seclusion. [End of Tag F744.]

F755

(Rev. 208; Issued:10-21-22; Effective: 10-21-22; Implementation:10-24-22)

§483.45 Pharmacy Services

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

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

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

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

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

§483.45(b)(2) 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 (See Appendix P, Section IV, E, Psychosocial Outcome Severity Guide).

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(h), F841, Medical Director
 - Determine whether the medical director, in collaboration with the facility and the pharmacist, and based on current standards of practice, helped the facility develop procedures for the safe and accurate provision of medications to meet the needs of the residents.
- 42 CFR §483.70(i), F842, Medical Records

- Determine whether the facility has maintained clinical records, including medication administration, in accordance with accepted professional standards and practices that are complete, accurately documented, and readily accessible.
- 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.

¹ Lurie, N., Jung, M., & Lavizzo-Mourey, R. (2005). *Disparities and quality improvement: Federal policy levers. Health Affairs, 24(2), 354- 364.*

² Betancourt, J. R., Green, A. R., Carillo, J. E., & Park, E. R. (2005). *Cultural competence and health care disparities: Key perspectives and trends. Health Affairs, 24(2), 499-505.*

F758

(Rev. 208; Issued:10-21-22; Effective: 10-21-22; Implementation:10-24-22)

§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 medication(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, pseudobulbar affect, and muscle spasms or stiffness. The requirements pertaining to psychotropic medications apply to these types of medications when their documented use appears to be a substitution for another psychotropic medication rather than for the original or approved indication.

For example, if a resident is prescribed valproic acid 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 Circumstances

Acute or Emergency Situations: When a psychotropic medication is being initiated or used to treat an emergency situation (i.e., acute onset or exacerbation of symptoms or immediate threat to health or safety of resident or others) related to a documented condition or diagnosis, a clinician in conjunction with the IDT must evaluate and document the situation to identify and address any contributing and underlying causes of the acute condition and verify the need for a psychotropic medication. Use of psychotropic medication to treat an emergency situation must be consistent with the requirements regarding PRN orders for psychotropic and antipsychotic medications and any continued use must be consistent with the requirements for gradual dose reduction (GDR).

Enduring Conditions: Psychotropic medications may be used to treat an enduring (i.e., non-acute; chronic or prolonged) condition. Before initiating or increasing a psychotropic medication for enduring conditions, the resident's symptoms and therapeutic goals must be clearly and specifically identified and documented. Additionally, the facility 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/PostmarketDrugSafetyInformationforPatientsand
Providers/ucm124830.htm](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 as chronic depression, Parkinson's disease psychosis, or recurrent seizures may need specific types of psychotropic medications or other medications which affect brain activity indefinitely.

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 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 F757 and/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.

<p align="center">SYMPTOMS, SIGNS, AND CONDITIONS THAT MAY BE ASSOCIATED WITH MEDICATIONS</p>	<p align="center">REVIEW FOR HOW THE IDT MANAGED MEDICATIONS FOR THE RESIDENT</p>
<p>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:</p> <ul style="list-style-type: none"> • Anorexia and/or unplanned weight loss, or weight gain • Apathy • Behavioral changes, unusual patterns (including increased expressions or indications of distress, social isolation or withdrawal) • Bleeding or bruising, spontaneous or unexplained • Bowel dysfunction including diarrhea, constipation and impaction • Dehydration, fluid/electrolyte imbalance • Depression, mood disturbance • Dysphagia, swallowing difficulty 	<p>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:</p> <ul style="list-style-type: none"> • Clinical indications for use of the medication • Implementation of person-centered, non-pharmacological approaches to care • Dose, including excessive dose and duplicate therapy • Duration, including excessive duration • Consideration of potential for tapering/GDR or rationale for clinical contraindication • Monitoring for and reporting of:

SYMPTOMS, SIGNS, AND CONDITIONS THAT MAY BE ASSOCIATED WITH MEDICATIONS	REVIEW FOR HOW THE IDT MANAGED MEDICATIONS FOR THE RESIDENT
<ul style="list-style-type: none"> • Falls, dizziness, or evidence of impaired coordination • Gastrointestinal bleeding • Headaches, muscle pain, generalized or nonspecific aching or pain • Lethargy • Mental status changes, (e.g., new or worsening confusion, new cognitive decline, worsening of dementia (including delirium), inability to concentrate) • Psychomotor agitation (e.g., restlessness, inability to sit still, pacing, hand-wringing, or pulling or rubbing of the skin, clothing, or other objects). • Psychomotor retardation (e.g., slowed speech, thinking, and body movements) • Rash, pruritus • Respiratory difficulty or changes • Sedation (excessive), insomnia, or sleep disturbance • Seizure activity • Urinary retention or incontinence <p>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.</p>	<ul style="list-style-type: none"> ○ Response to medications and progress toward therapeutic goals and resident’s goals ○ Emergence of medication-related adverse consequences • Adverse consequences, if present and potentially medication-related, note if there was: <ul style="list-style-type: none"> ○ Recognition, evaluation, reporting, and management by the IDT ○ Physician action regarding potential medication-related adverse consequences • The residents goals and preferences for medications and treatments

Interview the resident, his or her family, and representative(s) and the IDT, as needed to gather information about use of medications *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(h), F841, Medical Director
 - Review whether the medical director, when requested by the facility, interacted with the attending physician regarding a failure to respond or an inadequate response to identified or reported potential medication irregularities and adverse consequences; and whether the medical director collaborated with the facility to help develop, implement, and evaluate policies and procedures for the safe and effective use of medications in the care of residents.
- *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 publication.

¹ Handler, S.M., Wright, R.M., Ruby, C.M., Hanlon, J.T. (2006). Epidemiology of medication-related adverse events in nursing homes. *The American Journal of Geriatric Pharmacotherapy*, 4, pp. 264-272. Retrieved from <http://www.sciencedirect.com/science/article/pii/S1543594606000559>.

² Fong, T.G., Davis, D., Growdon, M.E., Albuquerque, A., Inouye, S.K. (2015). The interface between delirium and dementia in elderly adults. *The Lancet*, 14, pp.823-832. Retrieved from [http://thelancet.com/journals/laneur/article/PIIS1474-4422\(15\)00101-5/fulltext](http://thelancet.com/journals/laneur/article/PIIS1474-4422(15)00101-5/fulltext).

³ Steinberg, M., Lyketsos, C.G. (2012). Atypical antipsychotic use in patients with dementia: managing safety concerns. *The American Journal of Psychology*, 169, pp. 900-906. Retrieved from <http://ajp.psychiatryonline.org/doi/full/10.1176/appi.ajp.2012.12030342>.

F812

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§483.60(i) Food safety requirements.

The facility must –

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

- (i) This may include food items obtained directly from local producers, subject to applicable State and local laws or regulations.**
- (ii) This provision does not prohibit or prevent facilities from using produce grown in facility gardens, subject to compliance with applicable safe growing and food-handling practices.**
- (iii) This provision does not preclude residents from consuming foods not procured by the facility.**

§483.60(i)(2) - Store, prepare, distribute and serve food in accordance with professional standards for food service safety.

INTENT §483.60(i)(1)-(2) - To ensure that the facility:

- Obtains food for resident consumption from sources approved or considered satisfactory by Federal, State or local authorities;
- Follows proper sanitation and food handling practices to prevent the outbreak of foodborne illness. Safe food handling for the prevention of foodborne illnesses begins when food is received from the vendor and continues throughout the facility's food handling processes; and,
- Ensures food safety is maintained when implementing various culture change initiatives such as when serving buffet style from a portable steam table, or during a potluck.

DEFINITIONS §483.60(i)-(2)

The following definitions are provided to clarify terms related to professional standards for food service safety, sanitary conditions and the prevention of foodborne illness. Foodborne illness refers to illness caused by the ingestion of contaminated food or beverages.

"Critical Control Point" means a specific point, procedure, or step in food preparation and serving process at which control can be exercised to reduce, eliminate, or prevent the possibility of a food safety hazard.

"Cross-contamination" means the transfer of harmful substances or disease-causing microorganisms to food by hands, food contact surfaces, sponges, cloth towels, or utensils which are not cleaned after touching raw food, and then touch ready-to-eat foods. Cross-contamination can also occur when raw food touches or drips onto cooked or ready-to-eat foods.¹

"Danger Zone" means temperatures above 41 degrees Fahrenheit (F) and below 135 degrees F that allow the rapid growth of pathogenic microorganisms that can cause foodborne illness. Potentially Hazardous Foods (PHF) or Time/Temperature Control for Safety (TCS) Foods held in the danger zone for more than 4 hours (if being prepared

from ingredients at ambient temperature) or 6 hours (if cooked and cooled) may cause a foodborne illness outbreak if consumed.

“Dry Storage” means storing/maintaining dry foods (canned goods, flour, sugar, etc.) and supplies (disposable dishware, napkins, and kitchen cleaning supplies).

“Food Contamination” means the unintended presence of potentially harmful substances, including, but not limited to microorganisms, chemicals, or physical objects in food.²

“Food Preparation” means the series of operational processes involved in preparing foods for serving, such as: washing, thawing, mixing ingredients, cutting, slicing, diluting concentrates, cooking, pureeing, blending, cooling, and reheating.

“Food Distribution” means the processes involved in getting food to the resident. This may include holding foods hot on the steam table or under refrigeration for cold temperature control, dispensing food portions for individual residents, family style and dining room service, or delivering *meals* to residents’ rooms or *dining areas*, etc. *When meals are assembled in the kitchen and then delivered to residents’ rooms or dining areas to be distributed, covering foods is appropriate, either individually or in a mobile food cart.*

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

“Potentially Hazardous Food (PHF)” or **“Time/Temperature Control for Safety (TCS) Food”** means food that requires time/temperature control for safety to limit the growth of pathogens (i.e., bacterial or viral organisms capable of causing a disease or toxin formation).

“Storage” refers to the retention of food (before and after preparation) and associated dry goods.

GUIDANCE §483.60(i)(1)-(2)

Nursing home residents risk serious complications from foodborne illness as a result of their compromised health status. Unsafe food handling practices represent a potential source of pathogen exposure for residents. Sanitary conditions must be present in health care food service settings to promote safe food handling. CMS recognizes the U.S. Food and Drug Administration’s (FDA) Food Code and the Centers for Disease Control and Prevention’s (CDC) food safety guidance as national standards to procure, store, prepare, distribute, and serve food in long term care facilities in a safe and sanitary manner.

Effective food safety systems involve identifying hazards at specific points during food handling and preparation, and identifying how the hazards can be prevented, reduced or eliminated. It is important to focus attention on the risks that are associated with foodborne illness by identifying critical control points (CCPs) in the food preparation processes that, if not controlled, might result in food safety hazards. Some operational steps that are critical to control in facilities to prevent or eliminate food safety hazards are thawing, cooking, cooling, holding, reheating of foods, and employee hygienic practices

- *Web sites for additional information regarding safe food handling to minimize the potential for foodborne illness include: National Food Safety Information Network's Gateway to Government Food Safety Information at <http://www.FoodSafety.gov>;*
- *United States Food & Drug Administration Food Code Web site at <https://www.fda.gov/food/fda-food-code/food-code-2017>*

If there is reason to believe that a potential food borne illness/outbreak has occurred at the facility, surveyors should not attempt to investigate on their own but should consult with their State or local Department of Public Health that handles these types of investigations, i.e., Food & Drug or Infection Control departments. In addition, States or local public health agencies may have requirements for reporting a potential food borne illness/outbreak, facilities must follow these requirements as appropriate.

Much of this guidance is referenced from the 2017 Recommendations of the United States Food and Drug Administration Food Code. While we do not expect surveyors to determine compliance with this Food Code we are providing a link for reference and information only.

<https://www.fda.gov/food/fda-food-code/food-code-2017>

Food contaminants fall into 3 general categories:

1. Biological Contamination - are pathogenic bacteria, viruses, toxins, and spores that contaminate food. The two most common types of disease producing organisms are bacteria and viruses. Parasites may also contaminate food, but are less common.

Factors which may influence the growth of bacteria may include but are not limited to:

- Hazardous nature of the food. Although almost any food can be contaminated, certain foods are considered more hazardous than others and are called “potentially hazardous foods (PHF) or Time/Temperature Controlled for Safety (TCS)” food. Examples of PHF/TCS foods include ground beef, poultry, chicken, seafood (fish or shellfish), cut melon, unpasteurized eggs, milk, yogurt and cottage cheese;
- Acidity (pH) of the food. More acidic food (i.e., pH < 5), such as pineapple, vinegar, and lemon juice, tends to inhibit bacterial growth;

- Water percentage of the food. Foods that have a high level of water (e.g., fruits and vegetables) encourage bacterial growth; and
- Time and temperature control of the food. Time in conjunction with temperature controls is critical. The longer food remains in the danger zone, the greater the risks for growth of harmful pathogens. Bacteria multiply rapidly in a moist environment in the danger zone. Freezing does not kill bacteria. Rapid death of most bacteria occurs at 165 degrees F or above.

NOTE: Some foods may be considered a TCS food needing time/temperature control for safety to limit pathogenic microorganism growth or toxin formation. Examples include foods held for later service (e.g., cooked rice, beans, grilled sautéed onions, or baked potatoes).

2. Chemical Contamination - The most common chemicals that can be found in a food system are cleaning agents (such as glass cleaners, soaps, and oven cleaners) and insecticides. Chemicals used by the facility staff, in the course of their duties, may contaminate food (e.g., if a spray cleaner is used on a worktable surface while food is being prepared it becomes exposed to a chemical). An inadequately identified chemical may be mistaken for an ingredient used in food preparation. For example, incorrectly stored (e.g., dishwashing liquid stored in a syrup bottle) or unlabeled (e.g., white granulated cleaner that looks like salt) cleaning products may be inadvertently added to food and cause illness. Chemical products and supplies, must be clearly marked as such and stored separately from food items.

3. Physical Contamination - Physical contaminants are foreign objects that may inadvertently enter the food. Examples include, but are not limited to, staples, fingernails, jewelry, hair, glass, metal shavings from can openers, and pieces or fragments of bones from fish or chicken for example.

Potential Factors Implicated in Foodborne Illnesses - Many influences may contribute to foodborne outbreaks, such as:

- **Poor Personal Hygiene** - Employees, residents, family or visitor's health and hygiene are significant factors in preventing foodborne illness. "Infectious" individuals (persons capable of transmitting an infection or communicable disease) are a source of contaminants such as Norovirus, Influenza, etc. Proper hand washing techniques and exclusion of infectious individuals from handling food are critical for prevention of foodborne illness.
- **Inadequate Cooking and Improper Holding Temperatures** - Poorly cooked food or food that is not held at appropriate temperatures may promote the growth of pathogens that cause foodborne illness.
- **Contaminated Equipment** - Equipment can become contaminated in various ways including, but not limited to:
 - Poor personal hygiene;
 - Improper sanitation; and
 - Contact with raw food (e.g., poultry, eggs, seafood, and meat).

- **Unsafe Food Sources** - If surveyors have concerns or questions regarding the origin or processing of meat or other food products served to the facility residents, the surveyor should request that the facility provide documents which indicate the food product is from an approved or satisfactory source, as required by §483.60(i)(1) (F812).

NOTE: The food procurement requirements for facilities are not intended to restrict resident choice. All residents have the right to accept food brought to them by family or visitor(s).

Strategies for Control of Potential Foodborne Illness - The table below illustrates the more commonly identified ingestible food items and sources of contamination which have been associated with food borne illness and possible strategies to prevent illness.

Source of Contamination	Primary Agents of Concern	Primary Control Strategies
A. Hazards that are likely to occur - strategies that must be in place to prevent foodborne illness.		
Eggs - unpasteurized or raw	<ul style="list-style-type: none"> • Salmonella 	<ul style="list-style-type: none"> • PHF/TCS • Cook until all parts of the egg are completely firm • Prevention of cross-contamination to foods
Poultry, raw	<ul style="list-style-type: none"> • Campylobacter • Salmonella 	<ul style="list-style-type: none"> • PHF/TCS • Cook to proper temperature • Prevention of cross-contamination to other foods
	<ul style="list-style-type: none"> • Clostridium perfringens 	<ul style="list-style-type: none"> • PHF/TCS • Cook to proper temperature
Meat, raw	<ul style="list-style-type: none"> • E. coli 0157:H7 • Salmonella • Campylobacter 	<ul style="list-style-type: none"> • PHF/TCS • Cook to proper temperature • Prevention of cross-contamination to foods
	<ul style="list-style-type: none"> • Clostridium perfringens 	<ul style="list-style-type: none"> • PHF/TCS • Cook to proper temperature
Infectious food workers	<ul style="list-style-type: none"> • Norovirus • Hepatitis A virus • Shigella • Salmonella 	<ul style="list-style-type: none"> • Exclusion of infectious food workers • Proper hand-washing procedures • Avoid bare-hand contact with any foods
	<ul style="list-style-type: none"> • Staphylococcus aureus 	<ul style="list-style-type: none"> • Proper hand-washing procedures • Avoid bare-hand contact with foods
B. Hazards that may occur as a result of food products being adulterated, and for which good food handling practices are needed to minimize the potential for foodborne illness transmission. The US Food & Drug Administration (FDA) considers food adulteration as the act of intentionally debasing the quality of food offered for sale either by the admixture or substitution of inferior substances or by the removal of some valuable ingredient.		

Fruits and vegetables, fresh	<ul style="list-style-type: none"> • E. coli O157:H7 • Salmonella • Norovirus • Hepatitis A virus • Shigella 	<ul style="list-style-type: none"> • Wash by facility staff prior to use • Keep cut and raw fruits and vegetables refrigerated
Ready-to-eat meat and poultry products	<ul style="list-style-type: none"> • Listeria monocytogenes 	<ul style="list-style-type: none"> • Proper refrigeration during storage
Pasteurized dairy products	<ul style="list-style-type: none"> • Listeria monocytogenes 	<ul style="list-style-type: none"> • Proper refrigeration during storage
Ice	<ul style="list-style-type: none"> • Norovirus 	<ul style="list-style-type: none"> • Cleaning and sanitizing the internal components of the ice machine and utensils according to manufacturers' guidelines

Employee Health - Employees who handle food must be free of communicable diseases and infected skin lesions. (See the requirement at 42 CFR §483.80(a)(2)(v), F880, Infection Control, requiring a facility to have an infection prevention and control program that specifies policies for, among other things, the circumstances under which a facility must prohibit an employee from direct contact with residents or their food).

Hand Washing, Gloves, and Antimicrobial Gel - Employees should never use bare hand contact with any foods, ready to eat or otherwise. Since the skin carries microorganisms, it is critical that staff involved in food preparation, *distribution* and *servicing* consistently utilize good hygienic practices and techniques. Staff should have access to proper hand washing facilities with available soap (regular or anti-microbial), hot water, and disposable towels and/or heat/air drying methods.

The appropriate use of items such as gloves, tongs, deli paper, and spatulas is essential in minimizing the risk of foodborne illness. Gloved hands are considered a food contact surface that can get contaminated or soiled. Disposable gloves are a single use item and should be discarded between and after each use.

The use of disposable gloves is not a substitute for proper hand washing. Hands must be washed before putting on gloves and after removing gloves. Failure to change gloves and wash hands between tasks, such as medical treatments or contact with residents, between handling raw meats and ready to eat foods or between handling soiled and clean dishes, can contribute to cross-contamination.

