
CMS Manual System

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

Transmittal 127

Date: November 26, 2014

SUBJECT: Revisions to State Operations Manual (SOM), Appendix PP – “Guidance to Surveyors for Long Term Care Facilities”

I. SUMMARY OF CHANGES: This instruction revises the Interpretive Guidelines and, in some instances, associated Investigative Protocols for several F Tags to reflect incorporation of Survey & Certification policy memo guidance issued from Fiscal Year 2003 through May 2014.

NEW/REVISED MATERIAL - EFFECTIVE DATE: November 26, 2014

IMPLEMENTATION DATE: November 26, 2014

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	Appendix PP/F155/§483.10(b)(4) and (8)
R	Appendix PP/F161/ §483.10(c)(7) Assurance of Financial Security
R	Appendix PP/F202/§483.12(a)(3) Documentation
R	Appendix PP/F208/§483.12(d) Admissions Policy
R	Appendix PP/F222/§483.13(a) Restraints
R	Appendix PP/F278/§483.20(g) Accuracy of Assessment
R	Appendix PP/F281/§483.20(k)(3)
R	Appendix PP/F286/§483.20(d) Use
R	Appendix PP/F309/§483.25 Quality of Care
D	Appendix PP/F321/§483.25(g) Naso-Gastric Tubes
R	Appendix PP/F322/§483.25(g) Naso-Gastric Tubes
R	Appendix PP/F329/§483.25(l) Unnecessary Drugs
R	Appendix PP/F332andF333/§483.25(m) Medication Errors
R	Appendix PP/F371/§483.35(i) Sanitary Conditions
R	Appendix PP/F388/§483.40(c)(3) Except as provided in paragraphs (c)(4) and (f) of this section, all required physician visits must be made by the physician personally.
R	Appendix PP/F390/§483.40(e) Physician Delegation of Tasks in SNFs
R	Appendix PP/F425/§483.60 Pharmacy Services

R	Appendix PP/F428/§483.60(c) Drug Regimen Review
R	Appendix PP/F431/§483.60(b) Service Consultation. The facility must employ or obtain the services of a licensed pharmacist who--
R	Appendix PP/F441/§483.65 Infection Control
R	Appendix PP/F492/§483.75(b) Compliance With Federal, State, and Local Laws and Professional Standards
R	Appendix PP/F514/§483.75(l) Clinical Records
R	Appendix PP/F516/§483.20(f)(5)

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

IV. ATTACHMENTS:

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

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

F155

(Rev. 127, Issued: 11-26-14, Effective: 11-26-14, Implementation: 11-26-14)

§483.10(b)(4) and (8)

§ 483.10(b)(4) – The resident has the right to refuse treatment, to refuse to participate in experimental research, and to formulate an advance directive as specified in paragraph (8) of this section; and

§483.10(b)(8) – The facility must comply with the requirements specified in subpart I of part 489 of this chapter relating to maintaining written policies and procedures regarding advance directives. 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 individual's option, formulate an advance directive. This includes a written description of the facility's policies to implement advance directives and applicable State law.

INTENT: (F155) §483.10(b)(4) and (8) Rights Regarding Refusal of Treatment and Participation in Experimental Research and Advance Directives

The intent of this requirement is that the facility promotes these rights by:

- Establishing and maintaining policies and procedures regarding these rights;*
- Informing and educating the resident about these rights and the facility's policies regarding exercising these rights;*
- Helping the resident to exercise these rights; and*
- Incorporating the resident's choices regarding these rights into treatment, care and services.*

NOTE: *While the language of 42 C.F.R §483.10(b)(8) applies only to adults, states may have laws that govern the rights of parents or legal guardians of children to formulate an advance directive. The CMS believes that this is an important issue for the parents/guardians of terminally ill or severely disabled children. Therefore surveyors are encouraged to refer to state law in cases where concerns arise regarding advance directives in non-adult populations. The regulatory language found under 42 C.F.R. § 483.10(b)(4) applies to all residents, regardless of age.*

DEFINITIONS

“Advance care planning” *is a process used to identify and update the resident's preferences regarding care and treatment at a future time including a situation in which the resident subsequently lacks capacity to do so. For example, when life-sustaining treatments are a potential option for care and the resident is unable to make his or her choices known.¹*

“Advance directive” means, according to 42 C.F.R. §489.100, 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. Some States also recognize a documented oral instruction.