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

According to the Food Code, food service staff must wear hairnets when cooking, preparing, or assembling food, such as stirring pots or assembling the ingredients of a

salad. However, staff do not need to wear hairnets when distributing foods to residents at the dining table(s) or when assisting residents to dine.

Staff should maintain nails that are clean and neat, and wearing intact disposable gloves in good condition that are changed appropriately to reduce the spread of infection. Since jewelry can harbor microorganisms, it is recommended that staff keep jewelry to a minimum and cover hand or wrist jewelry with gloves when handling food. *According to the Food Code, gloves are necessary when directly touching ready-to-eat food. Additionally, per infection control guidance, gloves are necessary when serving residents who are on transmission-based precautions (See F880 for additional information on transmission-based precautions). However, staff do not need to wear gloves when distributing foods to residents at the dining table(s) or when assisting residents to dine, unless touching ready-to-eat food.*

Food Receiving and Storage - When food, food products or beverages are delivered to the nursing home, facility staff must inspect these items for safe transport and quality upon receipt and ensure their proper storage, keeping track of when to discard perishable foods and covering, labeling, and dating all PHF/TCS foods stored in the refrigerator or freezer as indicated.

When food is brought into the facility from an off-site kitchen (any kitchen that is not proximate to the facility), this kitchen must be approved and inspected by the appropriate Federal, State, or local authorities. This does not include food brought to residents from their family or visitors. Obtain a copy of the last approved inspection of the off-site kitchen to verify it has been approved and inspected by the appropriate Federal, State or local authorities. Do not visit the off-site kitchen. Continue to inspect the facility for safe food handling, storage, and food quality after receiving the food delivery.

Food handling risks associated with food stored on the units may include but are not limited to:

- Food left on trays or countertops beyond safe time and/or temperature requirements;
- Food left in refrigerators beyond safe "use by" dates (including, but not limited to foods that have been opened but were not labeled, etc.);
- Food stored in a manner (open containers, without covers, spillage from one food item onto another, etc.) that allows cross-contamination; and
- Failure to maintain refrigerated food temperatures at safe levels;

Personal Refrigerators – The specific food storage requirements at F812 are for the nursing home food storage and do not apply to residents' personal refrigerators. However, the nursing home must ensure, under Life Safety Code regulations, that the resident room has an adequate electrical system, such as proper outlets, to allow the connection of a refrigerator without overloading the electrical system. Please see F813 related to nursing facility requirements to have a policy regarding personal food items.

- **Dry Food Storage** - Dry storage may be in a room or area designated for the storage of dry goods, such as single service items, canned goods, and packaged or containerized bulk food that is not PHF/TCS. The focus of protection for dry storage is to keep non-refrigerated foods, disposable dishware, and napkins in a clean, dry area, which is free from contaminants. Controlling temperature, humidity, and rodent and insect infestation helps prevent deterioration or contamination of the food. Dry foods and goods should be handled and stored in a manner that maintains the integrity of the packaging until they are ready to use. It is recommended that foods stored in bins (e.g., flour or sugar) be removed from their original packaging. Food and food products should always be kept off the floor and clear of ceiling sprinklers, sewer/waste disposal pipes, and vents to maintain food quality and prevent contamination. Desirable practices include managing the receipt and storage of dry food, removing foods not safe for consumption, keeping dry food products in closed containers, and rotating supplies.

- **Refrigerated Storage** - PHF/TCS foods must be maintained at or below 41 degrees F, unless otherwise specified by law. Frozen foods must be maintained at a temperature to keep the food frozen solid. Refrigeration prevents food from becoming a hazard by significantly slowing the growth of most microorganisms. Inadequate temperature control during refrigeration can promote bacterial growth. Adequate circulation of air around refrigerated products is essential to maintain appropriate food temperatures. Foods in a walk-in unit should be stored off the floor. Practices to maintain safe refrigerated storage include:
 - Monitoring food temperatures and functioning of the refrigeration equipment daily and at routine intervals during all hours of operation;
 - Placing hot food in containers (e.g., shallow pans) that permit the food to cool rapidly;
 - Separating raw foods (e.g., beef, fish, lamb, pork, and poultry) from each other and storing raw meats on shelves below fruits, vegetables or other ready-to-eat foods so that meat juices do not drip onto these foods; and
 - Labeling, dating, and monitoring refrigerated food, including, but not limited to leftovers, so it is used by its use-by date, or frozen (where applicable) or discarded.

Safe Food Preparation - Many steps in safe food preparation must be controlled and monitored to prevent foodborne illness. Identification of potential hazards in the food preparation process and adhering to critical control points can reduce the risk of food contamination and thereby minimize the risk of foodborne illness. When verifying food temperatures, staff should use a thermometer which is both clean, sanitized, and calibrated to ensure accuracy.

- **Cross-Contamination** - Cross-contamination can occur when harmful substances, i.e., chemical or disease-causing microorganisms are transferred to

food by hands (including gloved hands), food contact surfaces, sponges, cloth towels, or utensils that are not adequately cleaned. Cross-contamination can also occur when raw food touches or drips onto cooked or ready-to-eat foods.

Examples of ways to reduce cross-contamination include, but are not limited to:

- Store raw meat (e.g., beef, pork, lamb, poultry, and seafood) separately and in drip-proof containers and in a manner that prevents cross-contamination of other food in the refrigerator;
- Between uses, store towels/cloths used for wiping surfaces during the kitchen's daily operation in containers filled with sanitizing solution at the appropriate concentration per manufacturer's specifications. Assure that these sanitizing solutions are safe and do not have a risk of chemical contamination when preparing foods. Periodically testing the sanitizing solution helps assure that it maintains the correct concentration.
- Clean and sanitize work surfaces, including cutting boards and food-contact equipment (e.g., food processors, blenders, preparation tables, knife blades, can openers, and slicers), between uses and consistent with applicable code.
- **Thawing** - Thawing some foods at room temperature may not be acceptable because it may be within the danger zone for rapid bacterial proliferation. Recommended methods to safely thaw frozen foods include:
 - Thawing in the refrigerator, in a drip-proof container, and in a manner that prevents cross-contamination;
 - Completely submerging the item under cold water (at a temperature of 70 degrees F or below) that is running fast enough to agitate and float off loose ice particles;
 - Thawing the item in a microwave oven, then cooking and serving it immediately afterward; or
 - Thawing as part of a continuous cooking process.
- **Final Cooking Temperatures** - Temperatures are critical in preventing foodborne illness. Cooking food to the temperature and for the time specified below will either kill dangerous organisms or inactivate them sufficiently so that there is little risk to the resident if the food is eaten promptly after cooking. Monitoring the food's internal temperature is important and will help ensure no microorganisms can no longer survive and food is safe for consumption. Foods should reach the following internal temperatures in these situations:
 - Poultry and stuffed foods, i.e., turkeys, pork chops, chickens, etc. - 165 degrees F;
 - Ground meat (e.g., ground beef, ground pork), ground fish, and eggs held for service - at least 155 degrees F;
 - Fish and other non-ground meats - 145 degrees F;
 - If the facility is using unpasteurized eggs these eggs must be cooked until all parts of the egg are completely firm, regardless of a resident's request for such

things as “sunny side up”. To accommodate residents choice for items such as “sunny side up” the facility must use pasteurized eggs only;

- When cooking raw foods in the microwave, they should be rotated and stirred during the cooking process so that all parts are heated to a temperature of at least 165 degrees F, and allowed to stand covered for at least 2 minutes after cooking to obtain temperature equilibrium.

NOTE: Fresh, frozen, or canned fruits and vegetables that are cooked do not require the same level of microorganism destruction as raw meats/foods. Cooking to a hot holding temperature (135 degrees F) prevents the growth of pathogenic bacteria that may be present in or on these foods.

- **Reheating Foods** - Reheated cooked foods present a risk because they have passed through the danger zone multiple times during cooking, cooling, and reheating. The PHF/TCS food that is cooked and cooled must be reheated so that all parts of the food reach an internal temperature of 165 degrees F for at least 15 seconds before holding for hot service. Ready-to-eat foods that require heating before consumption are best taken directly from a sealed container (secured against the entry of microorganisms) or an intact package from an approved food processing source and heated to at least 135 degrees F for holding for hot service. Although proper reheating will kill most organisms of concern, some toxins, such as that produced by *Staphylococcus aureus*, cannot be inactivated by reheating food.

NOTE: Using a steam table to reheat food is unacceptable since it does not bring the food to the proper temperature within acceptable timeframes.

- **Cooling** - Improper cooling is a major factor in causing foodborne illness. Taking too long to chill PHF/TCS foods has been consistently identified as one factor contributing to foodborne illness. Foods that have been cooked and held at improper temperatures promote the growth of disease-causing microorganisms that may have survived the cooking process (e.g., spore-formers). Cooled food items can be re-contaminated by unsanitary handling practices or cross-contaminated from other food products, utensils, and equipment.

Large or dense food items, such as roasts, turkeys, soups, stews, legumes, and chili may require interventions (e.g., placing foods in shallow pans, cutting roasts into smaller portions, utilizing ice water baths, and stirring periodically) in order to be chilled safely within an allowed time period. These foods take a long time to cool because of their volume and density. If the hot food container is tightly covered, the cooling rate may be slowed further, leading to longer cooling times during which the food remains in the danger zone.

Cooked potentially hazardous foods that are subject to time and temperature control for safety are best cooled rapidly within 2 hours, from 135 to 70 degrees

F, and within 4 more hours to the temperature of approximately 41 degrees F. The total time for cooling from 135 to 41 degrees F should not exceed 6 hours.

- **Modified Consistency** - Residents who require a modified consistency diet may be at risk for developing foodborne illness because of the increased number of food handling steps required when preparing pureed and other modified consistency foods. When hot pureed, ground, or diced food drop into the danger zone (below 135 degrees F), the mechanically altered food must be reheated to 165 degrees F for 15 seconds if holding for hot service.
- **Eggs** –
 - Pooled eggs are raw eggs that have been cracked and combined together. The facility should crack only enough eggs for immediate service in response to a resident's requests or as an ingredient immediately before baking.
 - Unpasteurized Eggs- Salmonella infections may be prevented by substituting unpasteurized eggs with pasteurized eggs in the preparation of foods that will not be thoroughly cooked, such as, but not limited to, Caesar dressing, Hollandaise or Béarnaise sauce, egg fortified beverages, ice cream, and French toast.
 - Raw eggs with damaged shells are also unsafe because of the potential for contamination.

Food Distribution - Various systems are available for distributing food items to residents. These include but are not limited to tray lines, portable steam tables transported to dining areas, or *mobile food* carts *that maintain food in the proper temperature and out of the Danger Zone*. The purpose of these systems is to provide safe holding and transport of the food to the resident's location. Food safety requires consistent temperature control from the *time food leaves the kitchen*, to transport and distribution to prevent contamination (e.g., covering food items). *Timely distribution is essential to ensure food and beverages are served at the proper temperature.*

Dining locations include any area where one or more residents eat their meals. These can be located adjacent to the kitchen or a distance from the kitchen, such as residents' rooms and dining rooms on other floors or areas of the building.

Food Service - Meal service may include, but is not limited to, the steam table where hot prepared foods are held and served, and the chilled area where cold foods are held and served. A resident's meal may consist of a combination of foods that require different temperatures.

Food preparation or service area problems/risks to avoid include, but are not limited to:

- Holding foods in danger zone temperatures which are between 41 degrees F and 135 degrees F;
- Using the steam table to heat food;
- Serving meals on soiled dishware and with soiled utensils;
- Handling food with bare hands or improperly handling equipment and utensils;

- *Staff distributing meals without first properly washing their hands; and*
- *Serving food to residents after collecting soiled plates and food waste, without proper hand washing.*

The temperature of *PHF/TCS* foods should be periodically monitored throughout the meal service to ensure proper hot or cold holding temperatures are maintained. If time is being used in place of temperature as a means of ensuring food safety, the facility must have a system in place to track the amount of time a PHF/TCS is held out of temperature control and dispose of it accordingly.

Snacks - Snacks refer to foods served between meals or at bed time. Temperature control and freedom from contamination are also important when ready-to-eat or prepared food items for snacks are sent to the unit and are held for delivery, stored at the nursing station in a unit refrigerator or unit cupboards, or stored in personal refrigerators in resident rooms.

Special Events - Facility-sponsored special events, such as cookouts and picnics where food may not be prepared in the facility's kitchen and is served outdoors or in other locations, require the same food safety considerations.

Potluck Events – Are generally events where families, volunteers or other non-facility staff may organize to provide enjoyment to nursing home residents and support a person-centered, homelike environment. These are different from a facility's special event.

Regarding food brought into a nursing home prepared by others, please remember the nursing home is responsible for:

- Storing visitor food in such a way to clearly distinguish it from food used by or prepared by the facility.
- Ensuring safe food handling once the food is brought to the facility, including safe reheating and hot/cold holding, and handling of leftovers.
- Preventing contamination of nursing home food, if nursing home equipment and facilities are used to prepare or reheat visitor food.
- Clearly identifying what food has been brought in by visitors for residents and guests when served.

Should a foodborne illness occur as a result of a potluck held at the facility, the nursing home could be held responsible. For example, the facility could be held responsible if the facility failed to ensure the food was protected from contamination while being stored in the refrigerator and became contaminated from raw meat juices or failed to ensure staff involved in food service used appropriate hand hygiene and a foodborne illness resulted.

Nursing Home Gardens – Nursing homes that have their own gardens such as, vegetable, fruit or herbs may be compliant with the food procurement requirements as long as the facility has and follows policies and procedures for maintaining and harvesting the gardens, including ensuring manufacturer's instructions are followed if any pesticide(s), fertilizer, or other topical or root-based plant preparations are applied.

NOTE: Facilities must be in compliance with any State or local requirements that may exist pertaining to food grown on facility grounds for resident consumption.

Transported Foods - If residents take prepared foods with them out of the facility (e.g., bag lunches for residents attending dialysis, clinics, sporting events, or day treatment programs), the foods must be handled and prepared for them with the same safe and sanitary approaches used during primary food preparation in the facility. Appropriate food transport equipment or another approach to maintaining safe temperatures for food at special events can help minimize the risk of foodborne illness.

Ice - Appropriate ice and water handling practices prevent contamination and the potential for waterborne illness. Ice must be made from potable water. Ice that is used to cool food items (e.g., ice in a pan used to cool milk cartons) is not to be used for consumption. Keeping the ice machine clean and sanitary will help prevent contamination of the ice. Contamination risks associated with ice and water handling practices may include, but are not limited to:

- Staff, residents, visitors, etc., who fail to wash their hands adequately and use the scoop in an ice machine, or handle ice with their bare hands, are not following appropriate infection control practices when dispensing ice; and
- Unclean equipment, including the internal components of ice machines that are not drained, cleaned, and sanitized as needed and according to manufacturer's specifications.
- Ice chests or coolers used to store and transport ice should be cleaned regularly, especially prior to use and when contaminated or visibly soiled.

Refrigeration - The facility's refrigerators and/or freezers must be in good working condition to keep foods at or below 41 degrees F and the freezer must keep frozen foods frozen solid. The following are methods to determine the proper working order of the refrigerators and freezers:

- Document the temperature of external and internal refrigerator gauges as well as the temperature inside the refrigerator. Measure whether the temperature of a PHF/TCS food is 41 degrees or less;
- To make sure the cooling process is effective, measure the temperature of a PHF/TCS that has a prolonged cooling time (e.g., one in a large, deep, tightly covered container). Determine if it is in the danger zone;
- Check for situations where potential for cross-contamination is high (e.g., raw meat stored over ready-to-eat items);
- Check the firmness of frozen food and inspect the wrapper to determine if it is intact enough to protect the food; and
- Interview food service personnel regarding the operation of the refrigerator and the freezer.

Temperature control and freedom from contamination is also important when food or snacks are sent to a unit and held at the nursing station in a unit refrigerator or unit cupboards, or stored in personal refrigerators in resident rooms. Food handling risks associated with food stored on the units may include but are not limited to:

- Food left on trays or countertops beyond safe time and/or temperature requirements;
- Food left in refrigerators beyond safe "use by" dates (including, but not limited to foods that have been opened but were not labeled, etc.);
- Food stored in a manner (open containers, without covers, spillage from one food item onto another, etc.) that allows cross-contamination; and
- Failure to maintain refrigerated food temperatures at safe levels;

Personal Refrigerators – The specific food storage requirements at F812 are for the nursing home food storage and do not apply to residents' personal refrigerators. However, the nursing home must ensure, under Life Safety Code regulations, that the resident room has an adequate electrical system, such as proper outlets, to allow the connection of a refrigerator without overloading the electrical system. Please see F813 related to nursing facility requirements to have a policy regarding personal food items.

Equipment and Utensil Cleaning and Sanitization - A potential cause of foodborne outbreaks is improper cleaning (washing and sanitizing) of equipment and protecting equipment from contamination via splash, dust, grease, etc.

Machine Washing and Sanitizing - Dishwashing machines use either heat or chemical sanitization methods. Manufacturer's instructions must **always** be followed. The following are general recommendations according to the U.S. Department of Health and Human Services, Public Health Services, Food and Drug Administration Food Code for each method.

High Temperature Dishwasher (heat sanitization):

- Wash - 150-165 degrees F;
- Final Rinse - 180 degrees F; (160 degrees F at the rack level/dish surface reflects 180 degrees F at the manifold, which is the area just before the final rinse nozzle where the temperature of the dish machine is measured); or 165 degrees F for a stationary rack, single temperature machine.

Low Temperature Dishwasher (chemical sanitization):

- Wash - 120 degrees F; and
- Final Rinse - 50 ppm (parts per million) hypochlorite (chlorine) on dish surface in final rinse.

The chemical solution must be maintained at the correct concentration, based on periodic testing, at least once per shift, and for the effective contact time according to manufacturer's guidelines.

Manual Washing and Sanitizing - A 3-step process is used to manually wash, rinse, and sanitize dishware correctly. The first step is thorough washing using hot water and detergent after food particles have been scraped off. The second is rinsing with hot water to remove all soap residues. The third step is sanitizing with either hot water or a chemical solution maintained at the correct concentration, based on periodic testing, at least when initially filled and as needed, such as with extended use, and for the effective contact time according to manufacturer's guidelines. Facilities must have appropriate and adequate testing equipment, such as test strips and thermometers, to ensure adequate washing and sufficient concentration of sanitizing solution is present to effectively clean and sanitize dishware and kitchen equipment.

After washing and rinsing, dishes and utensils are sanitized by immersion in either:

- Hot water (at least 171 degrees F) for 30 seconds; or
- A chemical sanitizing solution used according to manufacturer's instructions. Chemical sanitization requires greater controls than hot water sanitization. Manufacturer's instructions must **always** be followed.

A high concentration of sanitation solutions may be potentially hazardous (see manufacturer's instructions) and may be a chemical contaminant of food. Improper test strips yield inaccurate results when testing for chemical sanitation.

Drying food preparation equipment and utensils with a towel or cloth may increase risks for cross contamination.

Cleaning Fixed Equipment - When cleaning fixed equipment (e.g., mixers, slicers, and other equipment that cannot readily be immersed in water), the removable parts must be washed and sanitized and non-removable parts cleaned with detergent and hot water, rinsed, air-dried and sprayed with a sanitizing solution (at the effective concentration). Finally, the equipment is reassembled and any food contact surfaces that may have been contaminated during the process are re-sanitized (according to the manufacturer's instructions). Service area wiping cloths are cleaned and dried or placed in a chemical sanitizing solution of appropriate concentration.

PROCEDURES §483.60(i)(1)-(2)

Through observation, interviews, and record review, determine:

- If the facility obtained food safe for consumption from approved sources; If the facility stores, prepares, distributes, and serves food in a sanitary manner to prevent foodborne illness;
- If the facility has systems (e.g., policies, procedures, training, and monitoring) in place to prevent the spread of foodborne illness and minimize food storage,

- preparation and handling practices that could cause food contamination and could compromise food safety; and
- If the facility utilizes safe food handling from the time the food is received from the vendor and throughout the food handling processes in the facility.

Adhere to sanitary requirements (e.g., proper washing hands when entering the kitchen and between tasks, use of hair restraints) when assessing the kitchen and meal service throughout the survey process.

Observations - Complete the initial brief kitchen tour upon arrival at the facility, with observations focused on practices that might indicate potential for foodborne illness. Make additional observations throughout the survey process during times when food is being stored, prepared, cooked, plated, *distributed*, and *served* to determine if safe food handling practices are being followed. Corroborate observations through interview, record review, and other appropriate documentation.

Food Procurement Procedures: Determine whether food meets safe and sanitary conditions related to when, where, and how the food was received for residents' consumption. If a concern is identified, check invoices from food vendors when necessary to verify the source of food acquisition and the date of delivery.

Storage of Food:

- Observe for food storage practices that may place the food, including ice, at risk for biological, chemical, or physical contamination.
- Check dry storage areas for canned goods that have a compromised seal (e.g., punctures);
- Check all facility refrigerators, including those on resident units, to ensure foods are held at appropriate temperatures and PHF/TCS foods for labeling and dates (e.g., use by dates);
- Check freezers to ensure foods are frozen solid;
- Look for evidence of pests, rodents and droppings and other sources of contamination in food storage areas; and
- Check resident rooms for safe food storage practices.

Food Preparation Procedures:

- Observe staff food handling practices, such as proper hand washing, the appropriate use of utensils, gloves, and hairnets;
- Observe food handling practices that have potential for cross-contamination (e.g., use of food contact surfaces and equipment to prepare various uncooked and ready-to-eat foods);
- Have staff demonstrate the calibration technique to ensure the temperature readings on the thermometers are reliable;

- Determine if the dietary staff are ensuring PHF/TCS foods are at approved cold holding, hot holding, and final cook temperatures;
- Determine if the dietary staff follow approved cooling and reheating procedures for PHF/TCS foods;
- Observe staff preparing modified consistency (e.g., pureed, mechanical soft) PHF/TCS foods to determine whether food safety was compromised;
- If the staff is preparing resident requests for undercooked eggs (i.e. sunny side up, soft scrambled, soft boiled), determine if pasteurized shell eggs or liquid pasteurized eggs were used to prevent foodborne illness; and
- During meal service, observe whether the staff measure the temperature of all hot and cold menu items.

Service after Meal Times:

- Observe whether facility personnel are operating the dish washing machine according to the manufacturer's specifications.
- Check whether the facility has the appropriate equipment and supplies to verify the safe operation of the dish washing machine and the washing of pots and pans.
- Check the sanitizing method used (high temperature or chemical) in dishwashing and for storing sanitizing cloths is adequate for sanitizing of dishware, utensils, pots/pans, and equipment.
- Observe stored dishes, utensils, pots/pans, and equipment for evidence of soiling. These items should be stored in a clean dry location and not exposed to splash, dust or other contamination; and
- Evaluate whether proper hand washing is occurring between handling soiled and clean dishes to prevent cross-contamination of the clean dishes.

Interviews - During the course of the survey, interview the staff who performs the task about the procedures they follow to procure, store, prepare, distribute, and serve food to residents. In addition to food safety practices, determine:

- What is the facility's practice for dealing with employees who come to work with symptoms of contagious illness (e.g., coughing, sneezing, diarrhea, vomiting) or open wounds;
- Whether the facility has, and follows, a cleaning schedule for the kitchen and food service equipment; and
- If there is a problem with equipment, how staff informs maintenance and follows up to see if the problem is corrected.

Record Review - In order to investigate identified food safety concerns, review supporting data, as necessary, including but not limited to:

- Any facility documentation, such as dietary policies and procedures, related to compliance with food sanitation and safety, including but not limited to policies

- addressing facility food service, potluck events, food from visitors, facility gardens;
- Determine if the food service employees have received training related to such compliance;
 - Monitoring records, such as temperature logs from the tray line, refrigerators, and freezers, and dishwasher temperature and sanitizing records;
 - Maintenance records, such as work orders and manufacturer's specifications, related to equipment used to store, prepare, and serve food.

Review of Facility Practices - Review of facility practices may include, but is not limited to, review of policies and procedures for sufficient staffing, staff training, and following manufacturer's recommendations as indicated. In order to establish if the facility has a process in place to prevent the spread of foodborne illness, interview the staff to determine how they:

- Monitor whether the facility appropriately procures, stores, prepares, distributes, and serves food;
- Identify and analyze pertinent issues and underlying causes of a food safety concern;
- Implement interventions that are pertinent and timely in relation to the urgency and severity of a concern; and
- Monitor the implementation of interventions and determine if additional modification is needed.

DEFICIENCY CATEGORIZATION

- **Examples of Level 4, immediate jeopardy to resident health and safety, include, but are not limited to:**
 - A 10-quart covered stock pot with 8 quarts of cooked beans was in the refrigerator. The internal temperature of the beans at the time of survey was measured at 68 degrees F. The cook stated these beans had been cooked the day before and were going to be served at the next meal, unaware they had been improperly cooled. Improperly cooled beans are at risk for growing toxin producing bacteria that are not destroyed in the reheating process.
 - A roast (raw meat) thawing on a plate in the refrigerator had bloody juices overflowing and dripping onto uncovered salad greens on the shelf below. The contaminated salad greens were used to make salad for the noon meal;
 - The facility had a recent outbreak of Norovirus after the facility allowed a food worker who was experiencing vomiting and diarrhea to continue preparing food.
- **An example of Level 3, Actual harm (physical or psychological) that is not immediate jeopardy, includes, but is not limited to:**
 - The facility failed to properly cool leftover turkey. The turkey was served to the residents, which resulted in an outbreak of foodborne illness, which, based

on the facility population, did not result in or have the potential for causing serious harm to any resident.

- **Examples of Level.2 - No actual harm with a potential for more than minimal harm (physical or psychological) that is not immediate jeopardy, include but are not limited to:**
 - Food service workers sliced roast pork on the meat slicer. The meat slicer was not washed, rinsed, and sanitized after use;
 - During the initial tour of the kitchen, two food service workers were observed on the loading dock. One was smoking and the other employee was emptying trash. Upon returning to the kitchen, they proceeded to prepare food without washing their hands;
 - Upon inquiry by the surveyor, the food service workers tested the sanitizer of the dish machine, the chemical rinse of the pot-and-pan sink, and a stationary bucket used for wiping cloths. The facility used chlorine as the sanitizer. The sanitizer tested less than 50 ppm in all three locations. Staff interviewed stated they were unaware of the amount of sanitizer to use and the manufacturer's recommendations to maintain the appropriate ppm of available sanitizer.

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

POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION §483.60(i)(1)-(2)

During the investigation of F812, the surveyor may have identified concerns with additional requirements related to outcome, process, and/or structure requirements. The surveyor is advised to investigate these related requirements before determining whether non-compliance may be present at these other tags. Examples of some of the related requirements that may be considered when non-compliance has been identified include, but are not limited to, the following:

- §483.25(g)(1)-(5), F692, Nutrition/Hydration Status and F693, Tube Feeding
 - Determine if residents have experienced nausea, vomiting, diarrhea, or other gastrointestinal symptoms as a result of the failure to store, handle, administer, or remove and discard tube feeding solutions in a safe and sanitary manner.
- §483.35(a), F725 Sufficient Staffing
 - Determine if the facility has sufficient staffing to meet the needs of the residents.
- §483.60(a)(1)(2), F801, Dietary Services - Staffing
 - Determine if the facility employs or consults with a qualified dietitian. If not employed full-time, determine if the director of food service receives scheduled consultation from the dietitian concerning storage, preparation, distribution and service of food under sanitary conditions.
- §483.60(a)(3), F802-Standard Sufficient Staff
 - Determine if the facility employs sufficient support personnel competent to carry out the functions of the dietary service.
- §483.60(h), F811, Paid Feeding Assistants

- o Determine if the Paid Feeding Assistant(s) has/have successfully completed a State-approved training course that meets Federal requirements and that the Feeding Assistant(s) is/are utilizing proper techniques to prevent foodborne illness.
- §483.80, F880, Infection Control
 - o Determine if the facility's infection control program includes investigation, control, and prevention of foodborne illness.
 - o Determine if the facility has practices in place to prevent the spread of infection, including proper hand washing techniques.
- §483.90(c)(2), F908, Maintain All Essential Equipment
 - o Determine if the equipment in the kitchen, such as refrigerators, *mobile* food carts, tray line equipment, freezers, dishwashers, ovens, stoves, and ranges etc. is maintained in safe operating condition and according to manufacturers' specifications.
- §483.90(i)(4), F925, Effective Pest Control Program
 - o Determine if the facility has maintained an effective pest control program so that it remains free of pests and rodents. Determine whether there is evidence of insect larvae, roaches, ants, flies, mice, etc. in food storage, preparation and service areas.
- §483.75(d),(e),and (g)(1)-(2), F867, F868, Quality Assessment and Assurance
 - o Determine whether the quality assessment and assurance committee seeks and reviews concerns related to foodborne illness, and food safety and sanitation to develop and implement appropriate actions to correct identified quality deficiencies when indicated.

KEY ELEMENTS OF NONCOMPLIANCE:

To cite F812, the surveyor's investigation will generally show the facility failed to do any one or more of the following:

- Procure, store, handle, prepare, distribute, and serve food in accordance with the standards summarized in this guidance; **or**
 - Maintain PHF/TCS foods at safe temperatures, at or below 41 degrees F (for cold foods) or at or above 135 degrees F (for hot foods) except during preparation, cooking, or cooling, and ensure that PHF/TCS food plated for transport was not out of temperature control for more than four hours from the time it is plated; **or**
 - Store raw foods (e.g., meats, fish) in a manner to reduce the risk of contamination of cooked or ready-to-eat foods; **or**
 - Cook food to the appropriate temperature to kill pathogenic microorganisms that may cause foodborne illness; **or**
 - Cool food in a manner that prevents the growth of pathogenic microorganisms; **or**
 - Utilize proper personal hygiene practices (e.g., proper hand washing and the appropriate use of gloves) to prevent contamination of food; and
 - Use and maintain equipment and food contact surfaces (e.g., cutting boards, dishes, and utensils) to prevent cross-contamination.
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¹ Partnership for Food Safety Education. (n.d.). Retrieved from <http://www.fightbac.org>.

² Partnership for Food Safety Education. (n.d.). Retrieved from <http://www.fightbac.org>.

F847 Entering Into Binding Arbitration Agreements

(Rev. 208; Issued:10-21-22; Effective: 10-21-22; Implementation:10-24-22)

§483.70(n) 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(n)(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(n)(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(n)(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(n)(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(n)(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(n) 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 F847 emphasize 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(n)(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(n)(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(n)(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(n)(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(n)(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(n)(2)(iii), (iv).*

§483.70(n)(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(n)(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(n)(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(n)(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(n)(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, Resident Contact with External Entities.

PROCEDURES AND PROBES §483.70(n)(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(n), 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.*

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. 208; Issued:10-21-22; Effective: 10-21-22; Implementation:10-24-22)

§483.70(n) 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(n)(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(n)(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(n) 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(n)(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(n)(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(n)(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(n)(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.*

F851

(Rev. 208; Issued:10-21-22; Effective: 10-21-22; Implementation:10-24-22)

§483.70(q) Mandatory submission of staffing information based on payroll data in a uniform format.

Long-term care facilities must electronically submit to CMS complete and accurate direct care staffing information, including information for agency and contract staff, based on payroll and other verifiable and auditable data in a uniform format according to specifications established by CMS.

§483.70(q)(1) Direct Care Staff.

Direct Care Staff are those individuals who, through interpersonal contact with residents or resident care management, provide care and services to allow residents to attain or maintain the highest practicable physical, mental, and psychosocial well-being. Direct care staff does not include individuals whose primary duty is maintaining the physical environment of the long term care facility (for example, housekeeping).

§483.70(q)(2) Submission requirements.

The facility must electronically submit to CMS complete and accurate direct care staffing information, including the following:

- (i) The category of work for each person on direct care staff (including, but not limited to, whether the individual is a registered nurse, licensed practical nurse, licensed vocational nurse, certified nursing assistant, therapist, or other type of medical personnel as specified by CMS);**
- (ii) Resident census data; and**
- (iii) Information on direct care staff turnover and tenure, and on the hours of care provided by each category of staff per resident per day (including, but not limited to, start date, end date (as applicable), and hours worked for each individual).**

§483.70(q)(3) Distinguishing employee from agency and contract staff.

When reporting information about direct care staff, the facility must specify whether the individual is an employee of the facility, or is engaged by the facility under contract or through an agency.

§483.70(q)(4) Data format.

The facility must submit direct care staffing information in the uniform format specified by CMS.

§483.70(q)(5) Submission schedule.

The facility must submit direct care staffing information on the schedule specified by CMS, but no less frequently than quarterly.

INTENT §483.70(q)

To ensure that long-term care facilities are electronically submitting direct care staffing information (including agency and contract staff) per day, based on payroll and other verifiable and auditable data. The staffing hours, when combined with census information, can then be used to not only report on the level of staff in each nursing home, but also to report on employee turnover and tenure.

GUIDANCE §483.70(q)

The facility is responsible for ensuring all staffing data entered in the Payroll-Based Journal (PBJ) system is auditable and able to be verified through either payroll, invoices, and/or tied back to a contract.

*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).

F865

(Rev. 208; Issued:10-21-22; Effective: 10-21-22; Implementation:10-24-22)

§483.75(a) Quality assurance and performance improvement (QAPI) program. Each LTC facility, including a facility that is part of a multiunit chain, must develop, implement, and maintain an effective, comprehensive, data-driven QAPI program that focuses on indicators of the outcomes of care and quality of life. The facility must:

§483.75(a)(1) Maintain documentation and demonstrate evidence of its ongoing QAPI program that meets the requirements of this section. This may include but is not limited to systems and reports demonstrating systematic identification, reporting, investigation, analysis, and prevention of adverse events; and

documentation demonstrating the development, implementation, and evaluation of corrective actions or performance improvement activities;

§483.75(a)(2) Present its QAPI plan to the State Survey Agency no later than 1 year after the promulgation of this regulation;

§483.75(a)(3) Present its QAPI plan to a State Survey Agency or Federal surveyor at each annual recertification survey and upon request during any other survey and to CMS upon request; and

§483.75(a)(4) Present documentation and evidence of its ongoing QAPI program's implementation and the facility's compliance with requirements to a State Survey Agency, Federal surveyor or CMS upon request.

§483.75(b) Program design and scope.

A facility must design its QAPI program to be ongoing, comprehensive, and to address the full range of care and services provided by the facility. It must:

§483.75(b)(1) Address all systems of care and management practices;

§483.75(b)(2) Include clinical care, quality of life, and resident choice;

§483.75(b)(3) Utilize the best available evidence to define and measure indicators of quality and facility goals that reflect processes of care and facility operations that have been shown to be predictive of desired outcomes for residents of a SNF or NF.

§483.75(b) (4) Reflect the complexities, unique care, and services that the facility provides.

§483.75(f) Governance and leadership.

The governing body and/or executive leadership (or organized group or individual who assumes full legal authority and responsibility for operation of the facility) is responsible and accountable for ensuring that:

§483.75(f)(1) An ongoing QAPI program is defined, implemented, and maintained and addresses identified priorities.

§483.75(f)(2) The QAPI program is sustained during transitions in leadership and staffing;

§483.75(f)(3) The QAPI program is adequately resourced, including ensuring staff time, equipment, and technical training as needed;

§483.75(f)(4) The QAPI program identifies and prioritizes problems and opportunities that reflect organizational process, functions, and services provided

to residents based on performance indicator data, and resident and staff input, and other information.

§483.75(f)(5) Corrective actions address gaps in systems, and are evaluated for effectiveness; and

§483.75(f)(6) Clear expectations are set around safety, quality, rights, choice, and respect.

§483.75(h) Disclosure of information.

A State or the Secretary may not require disclosure of the records of such committee except in so far as such disclosure is related to the compliance of such committee with the requirements of this section.

§483.75(i) Sanctions.

Good faith attempts by the committee to identify and correct quality deficiencies will not be used as a basis for sanctions.

INTENT

These requirements are intended to ensure *that long-term care facilities (including multi-unit chains) implement a comprehensive QAPI program which addresses all the care and unique services a facility provides.*

DEFINITIONS

“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.

“Indicators” are measurement(s) of performance related to a particular care area or service.

“Quality Assurance and Performance Improvement (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 in practical and creative problem solving.

“Quality Assurance (QA)” is the specification of standards for quality of service and outcomes, and systems throughout the organization for assuring that care is maintained at acceptable levels in relation to those standards. QA is on-going, 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)” (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 areas of opportunity and testing new approaches to fix underlying causes of persistent/systemic problems or barriers to improvement. PI in nursing homes aims to improve processes involved in health care delivery and resident quality of life. PI can make good quality even better.

GUIDANCE

QAPI is a type of quality management program which takes a systematic, interdisciplinary, comprehensive, and data-driven approach to maintaining and improving safety and quality. An interdisciplinary approach encompasses all managerial, and clinical, services, which includes care and services provided by outside (contracted or arranged) providers and suppliers.

The purpose of a QAPI program is to ensure continuous evaluation of facility systems with the objectives of:

- Ensuring care delivery systems function consistently, accurately, and incorporate current and evidence-based practice standards where available;*
- Preventing deviation from care processes, to the extent possible;*
- Identifying issues and concerns with facility systems, as well as identifying opportunities for improvement; and*
- Developing and implementing plans to correct and/or improve identified areas.*

Program and Documentation

Each facility must develop, implement, and maintain an effective, comprehensive, data-driven QAPI program that focuses on indicators of the outcomes of care and quality of life.

The facility must maintain and be able to provide documentation and evidence of its ongoing QAPI program, which meets the requirements of §483.75.

Demonstration of compliance includes, but is not limited to:

- Evidence of systems and reports demonstrating identification, reporting, investigation, analysis and prevention of adverse events;*
- Data collection and analysis at regular intervals; and*
- Documentation demonstrating development, implementation and evaluation of corrective actions or performance improvement activities.*

Upon the request of a State Survey Agency, Federal surveyor or CMS, the facility must present evidence, including documentation, of its ongoing QAPI program's implementation and the facility's compliance with requirements.

QAPI Plan

A QAPI plan is the written plan containing the process that will guide the nursing home's efforts in assuring care and services are maintained at acceptable levels of performance and continually improved. The plan describes how the facility will conduct its required QAPI and QAA committee functions. The facility is required to develop a QAPI plan and present its plan to federal and state surveyors at each annual recertification survey and upon request during any other survey, and to CMS upon request.

The QAPI plan *should* describe the scope of the QAA committee's responsibilities and activities, and the process addressing how the committee will conduct the activities necessary to identify and correct quality deficiencies. Each nursing home, including facilities which are a part of a multi-chain organization, should tailor its QAPI plan to reflect the specific units, programs, departments, and unique population it serves, as identified in its facility assessment.