“Cardiopulmonary resuscitation (CPR)” refers to any medical intervention used to restore circulatory and/or respiratory function that has ceased.

“Durable Power of Attorney for Health Care” (a.k.a. “Medical Power of Attorney”) is a document delegating authority to an agent to make health care decisions in case the individual delegating that authority subsequently becomes incapacitated.

“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 an individual’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 choices.

“Investigational or experimental drugs” refer to new drugs that have not yet been approved by the FDA or approved drugs that have not yet been approved for a new use, and are in the process of being tested for safety and effectiveness.

“Life-sustaining treatment” is treatment that, based on reasonable medical judgment, sustains an individual’s life and without it the individual will die. The term includes both life-sustaining medications and interventions (e.g. mechanical ventilation, kidney dialysis, and artificial hydration and nutrition). The term does not include the administration of pain medication or other pain management interventions, the performance of a medical procedure related to enhancing comfort, or any other medical care provided to alleviate a resident’s pain.²

“Legal representative” (e.g., “Agent,” “Attorney in fact,” “Proxy,” “Substitute decision-maker,” “Surrogate decision-maker”) is a person designated and authorized by an advance directive or State law to make a treatment decision for another person in the event the other person becomes unable to make necessary health care decisions.

“Treatment” refers to interventions provided to maintain or restore health and well-being, improve functional level, or relieve symptoms.

OVERVIEW

Traditionally, questions of care were resolved at the bedside through decision-making by an individual, his or her family and health care practitioner. As technological advances have

increased the ability of medicine to prolong life, questions have arisen concerning the use, withholding, or withdrawing of increasingly sophisticated medical interventions.

The Federal Patient Self - Determination Act contained in Public Law 101-508 is the authority on an individual's rights and facility responsibilities related to Advance Directives. The right of an individual to direct his or her own medical treatment, including withholding or withdrawing life-sustaining treatment, is grounded in common law (judge-made law), constitutional law, statutory law (law made by legislatures) and regulatory mandates governing care provided by facilities. Several landmark legal decisions have established an enduring judicial precedence for the legal principles of advance directives and the right to refuse or withhold treatment³⁴⁵⁶.

These legal developments have influenced standards of professional practice in the care and treatment of individuals in health care facilities. Several decades of professional debate and discussion have simultaneously advanced the thinking on these matters and promoted implementation of pertinent approaches to obtaining and acting on patient/resident wishes.⁷⁸

ESTABLISHING AND MAINTAINING POLICIES AND PROCEDURES REGARDING THESE RIGHTS

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

The facility's policies and procedures delineate the various steps necessary to promote and implement these rights, including, for example:

- Determining on admission whether the resident has an advance directive and, if not, determining whether the resident wishes to formulate an advance directive;*
- Determining if the facility periodically assesses the resident for decision-making capacity and invokes the health care agent or legal representative if the resident is determined not to have decision-making capacity.*
- Identifying the primary decision-maker (e.g., assessing the resident's decision-making capacity and identifying or arranging for an appropriate legal 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/her legal 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;*
- *Reviewing the resident's condition and existing choices and continuing or modifying approaches, as appropriate;*
- *Establishing mechanisms for documenting and communicating the resident's choices to the interdisciplinary team; and*
- *Identifying the process (as provided by State law) for handling situations in which the facility 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.*

INFORMING AND EDUCATING THE RESIDENT ABOUT THESE RIGHTS

The facility is required (by 42 C.F.R. § 489.102 Requirements for Providers) to provide, at the time of a resident's admission, written information concerning the resident's rights to make decisions concerning medical care, including the right to refuse medical or surgical treatment, decline to participate in experimental research and the right to formulate advance directives. The resident must also receive a written description of the facility's policies that govern the exercise of these rights.