The QAPI plan *should* describe how the facility will ensure care and services delivered meet accepted standards of quality, identify problems and opportunities for improvement, and ensure progress toward correction or improvement is achieved and sustained.

The QAPI plan *should* describe the process for identifying and correcting quality deficiencies. Key components of the process include:

- Tracking and measuring performance;
- Establishing goals and thresholds for performance measurement;
- Identifying and prioritizing quality deficiencies;
- Systematically analyzing underlying causes of systemic quality deficiencies;
- Developing and implementing corrective action or performance improvement activities; and
- Monitoring or evaluating the effectiveness of corrective action/performance improvement activities, and revising as needed.

Program Design and Scope

Each facility must have a QAPI program that is ongoing, comprehensive and capable of addressing the full range of care and services it provides. At a minimum, the program must:

- *Address all systems of care and management practices;*
- *Include clinical care, quality of life and resident choice;*
- *Utilize the best available evidence to define measure indicators of quality and facility goals that reflect processes of care and facility operations that have been shown to be predictive of desired outcomes for residents; and*
- *Reflect the complexities, unique care and services that the facility provides.*

Effective QAPI programs address systems of care and management practices. Systems of care (or care delivery systems) are the processes in place to achieve an expected clinical outcome. Nursing homes have many systems of care which intersect and involve multiple disciplines and departments. For example, the system for prevention of pressure ulcers

also involves the system for ensuring adequate nutrition, as well as the systems for identification of changes in condition and infection prevention. In order to ensure all aspects of these systems of care occur consistently, accurately, timely, and with the intended outcome, an effective program includes methods for monitoring the systems.

In addition to systems of care, the facility should monitor important management practices such as resident finances and personal funds, admission and discharge practices, and other services that impact quality of life and resident rights. The QAPI program should address quality of life and resident choice by identifying the unique needs and preferences of the varying demographics of residents residing in the facility (i.e., young and/or culturally diverse residents) and seeking ongoing input and feedback from their residents.

Governance and Leadership

The Governing Body and/or executive leadership (or organized group or an individual who assumes full legal authority and responsibility for operation of the facility), must ensure the QAPI Program:

- Is defined, implemented and ongoing;*
- Addresses identified priorities;*
- Is sustained through transitions in leadership and staffing;*
- Has adequate resources, including staff time, equipment, and technical training as needed;*
- Uses performance indicator data, resident and staff input, and other information to identify and prioritize problems and opportunities;*
- Implements corrective actions to address gaps in systems and evaluates actions for effectiveness; and*
- Establishes clear expectations around safety, quality, rights, choice and respect.*

Disclosure of Information

The survey process is intended to be an objective assessment of facility compliance with the requirements of participation. This assessment is guided by facility performance and outcomes as reported by Quality Measures (QMs) and Minimum Data Set (MDS) data, as well as complaints and surveyor observations, interviews, and record reviews. The surveyor task to review-QAPI/QAA is intended to occur at the end of the survey, after completion of investigation into all other requirements to ensure that concerns are identified by the survey team independent of the QAPI/QAA review. Surveyors must use critical thinking and investigatory skills to identify noncompliance, rather than using information provided during the *QAPI/QAA* review as a source to identify deficiencies.

Surveyors may only require *a facility* to disclose QAA committee records if they are used to determine the extent to which *the facility is* compliant with the provisions for QAPI/QAA.

Protection from disclosure is generally afforded documents generated by the QAA committee, such as minutes, internal papers, or conclusions. However, if those documents contain the evidence necessary to determine compliance with QAPI/QAA regulations, the facility must allow the surveyor to review and copy them. The **key point** is that the facility must provide satisfactory evidence that it has, through its QAA committee, identified its own high risk, high volume, and problem-prone quality deficiencies, and *is* making a “good faith attempt” to correct them.

Examples of when disclosure may be necessary to determine compliance:

- *If the facility’s infection control data indicates that staff may not have responded in a timely and effective manner to address an outbreak of a communicable disease, the facility must allow the surveyor to review and copy QAA committee minutes and related documentation so that the surveyor is capable of evaluating the facility’s QAPI/QAA compliance.*
- *If the surveyor’s staff interviews and record reviews reveal the facility has a past history of failing to follow care instructions and recommendations from clinical specialists when residents obtain specialty care outside the facility, the facility must allow the surveyor to review and copy QAPI/QAA documentation. Under these circumstances, review of the QAPI/QAA documentation is necessary to evaluate whether the QAA Committee identified a problem with failure to follow care instructions and recommendations from outside specialists and, if it did, whether the QAA Committee adequately addressed the problem.*

NOTE: Prior to conducting the QAPI/QAA review, the survey team must conduct a thorough investigation of all issues identified, including expanding the sample as necessary to determine the scope of the issue.

Reports and Logs

Incident and accident reports, wound logs, *infection control logs*, or other reports or records used to track adverse events are not protected from disclosure. Surveyors may request these documents as part of their normal investigation of other areas of concern throughout the survey to support their findings.

Surveyor Access to QAPI/QAA Material and Confidentiality of Patient Safety Work Products

CMS supports and encourages nursing homes to work on a confidential basis with an Agency for Healthcare Research and Quality (AHRQ) approved Patient Safety Organization (PSO) to obtain technical assistance in identifying, analyzing and preventing quality deficiencies and adverse events. The Federal Patient Safety and Quality Improvement Act of 2005 (PSQIA), Public Law 109-41, established a voluntary reporting system designed to enhance the data available to assess and resolve patient safety and health care quality issues. PSQIA has afforded privileged and confidential status to “patient safety work product” (PSWP). PSWP includes data, reports, records, memoranda, analysis, or written and oral statements assembled and developed for

reporting to a PSO and have been submitted to a PSO approved and listed by the Department of Health and Human Services (HHS), AHRQ.

PSQIA and the Patient Safety Rule only limit the disclosure of PSWP. Neither PSQIA nor the Patient Safety Rule limit the disclosure of non-PSWP, including its disclosure to a Federal, state or local government for public health surveillance, investigation or health oversight. The preamble to the final Patient Safety Rule states:

“Information is not patient safety work product if it is collected to comply with external reporting, such as...certification or licensing records for compliance with health oversight agency requirements;...complying with required disclosures by particular providers or suppliers pursuant to Medicare’s Conditions of participation or conditions of coverage...” (73 FR 70742-70743, November 21, 2008).

Ultimately, it is the nursing home’s final decision as to whether to enter into a relationship with a PSO and to create a patient safety evaluation system (PSES) which is the collection, management, or analysis of information for reporting to or by a PSO. Additionally, the nursing home *should* determine what information to place within the PSES, considering a number of factors, including how they will demonstrate compliance with the Long-term Care Requirements for Participation, in particular, the QAPI/QAA requirements. A nursing home must be prepared to meet its obligation to provide surveyors access to QAPI/QAA program information to demonstrate compliance without disclosing PSWP as that term is defined in 42 CFR Part 3, the regulation implementing the Federal PSQIA. There is no barrier under the PSQIA for nursing homes to maintain duplicate systems, one consisting of patient safety work product within a protected patient safety evaluation system, and another to demonstrate compliance with local, State or Federal requirements.

Surveyors should consider the following key points:

- Surveyors assessing QAPI/QAA compliance must ask nursing homes to provide evidence of QAPI/QAA compliance.
- Surveyors must **never** ask or demand that a nursing home show them “patient safety work product.” If a nursing home states that all relevant QAPI/QAA material has been placed in its PSES, or is protected PSWP, surveyors must ask to see the agreement the nursing home has with an AHRQ-approved PSO, to confirm that it has an approved protected PSES.
- If a nursing home has placed all evidence related to QAPI/QAA compliance in its PSES as patient safety work product and does not also maintain a separate non-confidential system to provide evidence of compliance, or is unable to remove evidence of such compliance from its PSES, it may not be able to demonstrate its compliance to the surveyor.

Sanctions and Good Faith Attempts

If the facility, through its QAA committee, has identified and made a good faith attempt to correct the same issue identified by the survey team during the survey,

the facility will not be cited for QAA (it may however, still be cited with deficiencies related to actual or potential issues at other tags).

To establish that the facility's QAA committee has made a good faith attempt to correct an identified quality deficiency, a facility must do more than just subjectively assert it has made a good faith attempt; rather, the facility's actions, taken as a whole, must evidence a good faith attempt to identify and correct quality deficiencies.

To evaluate good faith attempts, surveyors will have to determine if the facility became aware of the issue as soon as it should have and where the facility is within the correction process. Additional areas of inquiry include, but are not limited to, the following: was the issue a high-risk, high-volume, or problem-prone issue the facility should have been tracking? Was there a negative outcome to a resident which should have alerted the facility to the issue? What steps did the facility take when it became aware of the issue? Has there been enough time to implement changes and to evaluate the effectiveness of those changes? Do the facility's efforts demonstrate diligence and a genuine attempt to correct the issue? Identifying and correcting problems requires *the facility* to:

- Collect data from various sources related to high risk, high volume, and problem-prone issues such as medical errors and adverse events;
- Analyze the data collected to identify performance indicators signaling deviation from expected performance;
- Study the issue to determine underlying causes and contributing factors;
- Develop and implement corrective actions; and
- Monitor data related to the issue to determine if they are sustaining corrections, or if revisions are necessary.

If the survey team has identified a current issue which will be cited at S/S level of E or above, or has identified substandard quality of care, the surveyor conducting the QAPI/QAA Review should consider if the facility's monitoring systems should also have identified the same issue.

The surveyor must take into consideration whether the QAA committee has had sufficient time through its monitoring systems to identify the issue, if it was a high risk, problem-prone issue they should have been monitoring, and whether there has been a reasonable amount of time to respond to the issue. Issues which are likely to cause serious harm, impairment, or death must be responded to immediately. If the facility has identified the issue through its QAA committee, the surveyor must then evaluate the extent to which their actions or plans to correct the issue demonstrate a "good faith attempt."

Surveyors must not use documentation provided by the facility during the QAPI/QAA review to identify additional concerns not previously identified by the survey team during the current survey, nor can they expand the scope or the severity of the problem based on information gleaned from this disclosure.

Facility Refusal to Provide Evidence of Compliance

To the extent a facility's QAPI/QAA information is necessary to demonstrate the facility's compliance with the requirements of 42 CFR § 483.75, a facility is required under 42 CFR § 483.75(h) to disclose this information to the State Agency and/or CMS. Refusal by a facility to produce evidence of compliance with QAPI/QAA will lead to citation of noncompliance with F865, requiring a plan of correction, and possible imposition of enforcement remedies up to and including termination of the facility's provider agreement (*per 42 CFR §489.53*). In the event of a facility refusal to produce evidence of compliance, the team coordinator should contact their State Agency supervisor.

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 *when* 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 F865, the surveyor's investigation will generally show that the facility failed to do any one of the following:

- *Maintain documentation and evidence of its ongoing QAPI program; or*
- *Present its QAPI plan to the Federal and/or State surveyors during recertification survey or upon request; or*
- *Present QAPI evidence necessary to demonstrate compliance with these requirements; or*
- *Develop, implement and maintain an effective, comprehensive QAPI program, that addresses the full range of services the facility provides; or*
- *Ensure governing body oversight of the facility's QAPI program and activities.*

F866

(Rev. 208; Issued:10-21-22; Effective: 10-21-22; Implementation:10-24-22)

Note: Regulatory requirements §483.75(c) and §483.75(c)(1)-(4) have been relocated to F867.

F867

(Rev. 208; Issued:10-21-22; Effective: 10-21-22; Implementation:10-24-22)

§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 §483.70(e) and including how such information will be used to develop and monitor performance indicators.

§483.75(c)(3) Facility development, monitoring, and evaluation of performance indicators, including the methodology and frequency for such development, monitoring, and evaluation.

§483.75(c)(4) Facility adverse event monitoring, including the methods by which the facility will systematically identify, report, track, investigate, analyze and use data and information relating to adverse events in the facility, including how the facility will use the data to develop activities to prevent adverse events.

§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 §483.70(e). 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 (§483.70(e)).

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: <ul style="list-style-type: none"> • Pneumonia • Influenza
Hypoglycemia related to use of antidiabetic medication	Electrolyte imbalance (including dehydration and acute kidney injury/insufficiency) associated with inadequate fluid maintenance	Skin and wound infections: <ul style="list-style-type: none"> • Surgical Site Infections (SSIs) • Soft tissue and non-surgical wound infections
Ketoacidosis related to use of antidiabetic medication	Thromboembolic events related to inadequate resident monitoring and provision of care	Urinary tract infections (UTIs) <ul style="list-style-type: none"> • Catheter Associated UTIs (CAUTIs) • UTIs (non-catheter associated)
Bleeding related to use of antithrombotic medication	Respiratory distress related to inadequate monitoring and provision of tracheostomy/ventilator care	Infectious diarrhea <ul style="list-style-type: none"> • Clostridium difficile • 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	<i>Instances of abuse, neglect, and misappropriation of resident property and exploitation (see §483.5)</i>	

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 §483.70(e). 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. 208; Issued:10-21-22; Effective: 10-21-22; Implementation:10-24-22)

§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(h), 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(h) 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. 208; Issued:10-21-22; Effective: 10-21-22; Implementation:10-24-22)

§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 §483.70(e) and following accepted national standards;

§483.80(a)(2) Written standards, policies, and procedures for the program, which must include, but are not limited to:

- (i) A system of surveillance designed to identify possible communicable diseases or infections before they can spread to other persons in the facility;**
- (ii) When and to whom possible incidents of communicable disease or infections should be reported;**
- (iii) Standard and transmission-based precautions to be followed to prevent spread of infections;**
- (iv) When and how isolation should be used for a resident; including but not limited to:
 - (A) The type and duration of the isolation, depending upon the infectious agent or organism involved, and**
 - (B) A requirement that the isolation should be the least restrictive possible for the resident under the circumstances.****
- (v) The circumstances under which the facility must prohibit employees with a communicable disease or infected skin lesions from direct contact with residents or their food, if direct contact will transmit the disease; and**
- (vi) The hand hygiene procedures to be followed by staff involved in direct resident contact.**

§483.80(a)(4) A system for recording incidents identified under the facility's IPCP and the corrective actions taken by the facility.

§483.80(e) Linens. Personnel must handle, store, process, and transport linens so as to prevent the spread of infection.

§483.80(f) Annual review. The facility will conduct an annual review of its IPCP and update their program, as necessary.

INTENT §483.80(a)(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 §483.70(e)*; *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 §483.70(e) (F838), the facility must conduct and document a facility-wide assessment to determine what resources are necessary to care for its residents competently during both day-to-day operations and emergencies. The facility must review and update that assessment, as necessary, and at least annually. The facility must also review and update this assessment whenever there is, or the facility plans for, any change that would require a substantial modification to any part of this assessment. The facility assessment must address or include, *among other things*, a facility-based and community-based risk assessment, utilizing an all-hazards approach. See §483.70(e)

(F838) for guidance on the facility assessment. The results of the facility assessment must be used, in part, to establish and update the IPCP, its policies and/or protocols to include a system for preventing, identifying, reporting, investigating, and controlling infections and communicable diseases for residents, staff, and visitors.

NOTE: A community-based risk assessment should include review for risk of infections (e.g., multidrug-resistant organisms/MDROs) and communicable diseases such as tuberculosis and influenza. Appropriate resident tuberculosis screening should be performed based on state requirements.

NOTE: While not required for compliance, a sample tool of an infection control risk assessment is available for adaptation.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 483.70(e)) which includes any facility and community risk;
- An ongoing system of surveillance designed to identify possible communicable diseases or infections before they can spread to other persons in the facility;
- When and to whom possible incidents of communicable disease or infections should be reported within the facility;
- Which communicable diseases are reportable to local/state public health authorities;
- *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 precautions¹⁵ 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 soiled¹⁶ (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 guidelines²³ 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 investigation²⁸*);
- 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 Criteria²⁹” 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 practices⁶⁰:

- 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; and⁶³
- 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 following⁶⁶:

- Availability and use of hand hygiene products, as well as appropriate PPE (i.e., gloves and gowns) while sorting and handling contaminated linens;
- The receiving area for contaminated textiles is clearly separated from clean laundry areas. Workflow should prevent cross-contamination;
- If using fans in laundry processing areas, prevent cross-contamination of clean linens from air blowing from soiled processing areas (i.e., the ventilation should not flow from soiled processing areas to clean laundry areas);
- Laundry equipment (e.g., washing machines, dryers) is used and maintained according to the manufacturer's IFU to prevent microbial contamination of the system;
- Damp laundry is not left in machines overnight;
- Laundry detergents, rinse aids or other additives are used according to the manufacturer's IFU. **NOTE:** Facilities should communicate information regarding allergies that may impact how an individual resident's laundry is processed;
- Ozone cleaning systems are acceptable for processing laundry;
- If laundry chutes are used, they are designed and maintained so as to minimize dispersion of aerosols from contaminated laundry (e.g., no loose items in the chute and bags are closed before tossing into the chute);^{and}
- The facility should be using the fabric manufacturer's recommended laundry cycles, water temperatures and chemical detergent products:
 - Recommendations for laundry processed in hot water temperatures is 160°F (71°C) for 25 minutes; and
 - For laundry that is not hot water compatible, low temperature washing at 71 to 77 °F (22-25 °C) plus chlorine or oxygen-activated bleach can reduce microbial contamination.

NOTE: The facility is not required to monitor water temperatures during laundry processing cycles, unless specified by state rules. A chlorine bleach rinse is not required for all laundry items processed in low temperature washing environments due to the availability of modern laundry detergents that are able to produce hygienically clean laundry without the presence of chlorine bleach. The facility should refer to the manufacturer's recommendations for the use of the detergent and items being laundered.

Offsite Professional Laundry Services

If linen is sent off-site to a professional laundry, the facility has practices that address how the service will be provided, including how linen is processed and handled to prevent contamination from dust and dirt during loading and transport. The facility should assure that this laundry service meets healthcare industry laundry standards.

Mattresses and Pillows

Standard permeable mattresses and pillows can become contaminated with body substances during resident care if the integrity of the covers of these items is compromised. A mattress cover is generally a fitted, protective material, the purpose of which is to prevent the mattress from becoming contaminated with body fluids and substances. A linen sheet placed on the mattress is not considered a mattress cover. Patches for tears and holes in mattress covers do not provide an impermeable surface over the mattress. **NOTE:** Bed and bath linens must be maintained in good condition (Refer to §483.10(i) Safe environment, F584, for further information).

The facility must have practices that address the methods for cleaning and disinfecting items that are to be used for another resident after an individual resident's use. *Such practices*⁶⁷ *include*, but are not limited to, the following:

- Mattress covers with tears or holes are replaced;
- Moisture resistant mattress covers are cleaned and disinfected between use for different residents with an EPA-approved germicidal detergent to help prevent the spread of infections;
- Fabric mattress covers are laundered between use for different residents;
- Pillow covers and washable pillows are laundered in a hot water laundry cycle between use for different residents or when they become contaminated with body substances; and
- Mattresses are discarded if bodily fluids have penetrated into the mattress fabric.

Annual Review of IPCP

Under §483.80(f), the facility's IPCP and its standards, policies and procedures must be reviewed at least annually to ensure effectiveness and that they are in accordance with current standards of practice for preventing and controlling infections; the IPCP must be updated as necessary. In addition, the facility population and characteristics may change over time, and the facility assessment may identify components of the IPCP that must be changed accordingly.

INVESTIGATIVE PROCEDURES

Use the Infection Prevention, Control & Immunizations Facility Task, along with the above interpretive guidance, when determining if the facility meets the requirements for, or when investigating concerns related to, infection prevention and control. One surveyor should coordinate the review of the facility's overall IPCP, however, each member of the survey team should assess for compliance throughout the entire survey when observing his/her assigned areas and tasks. The IPCP must be facility-wide and

include all departments and contracted services. *If potential non-compliance is identified*, the surveyor should corroborate *those* concerns through *observations*, interviews, and record and/or document review.

Observations

Specific observations for the provision of infection prevention and control practices such as following standard precautions (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 §483.70(e)] 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.

¹ Siegel, J.D., Rhinehart, E., Jackson, M., Chiarello, L., & the Healthcare Infection Control Practices Advisory Committee. "Guideline for isolation precautions: Preventing transmission of infectious agents in healthcare settings (2007)." Accessed on *February 27, 2021* from <https://www.cdc.gov/infectioncontrol/guidelines/isolation/index.html>

² See endnote 1

³ See endnote 1

⁴ See endnote 1

⁵ Centers for Disease Control and Prevention. "Guideline for disinfection and sterilization in healthcare facilities (2008)." Accessed on *February 27, 2021* from https://www.cdc.gov/hicpac/pdf/guidelines/Disinfection_Nov_2008.pdf

⁶ See endnote 5

⁷ Centers for Disease Control and Prevention. (2002, October 25). "Guideline for hand hygiene in health-

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- care settings: Recommendations of The Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force.” *MMWR*; 51(No.RR-16). Accessed on February 27, 2021 from <http://www.cdc.gov/mmwr/PDF/rr/rr5116.pdf>
- ⁸ Centers for Disease Control and Prevention. “Hand Hygiene in Healthcare Settings.” www.cdc.gov. Accessed on February 27, 2021 from <https://www.cdc.gov/handhygiene/providers/index.html>. (reference was updated from SOM Rev. 173)
- ⁹ Association for the Advancement of Medical Instrumentation (AAMI). (2009). ANSI/AAMI ST65:2008/(R)2013. Processing of reusable surgical textiles for use in health care facilities, 2008. Arlington, VA.
- ¹⁰ See endnote 1
- ¹¹ Healthcare Infection Control Practices Advisory Committee (HICPAC). (2017). “Core infection prevention and control practices for safe healthcare delivery in all settings—recommendations of the HICPAC.” www.cdc.gov. Accessed on February 27, 2021 from <https://www.cdc.gov/hicpac/recommendations/core-practices.html>.
- ¹² See endnote 1
- ¹³ See endnote 1
- ¹⁴ Association for Professionals in Infection Control and Epidemiology. “IC risk assessment tool form” and “IC risk assessment analysis.” Accessed on February 27, 2021 from <http://community.apic.org/sierra/resources/overview>
- ¹⁵ See endnote 1
- ¹⁶ See endnote 11
- ¹⁷ Dubberke, E.R., & Gerding, D.N. “Rationale for hand hygiene recommendations after caring for a patient with *Clostridium difficile* infection. A compendium of strategies to prevent healthcare-associated infections in acute care hospitals: A fall 2011 update.” <https://www.shea-online.org/> Accessed on February 27, 2021 from <https://www.shea-online.org/images/patients/CDI-hand-hygiene-Update.pdf>
- ¹⁸ See endnote 1
- ¹⁹ See endnote 1
- ²⁰ See endnote 1
- ²¹ Bolyard, E.A., Tablan, O.C., Williams, W.W., Pearson, M.L., Shapiro, C.N., Deitchman, S.D., & The Healthcare Infection Control Practices Advisory Committee. “Guideline for infection control in health care personnel, 1998.” www.cdc.gov Accessed on February 27, 2021 from <https://www.cdc.gov/hicpac/pdf/InfectControl98.pdf>
- ²² Kuhar, D.T., Carrico, R., Cox, K., de Perio, M.A., Irwin, K.L., Lundstrom, T. & the Healthcare Infection Control Practices Advisory Committee. (2019). “Infection Control in Healthcare Personnel: Infrastructure and Routine Practices for Occupational Infection Prevention and Control Services.” www.cdc.gov Accessed on February 27, 2021 from <https://www.cdc.gov/infectioncontrol/guidelines/healthcare-personnel/index.html>
- ²³ Sosa, L.E., Njie, G.J., Lobato, M.N., Morris, S.B., Buchta, W., & Casey, M.L. “Tuberculosis screening, testing, and treatment of U.S. health care personnel: Recommendations from the National Tuberculosis Controllers Association and CDC, 2019.” *MMWR*; 68:439–443. Accessed on February 27, 2021 from <https://www.cdc.gov/tb/publications/guidelines/infectioncontrol.htm>
- ²⁴ Stone, N.D., Ashraf, M.S., Calder, J., Crnich, C. J., Crossley, K., Drinka, P.J., ...Bradley, S.F. (2012). “Surveillance definitions of infections in long-term care facilities: Revisiting the McGeer criteria.” *Infect Control Hosp Epidemiology*. 33(10), 965-977.
- ²⁵ See endnote 1
- ²⁶ Siegel, J.D., Rhinehart, E., Jackson, M., and Chiarello, L. “Management of multidrug-resistant organisms in healthcare settings (2006).” www.cdc.gov. Accessed on February 27, 2021 from <https://www.cdc.gov/hicpac/pdf/mdro/mdroguideline2006.pdf>
- ²⁷ Smith, P.W., Bennett, G., Bradley, S., Drinka, P., Lautenbach, E., Marx, J.... Stevenson, K. (2008). “SHEA/APIC Guideline: infection prevention and control in the long-term care facility.” *Infect Control Hosp Epidemiology*. 29(9), 785-814.
- ²⁸ Guh, A., Carling, P, and Environmental Evaluation Workgroup. (2010). “Options for Evaluating Environmental Cleaning.” www.cdc.gov. Accessed on February 27, 2021 from <https://www.cdc.gov/hai/toolkits/evaluating-environmental-cleaning.html>
- ²⁹ See endnote 24

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- ³⁰ See endnote 27
- ³¹ Centers for Disease Control and Prevention. “Epidemiology glossary.” www.cdc.gov. Accessed on *February 27, 2021* from http://www.cdc.gov/reproductivehealth/data_stats/glossary.html#O
- ³² Kim, K.H., Fekety, R., Batts, D.H., Brown, D., Cudmore, M., Silva, J. Jr., & Waters, D. (1981, January 1). “Isolation of *Clostridium difficile* from the environment and contacts of residents with antibiotic-associated colitis.” *Journal of Infectious Disease*. 143(1), 42-50.
- ³³ Centers for Disease Control and Prevention. “Hepatitis B questions and answers for health professionals.” www.cdc.gov. Accessed on *February 27, 2021* from <http://www.cdc.gov/hepatitis/HBV/FAQ.htm>
- ³⁴ Centers for Disease Control and Prevention (CDC). “H1N1 Flu: General Info.” www.cdc.gov. Accessed on *February 27, 2021* from <https://www.cdc.gov/h1n1flu/qa.htm>
- ³⁵ See endnote 1
- ³⁶ See endnote 11
- ³⁷ See endnote 11
- ³⁸ See endnote 1
- ³⁹ See endnote 5
- ⁴⁰ See endnote 5
- ⁴¹ *Schulster, L.M., Chinn, R.Y., Arduino, M.J., Carpenter, J., Donlan, R., Ashford, D., ... Cleveland, J. (2003, Updated July 2019). “Guidelines for environmental infection control in health-care facilities (2003).” www.cdc.gov. Accessed on February 27, 2021 from https://www.cdc.gov/infectioncontrol/guidelines/environmental/index.html*
- ⁴² See endnote 1
- ⁴³ See endnote 26
- ⁴⁴ See endnote 1
- ⁴⁵ See endnote 1
- ⁴⁶ See endnote 1
- ⁴⁷ See endnote 1
- ⁴⁸ Hall, C.B., Douglas, Jr., R.G., Schnabal, K.C., and Geiman, J.M. (1981, September). Infectivity of respiratory syncytial virus by various routes of inoculation. *Infection and Immunity*. 33(3), 779-783.
- ⁴⁹ See endnote 1
- ⁵⁰ See endnote 1
- ⁵¹ See endnote 1
- ⁵² See endnote 1
- ⁵³ See endnote 1
- ⁵⁴ See endnote 1
- ⁵⁵ See endnote 1
- ⁵⁶ See endnote 1
- ⁵⁷ See endnote 1
- ⁵⁸ See endnote 1
- ⁵⁹ Centers for Disease Control and Prevention. “Frequently asked questions (FAQs) regarding assisted blood glucose monitoring and insulin administration.” www.cdc.gov. Accessed on *February 27, 2021* from https://www.cdc.gov/injectionsafety/providers/blood-glucose-monitoring_faqs.html
- ⁶⁰ See endnote 41
- ⁶¹ See endnote 41
- ⁶² Occupational Safety and Health Administration. “Title 29 Part 1910.1030. Bloodborne pathogens.” Accessed on *February 27, 2021* from http://www.ecfr.gov/cgi-bin/text-idx?SID=4e5245f66094d270bc2bd93105f6a92d&mc=true&node=se29.6.1910_11030&rgn=div8
- ⁶³ See endnote 41
- ⁶⁴ See endnote 41
- ⁶⁵ See endnote 41
- ⁶⁶ See endnote 41
- ⁶⁷ See endnote 41

F881

(Rev. 208; Issued:10-21-22; Effective: 10-21-22; Implementation:10-24-22)

§483.80(a) Infection prevention and control program. The facility must establish an infection prevention and control program (IPCP) that must include, at a minimum, the following elements:

§483.80(a)(3) An antibiotic stewardship program that includes antibiotic use protocols and a system to monitor antibiotic use.

INTENT

The intent of this regulation is to ensure that the facility:

- Develops and implements protocols to optimize the treatment of infections by ensuring that residents who require an antibiotic, are prescribed the appropriate antibiotic;
- Reduces the risk of adverse events, including the development of antibiotic-resistant organisms, from unnecessary or inappropriate antibiotic use; and
- Develops, promotes, and implements a facility-wide system to monitor the use of antibiotics.

DEFINITIONS

- **“Antibiotic”** *refers to* a medication used to treat bacterial infections. They are not effective for infections caused by viruses (e.g., influenza or most cases of bronchitis).
- **“Antibiotic Stewardship”** refers to a set of commitments and actions designed to optimize the treatment of infections while reducing the adverse events associated with antibiotic use.¹ This can be accomplished through improving antibiotic prescribing, administration, and management practices thus reducing inappropriate use to ensure that residents receive the right antibiotic for the right indication, dose, and duration.²
- **“Methicillin-resistant *Staphylococcus aureus* (MRSA) (a.k.a. Oxacillin-resistant *Staphylococcus aureus*)”** *refers to* *Staphylococcus aureus* bacteria that are resistant to treatment with one of the semi-synthetic penicillins (e.g., Oxacillin/Nafcillin/Methicillin).
- **“Vancomycin-resistant Enterococcus (VRE)”** *refers to a* species of enterococcus which have developed resistance to the antibiotic, vancomycin.

GUIDANCE

Antibiotic Stewardship

As part of their IPCP programs, facilities must develop an antibiotic stewardship program that promotes the appropriate use of antibiotics and includes a system of monitoring to improve resident outcomes and reduce antibiotic resistance.^{3, 4, 5} This means that the

antibiotic is prescribed for the correct indication, dose, and duration to appropriately treat the resident while also attempting to reduce the development of antibiotic-resistant organisms.

Nursing home residents are at risk for adverse outcomes associated with the inappropriate use of antibiotics that may include but are not limited to the following:

- Increased adverse drug events and drug interactions (e.g., allergic rash, anaphylaxis or death);
- Serious diarrheal infections from *C. difficile*;
- Disruption of normal flora (e.g., this can result in overgrowth of *Candida* such as oral thrush); and/or
- Colonization and/or infection with antibiotic-resistant organisms such as MRSA, VRE, and multidrug-resistant *gram negative bacteria*.

Resources are available to identify core actions to prevent antibiotic resistance within the control of the nursing home, such as:

- The Centers for Disease Control and Prevention’s (CDC) “*The Core Elements of Antibiotic Stewardship for Nursing Homes*” <http://www.cdc.gov/longtermcare/pdfs/core-elements-antibiotic-stewardship-appendix-a.pdf>; *and*
- The Agency for Healthcare Research and Quality’s “*Nursing Home Antimicrobial Stewardship Guide*” <http://www.ahrq.gov/nhguide/index.html> for examples of antibiotic use protocols, policies and practices.

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 (HHS)*. 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.*

Antibiotic Stewardship Program (ASP)

As summarized by the CDC, the core elements for antibiotic stewardship in nursing homes include:

- Facility leadership commitment to safe and appropriate antibiotic use;
- Appropriate facility staff accountable for promoting and overseeing antibiotic stewardship;
- Accessing pharmacists and others with experience or training in antibiotic stewardship;
- Implement policy(ies) or practice to improve antibiotic use;
- Track measures of antibiotic use in the facility (i.e., one process and one outcome measure);
- Regular reporting on antibiotic use and resistance to relevant staff such as prescribing clinicians and nursing staff; and

- Educate staff and residents about antibiotic stewardship.⁶

The facility must develop an antibiotic stewardship program which includes the development of protocols and a system to monitor antibiotic use. This development should include leadership support and accountability via the participation of the medical director, consulting pharmacist, nursing and administrative leadership, and individual with designated responsibility for the infection control program (*i.e., infection preventionist*).⁷

The antibiotic stewardship program protocols shall describe how the program will be implemented and antibiotic use will be monitored; consequently, protocols *should*:

- Be incorporated in the overall infection prevention and control program;
- Be reviewed on an annual basis and as needed;
- Contain a system of reports related to monitoring antibiotic usage and resistance data. Examples may include the following:
 - Summarizing antibiotic use from pharmacy data *or electronic health records*, such as the rate of new starts, types of antibiotics prescribed, or days of antibiotic treatment per 1,000 resident days;
 - Summarizing antibiotic resistance (e.g., antibiogram) based on laboratory data from, for example, the last 18 months; and/or
 - Tracking measures of outcome surveillance related to antibiotic use (e.g., *C. difficile*, MRSA, and/or CRE).⁸
- Incorporate monitoring of antibiotic use, including the frequency of monitoring/review. Monitor/review *response to antibiotics, and laboratory results when available, to determine if the antibiotic is still indicated or adjustments should be made (e.g., antibiotic time-out)*; when the resident is new to the facility; when a prior resident returns or is transferred from a hospital or other facility⁹; during each monthly medication regimen review when the resident has been prescribed or is taking an antibiotic, or any antibiotic regimen review as requested by the QAA committee. *Facilities should provide* feedback (e.g., verbal, written note in record) to prescribing practitioners regarding antibiotic resistance data, their antibiotic use and their compliance with facility antibiotic use protocols *to improve prescribing practices and resident outcomes*.¹⁰ Feedback on prescribing practices and compliance with facility antibiotic use protocols may include information from medical record reviews for new antibiotic starts to determine whether the resident had signs or symptoms of an infection; laboratory tests ordered and the results; *order* documentation including the indication for use (i.e., whether or not an infection or communicable disease has been documented), dosage and duration; and clinical justification for the use of an antibiotic beyond the initial duration ordered such as a review of laboratory reports/cultures in order to determine if the antibiotic remains indicated or if adjustments to therapy should be made (e.g., more narrow spectrum antibiotic);
- Assess residents for any infection using standardized tools and criteria¹¹ (e.g., SBAR tool for urinary tract infection (UTI) assessment¹², Loeb minimum criteria for initiation of antibiotics¹³);

- Include the mode (e.g., verbal, written, online) and frequency (as determined by the facility) of education for prescribing practitioners and nursing staff on antibiotic use (stewardship) and the facility's antibiotic use protocols. **NOTE:** Prescribing practitioners can include attending physicians and non-physician practitioners (NPP) (i.e., nurse practitioners, clinical nurse specialists, and physician assistants); *and*
- *Require antibiotic orders to include the indication, dose, and duration.*

The Antibiotic Stewardship Program in Relation to Pharmacy Services

The assessment, monitoring, and communication of antibiotic use shall occur by a licensed pharmacist in accordance with §483.45(c), F756, Drug Regimen Review. A pharmacist must perform a medication regimen review (MRR) at least monthly, including review of the medical record and identify any irregularities, including unnecessary drugs.

INVESTIGATIVE 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, the antibiotic stewardship program.

Determine whether the facility's antibiotic stewardship program includes antibiotic use protocol(s) addressing antibiotic prescribing practices (i.e., documentation of the indication, dose, and duration of the antibiotic; review of laboratory reports to determine if the antibiotic is indicated or needs to be adjusted; an infection assessment tool or management algorithm is used when prescribing) and a system to monitor antibiotic use (i.e., antibiotic use reports, antibiotic resistance reports). *If there are concerns with the ASP, surveyors must include at least one resident on an antibiotic in the resident sample to assess whether the resident(s) is being prescribed an antibiotic(s) unnecessarily and whether there were any negative outcomes such as an adverse drug event.*

Instances of prescribing antibiotics unnecessarily should be cited at §483.45(d), F757. These findings may support citing §483.80(a)(3), F881, as well, in which case the surveyor must also show that the facility does not have or is not implementing an ASP. It may also be necessary to interview the appropriate person, (e.g., director of nursing, medical director, consulting pharmacist, administrator, or infection preventionist) to verify how antibiotic use is monitored in the facility *and confirm with findings from review of the antibiotic stewardship program or resident records.* Furthermore, review records including evidence of actions taken by the QAA committee related to antibiotic use and stewardship.

POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION

- F756: for concerns related to the failure of the pharmacist to review and report any unnecessary antibiotic irregularity;
- F757: for concerns related to unnecessary antibiotic use; and
- F552: for concerns related to the right to be fully informed in advance about care and treatment.

KEY ELEMENTS OF NONCOMPLIANCE

To cite deficient practice at F881, the surveyor's investigation will generally show that the facility failed to do any one or more of the following:

- Develop and implement antibiotic use protocols to address the treatment of infections by ensuring that residents who require antibiotics are prescribed the appropriate antibiotics; *or*
- Develop and implement antibiotic use protocols that address unnecessary or inappropriate antibiotic use thereby reducing the risk of adverse events, including the development of antibiotic-resistant organisms; or
- Develop, promote and implement a facility-wide system to monitor the use of antibiotics.

DEFICIENCY CATEGORIZATION

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

- The facility failed to develop and implement an antibiotic use protocol which included reporting results of laboratory data to the ordering practitioner. Medical record review indicated the prescribing practitioner had ordered a culture and sensitivity for a resident and prescribed an antibiotic for treatment of pneumonia prior to receipt of the results of the lab test. The facility received the results of the lab test which indicated that the bacteria was resistant to the antibiotic prescribed, however, they did not provide this information to the practitioner. As a result, the antibiotic was not adjusted accordingly and the resident was hospitalized for complications related to the pneumonia.

An example of Level 3, actual harm that is not immediate jeopardy includes, but is not limited to:

- The facility did not develop a *program* for antibiotic *stewardship*, and did not develop or implement a system to monitor antibiotic use. Based on record review, *one resident was* currently being treated with antibiotics without an appropriate indication for use. The *resident* had *an* indwelling urinary catheter and was asymptomatic for *an* UTI. There was no established criteria for use in the facility for when to treat a catheter-associated urinary tract infection. As a result of the antibiotic therapy, the resident developed *nausea and diarrhea that caused avoidable dehydration and prevented the resident from participating in activities and appropriate sleep*. The medical record revealed that *the antibiotic was stopped and the resident did not have any further adverse effects*. The resident *was* treated *via oral rehydration* but did not require hospitalization and fully recovered.