ESTABLISHING ADVANCE DIRECTIVES

The facility must ensure compliance with Federal and State requirements regarding advance directives. At the time the resident is admitted to a nursing home, staff must determine whether the resident has executed an advance directive or has given other instructions to indicate what care he or she desires in case of subsequent incapacity. Such a directive or instructions could be a living will, a directive to the attending physician, a durable power of attorney for health care, 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. Several States have also adopted the use of a portable and enduring order form that documents the resident's choices related to life-sustaining treatments.⁹

If the resident or the resident's legal representative has executed one or more advance directive(s), or executes one upon admission, it is important that copies of these documents be obtained, incorporated and consistently maintained in the same section of the resident's medical record readily retrievable by any facility staff, and that the facility communicate the resident's wishes to the resident's direct care staff and physician. If the resident has not executed an advance directive, the facility is required to advise the resident and family of the right to establish an advance directive as set forth in the laws of the State; to offer assistance if the resident wishes to execute one or more directive(s); and to 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.

Advance Care Planning

In order for a resident to exercise his or her right to make knowledgeable choices about care and treatment or to decline treatment, the primary care provider and facility staff should provide information (in a language and terminology that the resident understands) to the resident and/or his/her legal representative regarding the resident's health status, treatment options, and expected outcomes. Whether or not the resident chooses to execute an advance directive, discussion and documentation of the resident's choices regarding future health care should take place during the development of the initial comprehensive assessment and care plan and periodically thereafter. The process of having such discussions, regardless of when they occur, is sometimes referred to as "advance care planning."

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 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. Advance care planning is a method to further a resident's control over his or her own medical treatment and choices.¹⁰ It also allows the decision-maker (whether it is the resident, family or other legal representative) to be better informed about the treatment alternatives available in a variety of circumstances.

RIGHT TO REFUSE MEDICAL OR SURGICAL TREATMENT

If a resident (directly or through an advance directive) declines treatment (e.g., refuses artificial nutrition or IV hydration, despite having lost considerable weight), the resident may not be treated against his/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 facility may not transfer or discharge a resident for refusing treatment unless the criteria for transfer or discharge are otherwise met.

If a resident's refusal of treatment results in a significant change in condition, the facility should reassess the resident and modify the care plan as appropriate. The facility is expected to assess the resident for decision-making capacity and invoke the health care agent or legal representative if the resident is determined not to have decision-making capacity. Once the decision-making capacity is assessed, the facility is expected to determine and document what the resident is refusing, to assess the reasons for the resident's refusal, to advise the resident about the consequences of refusal, to offer pertinent alternative treatments, and to continue to provide all other appropriate services. The resident's refusal of treatment does not absolve a facility from providing other care that allows him/her to attain or maintain his/her highest practicable physical, mental and psychosocial well-being. For example, a facility would still be expected to provide appropriate measures for pressure ulcer prevention, even if a resident has refused food and fluids and is expected to die.

RIGHT TO DECLINE TO PARTICIPATE IN EXPERIMENTAL RESEARCH

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 (e.g., medication, other treatment) and the possible consequences of participating. The resident must give informed consent in order to participate. If the resident is incapable of understanding the situation and of realizing the risks and benefits of the proposed research, but a legal representative gives proxy consent, the facility has a responsibility to ensure that the proxy consent is properly obtained and that essential measures are taken to protect the individual from harm or mistreatment. The resident (or his/her legal 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.

A facility participating in any experimental research involving residents must have a process for committee (e.g., an Institutional Review Board) approval of this research and mechanisms in place for its oversight. In this regard, §483.75(c), Relationship to Other HHS Regulations, applies (i.e., research conducted at a facility must adhere to 45 CFR Part 46, Protection of Human Subjects of Research).

INVESTIGATIVE PROTOCOL

§483.101(b)(4) AND (8) RIGHTS REGARDING REFUSAL OF MEDICAL OR SURGICAL TREATMENT, PARTICIPATION IN EXPERIMENTAL RESEARCH AND ADVANCE DIRECTIVES

Objectives

To determine whether a facility promoted the resident's right to refuse medical or surgical treatment, to refuse to participate in experimental research, and to formulate an advance directive by:

- Establishing and maintaining policies and procedures regarding these rights;*
- Informing and educating the resident about these rights and the facility's policies regarding these rights;*
- Helping the resident exercise these rights; and*
- Incorporating the resident's choices regarding these rights into treatment, care and services.*

Use

Use this protocol for:

- Complaints from residents, family members or other resident representatives concerning services related to a resident's right to refuse medical or surgical treatment, participate*

in experimental research, formulate an advance directive, or provide