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 implement its protocol for antibiotic use and failed to monitor actual antibiotic use. Record review indicated that the facility developed a protocol which indicated “residents with MDROs are not to be treated with antibiotics for colonization”. However, record review revealed one resident colonized with an MDRO receiving an antibiotic to eliminate colonization. As a result, the potential exists for *the* resident to develop *an adverse drug event*, antibiotic resistance, *and/ or CDI*.

An example of Level 1, no actual harm with potential for minimal harm includes, but is not limited to:

- The facility failed to implement their protocol to monitor the rate of antibiotic *uses*. On review, the monitoring was not completed for 6 weeks. There were no findings of increased MDROs or CDI in the facility.

¹ Centers for Disease Control and Prevention. “Core elements of hospital antibiotic stewardship programs.” www.cdc.gov. Accessed on *February 27, 2021* from <https://www.cdc.gov/getsmart/healthcare/implementation/core-elements.html>

² Centers for Disease Control and Prevention. “The core elements of antibiotic stewardship for nursing homes.” www.cdc.gov. Accessed on *February 27, 2021* from <https://www.cdc.gov/longtermcare/prevention/antibiotic-stewardship.html>

³ Centers for Disease Control and Prevention. “Antibiotic resistance threats in the United States, 2013.” www.cdc.gov. Accessed on *February 27, 2021* from <http://www.cdc.gov/drugresistance/threat-report-2013/pdf/ar-threats-2013-508.pdf>

⁴ Spellberg, B., Bartlett, J.G., & Gilbert, D. N. (January 24, 2013). “The future of antibiotics and resistance.” *The New England Journal of Medicine*, 368, 299-302.

⁵ The White House. (2014). “National Strategy for Combating Antibiotic Resistant Bacteria.” Accessed on *February 27, 2021* from https://obamawhitehouse.archives.gov/sites/default/files/docs/carb_national_strategy.pdf

⁶ See endnote 2

⁷ See endnote 2

⁸ See endnote 2

⁹ See endnote 2

¹⁰ See endnote 2

¹¹ See endnote 2

¹² Agency for Healthcare Research and Quality. “Toolkit 3. Minimum criteria for common infections.” Accessed on *February 27, 2021* from <http://www.ahrq.gov/nhguide/toolkits/determine-whether-to-treat/toolkit3-minimum-criteria.html>

¹³ Loeb, M., Brazil, K., Lohfeld, L., McGeer, A., Simor, A., Stevenson, K., Zoutman, D.Walter, S.D. (2005). “Effect of a multifaceted intervention on number of antimicrobial prescriptions for suspected urinary tract infections in residents of nursing homes: Cluster randomised controlled trial.” *BMJ*, 331, 669. Accessed on *February 27, 2021*, from <http://www.bmj.com/content/bmj/early/2004/12/31/bmj.38602.586343.55.full.pdf>

F882

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§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 §483.70(e), 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.*

F883

(Rev. 208; Issued:10-21-22; Effective: 10-21-22; Implementation:10-24-22)

§483.80(d) Influenza and pneumococcal immunizations

§483.80(d)(1) Influenza. The facility must develop policies and procedures to ensure that-

- (i) Before offering the influenza immunization, each resident or the resident's representative receives education regarding the benefits and potential side effects of the immunization;**
- (ii) Each resident is offered an influenza immunization October 1 through March 31 annually, unless the immunization is medically contraindicated or the resident has already been immunized during this time period;**
- (iii) The resident or the resident's representative has the opportunity to refuse immunization; and**
- (iv) The resident's medical record includes documentation that indicates, at a minimum, the following:**
 - (A) That the resident or resident's representative was provided education regarding the benefits and potential side effects of influenza immunization; and**
 - (B) That the resident either received the influenza immunization or did not receive the influenza immunization due to medical contraindications or refusal.**

§483.80(d)(2) Pneumococcal disease. The facility must develop policies and procedures to ensure that-

- (i) Before offering the pneumococcal immunization, each resident or the resident's representative receives education regarding the benefits and potential side effects of the immunization;**
- (ii) Each resident is offered a pneumococcal immunization, unless the immunization is medically contraindicated or the resident has already been immunized;**
- (iii) The resident or the resident's representative has the opportunity to refuse immunization; and**
- (iv) The resident's medical record includes documentation that indicates, at a minimum, the following:**
 - (A) That the resident or resident's representative was provided education regarding the benefits and potential side effects of pneumococcal immunization; and**
 - (B) That the resident either received the pneumococcal immunization or did not receive the pneumococcal immunization due to medical contraindication or refusal.**

INTENT

The intent of this regulation is to:

- Minimize the risk of residents acquiring, transmitting, or experiencing complications from influenza and pneumococcal disease by ensuring that each resident:
 - Is informed about the benefits and risks of immunizations; and
 - Has the opportunity to receive the influenza and pneumococcal vaccine(s), unless medically contraindicated, refused or was already immunized.
- Ensure documentation in the resident’s medical record of the information/education provided regarding the benefits and risks of immunization and the administration or the refusal of or medical contraindications to the vaccine(s).

DEFINITIONS

- **“The Advisory Committee on Immunization Practices (ACIP)”** *refers to* a group of medical and public health experts that develops recommendations on how to use vaccines to control diseases in the United States. ACIP’s recommendations stand as public health advice that will lead to a reduction in the incidence of vaccine preventable diseases and an increase in the safe use of vaccines and related biological products. See <http://www.cdc.gov/vaccines/acip/index.html> for further information.
- **“Medical contraindication”** *refers to* a condition or risk that precludes the administration of a treatment or intervention because of the substantial probability that harm to the individual may occur.
- **“Precaution”** *refers to* a condition in a potential recipient that might increase the risk for a serious adverse reaction or that might compromise the vaccine’s induction of immunity. For example, as a result of the resident’s condition, complications could result, or a person might experience a more severe reaction to the vaccine than would have otherwise been expected. However, the risk for this happening is less than expected with medical contraindications.

GUIDANCE

Overview

Receipt of vaccinations is essential to the health and well-being of long-term care residents. Establishing an immunization program against influenza and pneumococcal disease facilitates achievement of this objective. Influenza outbreaks place both the residents and staff at risk of infection. *In addition, pneumococcal disease carries serious morbidity and mortality due to its major clinical syndromes of pneumonia, bacteremia, and meningitis.* People 65 years or older are two to three times more likely than the younger population to get pneumococcal infections.

An effective immunization program involves collaborating with the medical director to develop resident care policies for immunization(s) that reflect current standards of practice and that include:

- Physician approved policies for orders of influenza and pneumococcal vaccines (administration must be based on an assessment of each resident for possible medical contraindications – see 483.30(b)(3), F711, for physician orders for vaccinations);
- Review of the resident’s record of vaccination and immunization status, including assessment for potential medical contraindications;
- How pertinent information and education will be provided to residents or their representatives. The facility may wish to use educational resources such as those provided by the U. S. Centers for Disease Control and Prevention (CDC)¹; and
- The vaccination schedule including mechanisms for recording and monitoring for administration of both influenza and pneumococcal vaccines in accordance with national recommendations.²

NOTE: Review facility policies regarding the provision of vaccines in order to determine if the policies reflect current standards of practice. Refer to §483.21(b)(3)(i)- the services provided or arranged by the facility must meet professional standards of quality (F658). Also, refer to F880 for concerns with infection prevention and control.

Provision of Immunizations

In order for a resident to exercise his or her right to make informed choices, it is important for the facility to provide the resident or resident representative with education regarding the benefits and potential side effects of immunizations. Facilities are required to document the provision of this education and the administration, refusal of the immunization or the medical contraindication of the immunization. There may be clinical indications or other reasons that a resident may not have received immunizations. The resident’s record should show vaccination administration unless it contains documentation as to why the vaccine was not administered, including but not limited to the following:

- A decision may have been made to delay vaccination for a resident because a precaution is present. According to the CDC, “in general, vaccinations should be deferred when a precaution is present. However, a vaccination might be indicated in the presence of a precaution because the benefit of protection from the vaccine outweighs the risk for an adverse reaction... The presence of a moderate or severe acute illness with or without a fever is a precaution to administration of all vaccines”.³ The benefits and risks of receiving the vaccine should be discussed with the resident or resident representative if a resident has a precaution to a vaccine. The vaccine can be administered if the benefit of the vaccine outweighs the risk, the resident or resident representative provides consent, and the resident’s physician approves (refer to §483.30 Physician Services for further information on physician supervision);
- A resident may be in the end stages of a terminal illness and receiving care that is limited to comfort or palliative measures only and although eligible, the resident or representative has refused the vaccination(s);

- A resident may have a medical contraindication to receiving an influenza or pneumococcal vaccine such as severe allergic reaction to a vaccine component or following prior dose of vaccine;
- The resident or representative refused the vaccine; or
- The resident has already been immunized.

NOTE: *Additional information* related to current vaccine recommendations including scheduling and contraindications *may be found in CDC's "Epidemiology and Prevention of Vaccine-Preventable Diseases" otherwise known as "The Pink Book" at <http://www.cdc.gov/vaccines/acip/index.html> or <https://www.cdc.gov/vaccines/pubs/pinkbook/chapters.html>.*

***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 (HHS). 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.*

NOTE: A nursing home may encounter residents who do not have adequate documentation of vaccinations. With the **exception** of influenza vaccine and pneumococcal polysaccharide vaccine (PPSV), providers should only accept written, dated records as evidence of vaccination. Self-reported doses of influenza vaccine and PPSV are acceptable. A resident representative can report on behalf of the resident if he/she is unable to self-report and the representative has knowledge of the resident's medical care. State laws may have more stringent requirements related to documentation.

Influenza Immunization

The influenza vaccine is given seasonally. The CDC indicates that administering the vaccine **when it becomes available each season**, rather than date specific, (i.e., "October 1") is most effective. Facilities should administer the influenza vaccine when it becomes available to the facility. Residents admitted late in the influenza season (typically February or March) should be offered the influenza vaccine as late season outbreaks do occur. If a resident was admitted outside the influenza season, the facility is not expected to offer the influenza vaccine to the resident, but it may, at its discretion.

NOTE: Flu seasons are unpredictable in a number of ways. They can vary in different parts of the country and from season to season. While flu spreads every year, the timing, severity, and length of the season varies from one year to another.

If there is a national shortage of influenza vaccine or other issue with availability leading to an inability to implement the influenza vaccine program, ask the facility to demonstrate that:

- The vaccine has been ordered and the facility received either the vaccine or a confirmation of the order indicating that the vaccine has been shipped or that the product is not available but will be shipped when the supply is available;
- Plans are developed on how and when the vaccines are to be administered;
- Residents have been screened to determine how many and which residents are eligible and wish to receive the vaccine; and
- Education regarding immunizations has been implemented.

Pneumococcal Immunizations

The regulation requires that each resident is offered pneumococcal immunization, unless the immunization is medically contraindicated or the resident has already been immunized. There should be documentation in the medical record if there is reason to believe that pneumococcal vaccine(s) was given previously, but the date cannot be verified, and this had an impact upon the decision regarding administration of the vaccine(s). Facilities *should* follow the CDC and ACIP recommendations for vaccines. For up-to-date information on *indications and* timing of *pneumococcal* vaccines, please refer to *CDC's ACIP Vaccine Recommendations and Guidelines website* located at <http://www.cdc.gov/vaccines/hcp/acip-recs/index.html>, <https://www.cdc.gov/vaccines/vpd/pneumo/downloads/pneumo-vaccine-timing.pdf> and <https://www.cdc.gov/vaccines/schedules/hcp/index.html>.

INVESTIGATIVE PROCEDURES

Use the Infection Prevention, Control & Immunizations Facility Task, along with the above interpretive guidance, when determining if the facility meets requirements for, or when investigating concerns related to, influenza and pneumococcal immunizations.

Sampling Procedure

Select five residents in the sample to review for the provision of influenza and pneumococcal immunizations.

Record Review

Review sampled residents' records for education on and provision, refusal, or documentation of medical contraindications for influenza and pneumococcal immunizations. As necessary, determine if the facility developed influenza and pneumococcal vaccine policies and procedures.

KEY ELEMENTS OF NONCOMPLIANCE

To cite deficient practice at F883, the surveyor's investigation will generally show that the facility failed to do any one or more of the following:

- Develop, maintain, or follow policies and procedures for immunization of residents against influenza and pneumococcal disease in accordance with national standards of practice; *or*
- Vaccinate an eligible resident with the influenza and/or the pneumococcal vaccine(s), unless the resident had previously received the vaccine, refused, or had a medical contraindication present; *or*
- Allow a resident or a resident's representative to refuse either the influenza and/or the pneumococcal vaccine(s); *or*
- Provide and/or document the provision of pertinent information regarding the immunizations to the resident or the resident's representative such as the benefits and potential side effects of the influenza and, as applicable, the pneumococcal immunization(s); or
- Document that the resident either received the pneumococcal and influenza vaccine(s) or did not receive the vaccine(s) due to medical contraindications, previous vaccination, or refusal.

DEFICIENCY CATEGORIZATION

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

- The facility failed to ensure that medical contraindications were identified for the influenza or pneumococcal vaccine, and administered the vaccine to a resident with identified allergies/contraindications. As a result, the resident experienced a life-threatening reaction of anaphylactic shock requiring immediate treatment and admission to the hospital.
- The facility failed to ensure that eligible residents received the influenza vaccine, because it did not have a program for vaccinating residents. As a result, several unvaccinated residents in one unit developed influenza, with elevated temperatures, coughing, labored breathing, and required hospitalization for respiratory compromise and dehydration.

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

- A resident who was not eligible to receive the influenza vaccine due to medical contraindications received the vaccine and experienced a reaction that was not serious or life-threatening (i.e., hives and dizziness). The reaction resulted in fear and anxiety that was not to the level of panic and immobilization, but required treatment.
- The facility failed to administer the influenza vaccine for several weeks, despite its availability. The facility failed to offer influenza immunization to three residents who were eligible to receive the vaccine. Record review and staff interview revealed that the three residents had been admitted in the past two months, but their names were not included in the facility's monitoring log for residents who had not received the vaccine and when they had last received one. During interviews, two of the three residents stated that they had not taken "a flu shot in over a year", and one stated that he had never taken a flu shot, but all three

stated they would have taken one if offered. Based on record review, two of the three residents were diagnosed with influenza with symptoms of fever, chills, body aches, and had received treatment with an antiviral in the facility. The two residents were unable to participate in activities or leave their rooms due to the acute illness. Record review corroborated the interview information and when interviewed, staff stated they had overlooked the three residents.

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

- An eligible resident did not receive the vaccine, but did not develop symptoms of influenza.
- An eligible resident received two doses of the same pneumococcal vaccine. The facility could have determined the resident already received the vaccine had it documented in the medical record when it was previously given by the facility. The resident did not experience any untoward reactions from the second immunization.
- The staff did not assess a resident for medical contraindications prior to providing the vaccines, but there were no reactions to the vaccines.

An Example of Level 1, no actual harm with potential for minimal harm includes, but is not limited to:

The facility failed to document that the resident was provided education on the influenza vaccine prior to administration. When interviewed, the resident stated he had received a copy of the information on influenza risks and benefits and provided the copy to the surveyor. However, the medical record did not reflect receipt of the information.

¹ Centers for Disease Control and Prevention. “Vaccine information statements.” www.cdc.gov. Accessed on *February 27, 2021* from <https://www.cdc.gov/vaccines/hcp/vis/index.html>

² Kroger AT, Duchin J, Vázquez M. “General Best Practice Guidelines for Immunization. Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP).” www.cdc.gov. Accessed on *February 27, 2021* from <https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html>

³ See endnote 2

F895

(Rev. 208; Issued:10-21-22; Effective: 10-21-22; Implementation:10-24-22)

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 §483.70(e) 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.

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

<i>Zone Location</i>	<i>Containment (Sa)</i>		<i>Extinguishment (Sb)</i>		<i>People Movement (Sc)</i>	
	<i>New</i>	<i>Exist.</i>	<i>New</i>	<i>Exist.</i>	<i>New</i>	<i>Exist.</i>
<i>1st story</i>	<i>11</i>	<i>5</i>	<i>15(12)*</i>	<i>4</i>	<i>8(5)*</i>	<i>1</i>
<i>2nd or 3rd story</i>	<i>15</i>	<i>9</i>	<i>17(14)*</i>	<i>6</i>	<i>10(7)*</i>	<i>3</i>
<i>4th story or higher</i>	<i>18</i>	<i>9</i>	<i>19(16)*</i>	<i>6</i>	<i>11(8)*</i>	<i>3</i>

** 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.

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.

F919

(Rev. 208; Issued:10-21-22; Effective: 10-21-22; Implementation:10-24-22)

§483.90(g) Resident Call System

The facility must be adequately equipped to allow residents to call for staff assistance through a communication system which relays the call directly to a staff member or to a centralized staff work area *from*–

***§483.90(g)(1) Each resident's bedside; and
§483.90(g)(2) Toilet and bathing facilities.***

INTENT: §483.90(g)(1) and (g)(2)

The intent of this requirement is that residents, when in their rooms and toilet and bathing areas, have a means of directly contacting caregivers. In the case of an existing centralized nursing station, this communication may be through audible or visual signals and may include “wireless systems.” In those cases, in which a facility has moved to decentralized nurse/care team work areas, the intent may be met through other electronic systems that provide direct communication from the resident to the caregivers.

GUIDANCE: §483.90(g)(1) and (g)(2)

This requirement is met only if all portions of the system are functioning (e.g., system is not turned off at the nurses' station, the volume too low to be heard, the light above a room or rooms is not working, no staff at nurses' station), and calls are being answered. For wireless systems, compliance is met only if staff who answer resident calls have functioning devices in their possession and are answering resident calls.

The call system must be accessible to residents while in their bed or other sleeping accommodations within the resident's room.

The call system must be accessible to the resident at each toilet and bath or shower facility. The call system should be accessible to a resident lying on the floor.

POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION

Issues related to the timeliness of calls being answered should be referred to and examined for sufficient staffing under §483.35 Nursing Services.

PROBES: §483.90(g)(1) and (g)(2)

Is there a functioning communication system from rooms, at the bedside, toilets, and bathing facilities in which resident calls are received and answered by staff? Is the *call* system accessible if the resident were lying on the floor?

If a resident has disabilities that make use of the facility's communication system inaccessible, are alternatives, auxiliary aids, or services available to meet this requirement and to meet the resident's needs as identified in the resident's assessment or plan of care?

Residents and their representatives should be interviewed about whether calls are being answered.

- *Has the call system been in need of repair recently? If yes, ask:*
 - *What did the facility do if the call system was not working?*
 - *How many times was the call system non-functional/not operating?*
 - *Were any needed repairs made timely?*
 - *How long was the call system non-functional/not operating?*

Does the facility have process to routinely ensure the call system for residents is operational?

During a loss of power, will the resident call system be operational or is an alternate means of communicating with the staff put into place?

F940

(Rev. 208; Issued:10-21-22; Effective: 10-21-22; Implementation:10-24-22)

§483.95 Training Requirements

A facility must develop, implement, and maintain an effective training program for all new and existing staff; individuals providing services under a contractual arrangement; and volunteers, consistent with their expected roles. A facility must determine the amount and types of training necessary based on a facility assessment as specified at § 483.70(e). Training topics must include but are not limited to—

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 §483.70(e)(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.

F941

(Rev. 208; Issued:10-21-22; Effective: 10-21-22; Implementation:10-24-22)

§483.95 Training Requirements.

Training topics must include but are not limited to—

§483.95(a) Communication.

A facility must include effective communications as mandatory training for direct care staff.

DEFINITIONS

“Communications” include services such as Teletypewriter (TTY) and Telecommunications Device for the Deaf (TDD), use of devices such as cellular telephones, and accessibility such as reasonable access and privacy for electronic communications like email or internet-based interpersonal video communications. See 483.10(g)(6)(7).

“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.

“Effective communications” describe a process of dialogue between individuals. The skills include speaking to others in a way they can understand and active listening and observation of verbal and non-verbal cues. Understanding what the resident is trying to communicate is essential to giving a response. Additionally, effective communication ensures that information provided to the resident is provided in a form and manner that the resident can access and understand, including in a language that the resident can understand. See 483.10(g)3).

INTENT

We did not propose to require a specific amount of time, specific communications topics, or specific training mechanisms to meet this requirement. The topics for training should reflect the needs of the resident population and the needs of staff. These needs should correspond with the Facility Assessment. We expect training activities will encourage participation and allow for open dialogue among participants in order to be productive.

Facilities must inform residents in a language they can understand of their total health status and to provide notice of rights and services both orally and in writing in a language the resident understands (see §483.10, Resident Rights).

For the purposes of this training requirement, staff includes all staff providing direct care services (training topics as appropriate to role).

GUIDANCE

Recommended methods of effective communication, include, but are not limited to, the following:

- 1. Identify yourself and use the resident's name each time you speak with them.*
- 2. Use the proper names for people, places, and objects; avoid saying he, she, it, or they so that the resident can understand.*
- 3. Allow extra time. Many nursing home residents have conditions which require longer information processing time.*
- 4. Avoid distractions, and maintain eye contact, if culturally appropriate. Focus on the resident, make each interaction quality time.*
- 5. Listen carefully to the resident's responses and directly respond to the questions and concerns. Give residents an opportunity to ask questions and express themselves.*
- 6. Sit face to face, residents may have vision and hearing loss, and reading your lips may be crucial. Even if the resident uses a hearing aid, it can be difficult for the resident to understand you because a hearing aid amplifies all sounds, including background noise.*
- 7. Speak slowly, clearly and in a normal tone, and use short, simple words (no medical or slang jargon)*
- 8. Maintain a positive attitude, including a pleasant tone of voice and facial expression. Residents with dementia respond to the feelings you convey more than the actual words.*
- 9. If the communication form is written, simplify the questions, and stick to one topic at a time. Frequently summarize the most important points.*
- 10. Be aware of a resident's body language communications.*
- 11. Eliminate assumptions, make adjustments to the communication method as required during a conversation.*
- 12. Visual aids may be required as communication methods.*
- 13. Repeat back what the person has said to make sure that you understand. Ask for clarification if you aren't sure what the person means.*

Training Resource

- *Getting the Facts: Effective Communication with Elders Support Materials*
<https://pogoe.org/sites/default/files/Commun-Support-Mat.pdf>
- *Mental Illness:* <https://www.mentalhealth.gov/talk>
<https://www.nami.org/Find-Support/Family-Members-and-Caregivers/Maintaining-a-Healthy-Relationship>

***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.*

PROBES

If there is a concern about effective communication utilize interviews and review of training records to determine the following:

- *Does the facility provide on-going in-service training, as necessary, for permanent, temporary and volunteer direct care staff to improve their ability to communicate effectively?*
- *Does the facility admit and care for residents that do not use the English language?*
- *How does the facility assessment reflect the need for direct care staff training related to communication with residents who do not speak English? What communication tools are provided and how are staff educated about using those tools?*
- *Does the facility have alternative means of communication for residents in need who require them and how are staff educated about using them (e.g. communication boards)?*
- *How are ethnic and cultural differences reflected in communications?*
- *How well do permanent and temporary direct care staff and volunteers communicate with residents?*
- *Does the facility have a process in place to communicate with residents including those with a language/communication barriers during an emergency?*
- *How does the facility train direct care staff on identifying resident non-verbal communication?*
- *How does the facility train direct care staff on identifying and understanding their own non-verbal communication?*

F942

(Rev. 208; Issued:10-21-22; Effective: 10-21-22; Implementation:10-24-22)

§483.95 Training Requirements.

Training topics must include but are not limited to

§483.95(b) Resident's rights and facility responsibilities.

A facility must ensure that staff members are educated on the rights of the resident and the responsibilities of a facility to properly care for its residents as set forth at §483.10, respectively.

INTENT

To ensure all facility staff understand and foster the rights of every nursing home resident. 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).

GUIDANCE §483.95(b)

Facilities must develop and implement an ongoing education program on all resident rights and facility responsibilities for caring of residents as outlined in §483.10.

The education program should support current scope and standards of practice through curricula which incorporate learning objectives, performance standards, and evaluation criteria. Staff performance assessments should evaluate the ability to integrate knowledge and skills specific to the requirements at §483.10.

There should be a process in place to validate that training was completed, whether in a group setting or on an individual basis.

If concerns with staff knowledge and understanding of resident rights and facility responsibilities are identified by the survey team, the following probes should be utilized in interview, observation and record review to help determine compliance with F942:

- Interview staff to determine if they've received training regarding the rights of residents and facility responsibilities.*
- Observe staff interactions with residents.*
- Review training documentation provided by the facility related to resident rights and facility responsibilities.*
- Interview staff from various departments and disciplines about their knowledge of resident rights and facility responsibilities.*

F944

(Rev. 208; Issued:10-21-22; Effective: 10-21-22; Implementation:10-24-22)

§483.95(d) Quality assurance and performance improvement.

A facility must include as part of its QAPI program mandatory training that outlines and informs staff of the elements and goals of the facility's QAPI program as set forth at § 483.75.

DEFINITIONS

“Quality Assurance and Performance Improvement (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 in practical and creative problem solving (<https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/QAPI/qapidefinition>, accessed 12/18/2020).

GUIDANCE

For the purpose of this guidance, the term “staff” includes all new and existing facility staff (with direct and indirect care functions); individuals providing services under a contractual arrangement; and volunteers, consistent with the volunteers’ expected roles (see requirements in §483.95).

Facilities must conduct mandatory training, for all staff, on the facility’s QAPI Program, that includes the goals and various elements of the program. It should also include how the facility intends to implement the program. The training should also include the staff’s role in the facility’s QAPI program and how to communicate concerns, problems or opportunities for improvement to the facility’s QAA Committee.

As updates are made to the facility's QAPI program or goals, the facility's training should also be updated and staff trained on the updates, as appropriate.

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.

PROBES

- Verify that the facility has a mandatory requirement that all staff receive QAPI training.
- Does the facility have a method for verifying staff attendance at the mandatory QAPI training? If so, do these records confirm that staff attended the mandatory QAPI training?
- Does the facility’s training program inform staff of the current elements and goals of the facility’s QAPI program?
- Are staff aware of what the facility’s QAPI program entails and how the facility intends to implement and monitor their program?
- Are staff aware of how to bring ideas or concerns to the attention of the QAA committee?
- How does the facility determine when training content requires updating to be consistent with current professional standards and guidelines?

It is not required to have an outcome deficiency cited for this tag to be cited for deficient staff training. If QAPI deficiencies are identified, refer to §483.75 for citation authority.

POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION

- F865-F868: for concerns related to the facility's QAPI program.

F945

(Rev. 208; Issued:10-21-22; Effective: 10-21-22; Implementation:10-24-22)

§483.95(e) Infection control.

A facility must include as part of its infection prevention and control program mandatory training that includes the written standards, policies, and procedures for the program as described at §483.80(a)(2).

GUIDANCE §483.95(e)

All facilities must develop, implement and permanently maintain an effective training program for all staff, which includes, training on the standards, policies, and procedures for the infection prevention and control program as described at §483.80(a)(2), that is appropriate and effective, and as determined by staff need. 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, community infection risk, national standards, staff turnover, the facility's physical environment, or facility assessment may necessitate ongoing revisions to the facility's training program for infection prevention and control.

All training should support current scope and standards of practice through curricula which detail learning objectives, performance standards, 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 and understanding of the required training.

Such infection control training must, at a minimum, include the following areas (as described in §483.80(a)(2)):

- *The facility's surveillance system 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 in the facility should be reported;*
- *How and when to use standard precautions, including proper hand hygiene practices and environmental cleaning and disinfection practices;*
- *How and when to use transmission-based precautions for a resident, including but not limited to, the type and its duration of use depending upon the infectious agent or organism involved;*
- *Occupational health policies, including the circumstances under which the facility must enforce work restrictions and when to self-report illness or exposures to potentially infectious materials (See 483.80(a)(2)(v)); and*

- *Proper infection prevention and control practices when performing resident care activities as it pertains to particular staff roles, responsibilities, and situations.*

Please refer to F880 for a detailed description of these topics.

PROBES §483.95(e)

If there is a concern about infection prevention and control practices or healthcare-associated infections in the facility (F880), interview staff and review training records to determine the following:

- *Did staff observations or did interviews with residents and/or resident representatives indicate a training need? Did staff report not receiving training 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? Does the facility respond to staff's concerns and requests for training?*
- *Review the training coursework to determine if the content meets professional standards/guidelines and covers facility policy and procedures for infection prevention and control.*
- *Does the facility implement the training program and ensure staff are instructed to meet the requirements of §483.80(a)(2), Infection Control, F880?*
- *Verify that the facility has a mandatory requirement that all facility staff participate in infection prevention and control training, with a process in place to track such participation.*

POTENTIAL ADDITIONAL TAGS FOR INVESTIGATION

For concerns related to infection prevention and control practices, see 42 CFR §483.80, Infection Control, tag F880.

F946

(Rev. 208; Issued:10-21-22; Effective: 10-21-22; Implementation:10-24-22)

§483.95(f) Compliance and ethics.

The operating organization for each facility must include as part of its compliance and ethics program, as set forth at §483.85—

§483.95(f)(1) An effective way to communicate the program's standards, policies, and procedures through a training program or in another practical manner which explains the requirements under the program.

§483.95(f)(2) Annual training if the operating organization operates five or more facilities.

DEFINITION:

For the purpose of this guidance, the term “Staff” includes all new and existing staff (direct and indirect care functions); individuals providing services under a contractual arrangement; and volunteers, consistent with the volunteers’ expected roles (see requirements in §483.95).

GUIDANCE §483.95(f)

The operating organization (the individual or entity that operates a facility) must provide a training program or another practical manner to effectively communicate the standards, policies, and procedures of the compliance and ethics program to its entire staff.

For the operating organizations that operate five or more facilities, annual training for staff on the compliance and ethic program must be conducted.

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.

PROBES §483.95(f)

- Does the facility provide training or effectively communicate, in some manner, the facility’s standards, policies and procedures of the compliance and ethics program?*
- Does the facility have a system in place to track staff attendance at required trainings?*
- For organizations with five or more facilities, determine if annual compliance and ethics training is provided.*

F947

(Rev. 208; Issued:10-21-22; Effective: 10-21-22; Implementation:10-24-22)

§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 §483.70(e) 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 §483.70(e). Changes to the facility’s resident population, the facility’s physical environment, staff turnover, and modifications to the facility assessment may necessitate ongoing revisions to the facility’s training program.

There are a variety of methods that could be used to provide training. For example, nurse aide training may be facilitated through any combination of in-person instruction, webinars (*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. 208; Issued:10-21-22; Effective: 10-21-22; Implementation:10-24-22)

§483.95(i) Behavioral health.

A facility must provide behavioral health training consistent with the requirements at §483.40 and as determined by the facility assessment at §483.70(e).

§483.95 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 §483.70(e).

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 §483.70(e)). 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 483.70?*

Exhibit 23- ACTS Required Fields

(Rev. 208; 10-21-22)

ACTS REQUIRED FIELDS

TAB	FIELD(s)	DEFINITION
Intake	Intake Type	<p>1) <i>Complaint</i> - A <u>complaint</u> is a report made to the SA or RO by anyone other than the administrator or authorized official for a provider or supplier that alleges noncompliance with Federal and/or State laws and regulations.</p> <p>2) <i>Incident</i> - An <u>incident</u> is an official notification to the SA or RO from a self-reporting provider or supplier (i.e., the administrator or authorized official for the provider or supplier).</p>
	Intake Subtype (for Complaints)	<p>A) <i>Federal COPs, CFCs, RFPs, EMTALA</i>: The allegation relates to noncompliance with the Federal condition(s) of participation (COPs), condition(s) for coverage (CFCs), requirement(s) for participation (RFPs), or EMTALA requirement(s). This would include allegations of noncompliance with Federal requirements only or both Federal and State requirements. (SAs and ROs are required to enter these cases into ACTS.)</p> <p>B) <i>State-only, licensure</i>: The allegation is related to noncompliance with State licensure requirements only. (SAs have the option to enter these cases into ACTS.)</p> <p>C) <i>No State or Federal provider compliance issue involved</i>: The allegation does not relate to noncompliance with Federal or State survey and certification requirements. (SAs have the option to enter these cases into ACTS.)</p>

TAB	FIELD(s)	DEFINITION
	Intake Subtype (for Incidents)	<p>A) <i>Federally required, entity-reported</i>: A provider or supplier is required by Federal law, regulation, or policy to report this type of incident, which includes the following:</p> <ul style="list-style-type: none"> a. 42 C.F.R. §482.13(g) <i>Standard: Death Reporting Requirements: Hospitals must report deaths associated with the use of seclusion or restraint</i>. The hospital must report to CMS any death that occurs while a patient is restrained or in seclusion, or where it is reasonable to assume that a patient's death is a result of restraint or seclusion. (SAs and ROs are required to enter into ACTS all incidents that lead to an onsite survey of Federal requirements or conditions.) b. 42 C.F.R. §483.12(c)(1)- For skilled nursing facilities (SNFs) and nursing facilities (NFs), the facility must ensure that all alleged violations involving <i>abuse, neglect, exploitation or mistreatment</i>, including injuries of unknown source, and misappropriation of resident property are reported ...to other officials in accordance with State law through established procedures (including to the State survey and certification agency). (SAs and ROs are required to enter into ACTS all incidents.) <p>B) <i>State-required, may result in Federal noncompliance, entity-reported</i>: A provider or supplier is required by State law, regulation, or policy to report this type of incident to the SA. This type of incident may result in noncompliance with a Federal condition(s) of participation, condition(s) for coverage, requirement(s) for participation, or EMTALA requirement(s). For incidents of this type, the SA must follow CMS policies and procedures to investigate Medicare/Medicaid complaints, no matter the source of information. (SAs and ROs are required to enter into ACTS all incidents that lead to an onsite survey of Federal requirements or conditions.)</p> <p>C) <i>State-required, all other, entity-reported</i>: A provider or supplier is required by State law, regulation, or policy to report this type of incident to the SA. This type of incident does not imply noncompliance with Federal conditions or requirements. (SAs and ROs are required to enter into ACTS all incidents that lead to an onsite survey of Federal requirements or conditions.)</p> <p>D) <i>Reported by other agencies</i>: As defined by the State.</p> <p>E) <i>None of the above</i>: A provider or supplier is not required by Federal or State laws, regulations, or policies to report this type of incident. (SAs and ROs are required to enter into ACTS all incidents that lead to an onsite survey of Federal requirements or conditions.)</p>
	Complainant's Name	For an incident the name of the official reporting the information is entered.
	Source	<i>A selection is made from a predefined list. The user cannot select more than 3.</i>

TAB	FIELD(s)	DEFINITION
	Received Dates: Start/End	<p><i>Start Date:</i> The date of the telephone call or electronic correspondence; or, the date stamped by the SA or RO receiving office of the written correspondence. <i>Receipt of the initial complaint or incident report means when the report is received by the SA, whether it is received by the SA directly, or another State agency under arrangement or contractor that is receiving the report on behalf of the SA from the complainant or facility.</i></p> <p><i>End Date:</i> The date the SA or RO has sufficient information to prioritize the complaint or incident. This is the date in which the SA or RO determines 1) whether an onsite survey to assess Federal compliance or further action is necessary and 2) the appropriate time frame for investigation.</p>
	Priority	<p><i>At least one priority must be selected for each intake. Some combinations are not permitted.</i></p> <p>A) <i>Immediate Jeopardy:</i> Intakes assigned this priority indicate immediate corrective action is necessary because a provider's or supplier's noncompliance with one or more conditions or requirements may have caused, or is likely to cause, serious injury, harm, impairment or death to a resident, patient or client. <i>In addition, for nursing homes, all facility-reported incidents are assigned this priority if immediate jeopardy may have occurred, regardless of whether an immediate risk may continue to exist.</i></p> <p>B) <i>Non-Immediate Jeopardy - High:</i> <i>For nursing homes,</i> intakes are assigned this priority if a provider's alleged noncompliance with one or more requirements or conditions may have caused <i>actual physical and/or psychosocial harm to the resident(s)</i>. This level of complaint is represented by specific rather than general information, such as, descriptive identifiers, individual names, date/time/location of occurrence, description of harm, etc. <i>For non-long term care providers/suppliers and EMTALA, intakes are assigned this priority if the alleged noncompliance with the applicable Conditions of Participation, Coverage or Certification, or EMTALA requirements, if found to be true and uncorrected, would not represent an IJ, but would result in a determination of substantial noncompliance, i.e., at least one condition-level deficiency.</i></p> <p>C) <i>Non-Immediate Jeopardy - Medium:</i> <i>For nursing homes, complaints are assigned this priority if the alleged noncompliance with one or more requirements caused no actual physical and/or psychosocial harm but there is the potential for more than minimal harm to the resident(s) (Severity Level 2). Facility-reported incidents are assigned this priority if the alleged noncompliance with one or more requirements caused no actual physical and/or psychosocial harm but there is the potential for more than minimal harm to the resident(s) (Severity Level 2)</i></p>

TAB	FIELD(s)	DEFINITION
		<p><i>and the facility has not provided an adequate response to the allegation or it is not known whether the facility provided an adequate response. For non-long term care providers/suppliers, intakes are assigned this priority if the alleged noncompliance with one or more standards within a Condition of Participation, Condition for Coverage or Condition for Certification is limited in manner and degree and/or caused, or may cause, harm that is of limited consequence and does not impair the individual's mental, physical and/or psychosocial status or function.</i></p> <p>D) <i>Non-Immediate Jeopardy - Low: For nursing homes, intakes are assigned this priority if the alleged noncompliance with one or more requirements may have no actual harm with a potential for minimal harm (Severity Level 1). In addition, facility-reported incidents are assigned a "low" priority if the alleged noncompliance with one or more requirements may have caused no actual physical and/or psychosocial harm but there is the potential for more than minimal harm to the resident(s) (Severity Level 2) and the facility has provided a potentially adequate response to the allegation. For non-long term care, intakes are assigned this priority if the alleged noncompliance with one or more standards within a Condition of Participation, Coverage or Certification may have caused physical, mental and/or psychosocial discomfort that does not constitute injury or damage.</i></p> <p>E) <i>Administrative Review/Offsite Investigation:</i> This priority is used for complaints/incidents that are triaged as not needing an onsite investigation. However, further investigative action (written/verbal communication or documentation) initiated by the SA or RO to the provider may be needed to ensure compliance with the Federal requirements. The additional information is adequate in scope and depth to determine that an onsite investigation is not necessary; however, a SA has the discretion to review the information at the next onsite survey.</p> <p>F) <i>Referral – Immediate:</i> Complaints/incidents are assigned this priority if the seriousness of a complaint/incident and/or State procedures requires referral or reporting to another agency, board or network immediately for investigation. <i>For example, if a complaint has criminal implications and the complainant has not reported the incident to law enforcement, the SA must report the suspected crime to law enforcement immediately (NOTE: In such cases, the referral is recorded in the Contact/Refer tab under the ACTS intake).</i></p> <p>G) <i>Referral - Other:</i> Complaints/incidents assigned this priority indicate referral to another agency, board, or network for investigation or for informational purposes.</p> <p>H) <i>No action necessary: Intakes are assigned a "No Action Necessary" priority if the SA can determine with certainty that no further investigation, analysis, or action is necessary. For all</i></p>

TAB	FIELD(s)	DEFINITION
		<p>cases except EMTALA, that do not allege immediate jeopardy, and at the SAs discretion an intake may not require a new onsite investigation if, at a previously completed survey, the same events were investigated; the previously completed survey evaluated the appropriate individuals, including those identified in the intake; and the situation did not worsen. These types of intakes should be linked to the appropriate survey that has already reviewed the issue.</p>
	Investigate Within X Days	<p><i>Completion is required if the Priority is Immediate Jeopardy or Non-immediate Jeopardy (Priorities A – D).</i></p> <p><i>A numerical time frame in calendar days or working days is entered to support the Priority selected. The calendar date of the intake is counted as day zero.</i></p>
	Investigation Due By	<p><i>Completion is required if the Priority is Immediate Jeopardy or Non-immediate Jeopardy (Priorities A – D).</i></p> <p><i>A corresponding calendar date is entered.</i></p>
Allegations	Allegation Category	<p><i>At least one allegation category from a predefined list per intake is required unless Priority H - No Action Necessary is selected.</i></p>
	Findings	<p><i>Not required.</i></p>
	Link Deficiencies	<p><i>Users indicate which Federal deficiencies are related to any of the allegations.</i></p>
	Priority	<p><i>This field is shared with the Intake page and Deemed page (when applicable).</i></p>
	Investigate Within X Days	<p><i>This field is shared with the Intake page and Deemed page (when applicable).</i></p>
	Investigation Due By	<p><i>This field is shared with the Intake page and Deemed page (when applicable).</i></p>

TAB	FIELD(s)	DEFINITION
	Death Associated with Restraint/ Seclusion [Grid]	<p><i>For Hospitals: When allegation type = Death Associated with Restraint/Seclusion (05), the following must be completed:</i></p> <ul style="list-style-type: none"> • Patient; • Death type; • Reported; • Date of death; • AO Notify; and • To P&A.
EMTALA (Fields required only if 'Create EMTALA Allegation' box is checked)	EMTALA Request for RO Approval Checkbox	
	EMTALA Request for RO Approval Date	
	EMTALA RO Response Checkbox	Required when EMTALA Request for RO Approval is checked.
	EMTALA RO Response Date	Required when EMTALA Request for RO Approval is checked.
	Type of Emergency	
	RO EMTALA Determination	Not required if RO disapproves investigation.

TAB	FIELD(s)	DEFINITION
	Resolution	Not required if RO disapproves investigation.
	RO Confirmed Violation Date or RO Confirmed No Violation Date	One of these fields should always be completed, unless RO disapproves investigation.
	EMTALA Allegation Type	Entry of EMTALA allegation here ties to an allegation record on the Allegation Page. Once an RO Response is entered, SA users cannot modify the EMTALA page. Also, once an EMTALA RO Response has been entered, EMTALA allegations may no longer be added or deleted by SA users; however, Allegation Findings categories and text may be entered by any user. Once the Determination has been entered, SA users may not add, delete, or modify EMTALA allegations.
Deemed and Accredited (Fields enabled if 'Deemed for Medicare Participation' or 'Accredited' box is checked. Fields are required if 'Request for RO Approval' box is checked.).	Priority	<i>This field is shared with Intake and Allegation pages.</i>
	Request for RO Approval	
	Date of Request for RO Approval	
	Condition(s) of Participation	
	RO Response	<i>There are no edits on these fields at this time.</i>
	Regional Representative	
	Region	
Date		

TAB	FIELD(s)	DEFINITION
Investigation	Investigated By	<i>Required when Complaint Priority is Immediate Jeopardy or Non-immediate Jeopardy (Priorities A – D)</i>
	Investigation Completed	<i>Required when Complaint Priority is Immediate Jeopardy or Non-immediate Jeopardy (Priorities A – D) The date that the result of the investigation is communicated to the provider or supplier.</i>
Actions/Close	Forwarded to RO/MSA	<p>If the intake originates from the CMS RO, the SA should check the “Forwarded to CMS/MSA” box in all complaint/incident scenarios.</p> <p>If the intake originates from the SA, SAs <u>should not</u> check the box or enter a date for all <u>nursing home</u> intakes.</p> <p>For non-long-term care intakes, the SA should check the “Forwarded to RO/MSA” box on the complaint/incident record in the three following scenarios:</p> <ul style="list-style-type: none"> i. If the complaint/incident survey is on an accredited/deemed provider/supplier. ii. If the complaint results in an EMTALA investigation. iii. If the complaint/incident survey is on an “other than accredited/deemed provider or supplier” and the SA is recommending termination.
	Proposed Action	<i>At least one proposed action per complaint/incident record if a survey is present.</i>
	Proposed Action Date	<p><i>Date of the notice sent to the provider/supplier informing the provider/supplier of actions that may be taken as a result of the investigation findings. If the provider/supplier is in compliance, the proposed action date is the date the provider/supplier is notified that it is in compliance.</i></p> <p><i>At least one proposed action date per complaint/incident record if a survey is present.</i></p>
	Overall Findings	<i>Supplied by ACTS (For complaints, uses same rule as Findings: Required when Complaint Priority = Immediate Jeopardy or Non-immediate Jeopardy (Priorities A – D); for incidents, defaults on-screen to Not Applicable).</i>

TAB	FIELD(s)	DEFINITION
	Reason Closed	<p><i>Field is completed by selecting one or more of the following:</i></p> <p>A. <i>Paperwork complete</i> – All information and documentation related to this complaint or incident has been completed in the SA or RO file. If applicable, this would include the notification of the results of the investigation to the complainant and provider, and the successful upload of the investigation record to the Certification and Survey Provider Enhanced Reports (CASPER) system. For nursing homes, if applicable, the intake may be closed prior to the revisit and imposition of an enforcement action.</p> <p>B. <i>Withdrawn</i> – The complainant contacted the entity receiving the allegation and asked that the allegation be removed.</p> <p>C. <i>Referred</i> – At the intake, during administrative review, or after the onsite complaint survey, it is determined that the issues involved must be directed to another agency or organization for resolution.</p> <p>D. <i>No jurisdiction</i> – The issues identified at intake, during an administrative review or after a survey do not involve Medicare/Medicaid participation requirements.</p> <p>E. <i>Provider/Supplier Termination</i> – The provider or supplier has been terminated from participation in the Medicare and/or Medicaid programs.</p>
	Date Closed	<i>Date associated with the latest reason closed action selected.</i>
<p>NOTIFICATION: Notices Button (every tab) and the Acknowledgement and Parties Notified section on the Investigation Properties tab</p>		<p><i>At least one notification is required, except when Priority is No Action Necessary.</i></p> <p>For each notice, enter the Type, Party, Method, and Notification Date.</p>

EXHIBIT 358
(Rev. 208; 10-21-22)

Sample Form for Facility Reported Incidents

This sample form can be used to ensure the reporting of reasonable suspicion of crimes against a resident or individual receiving care from the facility within prescribed timeframes to the appropriate entities, consistent with Section 1150B of the Act; and all alleged violations involving abuse, neglect, exploitation or mistreatment, including injuries of unknown source and misappropriation of resident property. The information collected is critical in determining what may be occurring in a facility and the effect(s) that it may have on residents.

Section 1150B(b) of the Social Security Act –

(1) Each covered individual shall report to the Secretary and 1 or more law enforcement entities for the political subdivision in which the facility is located any reasonable suspicion of a crime (as defined by the law of the applicable political subdivision) against any individual who is a resident of, or is receiving care from, the facility.

(2) Timing —If the events that cause the suspicion—

(A) Result in serious bodily injury, the individual shall report the suspicion immediately, but not later than 2 hours after forming the suspicion; and

(B) Do not result in serious bodily injury, the individual shall report the suspicion not later than 24 hours after forming the suspicion.

42 C.F.R. 483.12(c)(1) (F609) - *In response to allegations of abuse, neglect, exploitation, or mistreatment, the facility must: (1) Ensure that all alleged violations involving abuse, neglect, exploitation or mistreatment, including injuries of unknown source and misappropriation of resident property, are reported immediately, but not later than 2 hours after the allegation is made, if the events that cause the allegation involve abuse or result in serious bodily injury, or not later than 24 hours if the events that cause the allegation do not involve abuse and do not result in serious bodily injury, to the administrator of the facility and to other officials (including to the State Survey Agency and adult protective services where state law provides for jurisdiction in long-term care facilities) in accordance with State law through established procedures.*

483.12(c)(4) - *Report the results of all investigations to the administrator or his or her designated representative and to other officials in accordance with State law, including to the State Survey Agency, within 5 working days of the incident, and if the alleged violation is verified appropriate corrective action must be taken.*

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

pain or mental anguish. It includes verbal abuse, sexual abuse, physical abuse, and mental abuse including abuse facilitated or enabled through the use of technology.”

*“**Alleged violation**” is a situation or occurrence that is observed or reported by staff, resident, relative, visitor or others but has not yet been investigated and, if verified, could be noncompliance with the Federal requirements related to mistreatment, exploitation, neglect, or abuse, including injuries of unknown source, and misappropriation of resident property.*

*“**Crime**”: Section 1150B(b)(1) of the Act provides that a “crime” is defined by law of the applicable political subdivision where the facility is located. A political subdivision would be a city, county, township or village, or any local unit of government created by or pursuant to State law.*

*“**Criminal sexual abuse**”: In the case of “criminal sexual abuse” which is defined in section 2011(19)(B) of the Act (as added by section 6703(a)(1)(C) of the Affordable Care Act), serious bodily injury/harm shall be considered to have occurred if the conduct causing the injury is conduct described in section 2241 (relating to aggravated sexual abuse) or section 2242 (relating to sexual abuse) of Title 18, United States Code, or any similar offense under State law. In other words, serious bodily injury includes sexual intercourse with a resident by force or incapacitation or through threats of harm to the resident or others or any sexual act involving a child. Serious bodily injury also includes sexual intercourse with a resident who is incapable of declining to participate in the sexual act or lacks the ability to understand the nature of the sexual act.*

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

*“**Injuries of unknown source**” – An injury should be classified as an “injury of unknown source” when all of the following criteria are met:*

- The source of the injury was not observed by any person; and*
- The source of the injury could not be explained by the resident; and*
- The injury is suspicious because of the extent of the injury or the location of the injury (e.g., the injury is located in an area not generally vulnerable to trauma) or the number of injuries observed at one particular point in time or the incidence of injuries over time.*

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

*“**Mistreatment,**” as defined at §483.5, is “inappropriate treatment or exploitation of a resident.”*

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

“Serious bodily injury” means an injury involving extreme physical pain; involving substantial risk of death; involving protracted loss or impairment of the function of a bodily member, organ, or mental faculty; requiring medical intervention such as surgery, hospitalization, or physical rehabilitation; or an injury resulting from criminal sexual abuse (See section 2011(19)(A) of the Act).

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

“Willful,” is defined at §483.5 in the definition of “abuse,” and “means the individual must have acted deliberately, not that the individual must have intended to inflict injury or harm.”

Initial Report

It is important that the facility provide as much information as possible, to the best of its knowledge, at the time of submission of the report.

1. Facility Information

<i>Facility Name:</i>
<i>CMS Certification Number (CCN):</i>
<i>Address:</i>
<i>Phone number:</i>
<i>Email address</i>

2. Allegation Type

Select all that apply to the reporting incident.

<i>Abuse specify whether:</i>	<i>Physical</i>	<i>Sexual</i>	<i>Mental/Verbal</i>
<i>Deprivation of Goods and Services by Staff</i>			
<i>Neglect</i>	<i>Misappropriation of Resident</i>		
<i>Property/Exploitation</i>			
<i>Injury of Unknown Source</i>	<i>Suspected Crime</i>		

3. Information about when the Facility became aware of the incident

<i>Date/Time/Name of when staff became aware of the incident</i>
<i>Date/Time administrator was notified of the incident and by whom</i>

4. Alleged Victim(s)

Please be sure to input the current location of alleged victim at time of filling out this form.

<i>Full Name:</i>	<i>Date of Birth:</i>
<i>Current location of alleged victim:</i>	

5. Alleged Perpetrator(s)

If not a staff member, please insert as much accurate information as possible.

<i>Full Name</i>
<i>Position (if staff)</i>
<i>Contact information, if known</i>
<i>Relationship to the alleged victim</i>

6. Allegation Details

Provide a brief description of the specific allegation, including but not limited to, identifying:

<i>Who made the allegation (unless it was reported anonymously), and their relationship to the alleged victim</i>
<i>What was reported and to whom or which agency/entity</i>
<i>Date and time when the alleged incident occurred</i>
<i>Where the alleged incident occurred</i>

Provide details of any physical harm, pain, or mental anguish to the alleged victim(s), including but not limited to:

<i>Whether serious bodily injury occurred, if known</i>
<i>Describe any type of injury such as a bruise, scratch, laceration, puncture wound, fracture, bleeding, redness on the skin, etc.</i>

Describe any changes in the resident's behavior that indicate something different from the resident's normal baseline such as crying, expressions or displays of fear, cowering, anger, withdrawal, difficulty sleeping, etc.

Provide all steps taken immediately to ensure resident(s) are protected. Such steps could include:

- Immediate assessment of the alleged victim and provision of medical treatment as necessary;*
- Evaluation of whether the alleged victim feels safe and if he/she does not feel safe, taking immediate steps to protect the resident, such as a room relocation and/or increased supervision;*
- Immediate notification to the alleged perpetrator's (if a resident) and/or the alleged victim's physician and the resident representative when there is injury, a significant change in condition or status, and/or a need to alter treatment significantly;*
- If the alleged perpetrator is facility staff, removal of the alleged perpetrator's access to the alleged victim and other residents and assurance that ongoing safety and protection is provided for the alleged victim and other residents;*
- If the alleged perpetrator is a resident or visitor, removal of the alleged perpetrator's access to the alleged victim and, as appropriate, other residents and assurance that ongoing safety and protection is provided for the alleged victim and other residents;*
- Other measures the facility is taking to prevent further potential abuse, neglect, exploitation, and misappropriation of resident property.*

7. Witness(es)

<i>Full Name:</i>	<i>Position (if staff):</i>
<i>Relationship to alleged victim:</i>	<i>Contact information, if known:</i>

8. Notification to Law Enforcement, if applicable

<i>Was the incident reported to a law enforcement agency? (Yes/No)</i>
<i>If yes, name of the law enforcement agency notified and contact person</i>
<i>Name of reporting individual(s) and position(s)</i>
<i>Date and time (including am/pm) the report was made, report number if available:</i>

9. Notification to Other Agencies

<i>Were other agencies notified?</i>
<i>If YES, which other agency and who at that agency was notified of the allegation (ex: Adult Protective Services, Ombudsman)</i>
<i>Date and Time (include am/pm) the report was made:</i>

10. Submission Report

<i>Name/title of person submitting report</i>
<i>Date/time (am/pm) report was submitted</i>
<i>Contact number and E-mail address of person submitting report for follow up</i>

Exhibit 359
(Rev. 208; 10-21-22)

Follow-up Investigation Report

Within five (5) business days of the incident, the facility must provide in its report sufficient information to describe the results of the investigation, and indicate any corrective actions taken if the allegation was verified. It is important that the facility provide as much information as possible, to the best of its knowledge at the time of submission of the report. The facility should include any updates to information provided in the initial report and the following additional information, which should include, but are not limited to, the following:

1. Additional/Updated Information Related to the Reported Incident:

Provide a brief description of any additional information and/or updates, if applicable.

<i>Describe any additional outcomes to the resident(s), identifying/describing any physical and mental harm</i>
<i>Whether the allegation was reported to the resident representative, and if so, date/time</i>
<i>Whether the allegation was reported to another agency (e.g., nurse aide registry or professional licensing boards if staff to resident abuse), and if so, which agency, date/time, and outcome if they conducted an investigation</i>

2. Steps taken to investigate the allegation:

Provide a detailed summary of ALL steps taken to investigate allegation.

<i>Summary of interview(s) with the alleged victim and/or the victim's responsible party, if applicable. Indicate any visual cues from the resident of psychosocial distress and harm and the resident's perspective on incurred psychological harm and distress</i>
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Summary of interview(s) with witness(es), what the individual observed or knowledge of the alleged incident or injury

Summary of interview(s) with the alleged perpetrator(s) (staff, resident, visitor, contractor, etc.)

Summary of interview(s) with other residents who may have had contact with the alleged perpetrator

Summary of interview(s) with staff responsible for oversight and supervision of the location where the alleged victim resides

Summary of interview(s) with staff responsible for oversight and supervision of the alleged perpetrator, if staff or a resident

Provide summary information from the investigation related to the incident from the resident's clinical record, such as relevant portions of the RAI, the resident's care plan, nurses' notes, social services note, lab reports, x-ray reports, physician or other practitioner reports or reports from other disciplines that are related to the incident. If a resident to resident altercation occurred, provide any relevant details that may have caused the alleged perpetrator's behavior, such as habits, routines, medications, diagnosis, how long he/she may have lived at the building, or BIMS score.

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If available within the five business day timeframe, provide summary information of other documents obtained, such as hospital/medical progress notes/orders and discharge summaries, law enforcement reports, and death reports as applicable

3. Conclusion

Provide a brief description of the conclusion of the investigation and indicate if findings were:

[Note: For incidents reported as injuries of unknown source, indicate if the injury resulted from abuse or neglect, based on evidence from the investigation.]

Verified – The allegation was verified by evidence collected during the investigation. Indicate if the allegation was verified by evidence collected during the investigation.

Not Verified – The allegation was refuted by evidence collected during the investigation. Indicate and describe why the allegation was unable to be verified during the investigation.

Inconclusive– The allegation could not be verified or refuted because there was insufficient information to determine whether or not the allegation had occurred. If this was identified as inconclusive, indicate and describe how this was determined.

4. Corrective Action(s) Taken

Provide in detail a summary of all corrective action(s) taken.

Describe any action(s) taken as a result of the investigation or allegation

Describe the plan for oversight of implementation of corrective action, if the allegation is verified.

As a result of a verified finding of abuse, such as physical, sexual or mental abuse, identify counseling or other interventions planned and implemented to assist the resident

If systemic actions (e.g., changes to facility staffing patterns, changes in facility policies, training) were identified that require correction, identify the steps that have been taken to address the systems

If the allegation was reported to law enforcement or another state agency, where applicable and if available, what is the status or provide conclusions of their investigation.

5. Facility investigator

Provide the name of the facility individual who had the primary responsibility for conducting the investigation.

Name of person(s) investigating allegation:

6. Submitted by

Name of administrator/designee:

Date/time of submission:

Contact number and E-mail address for follow up: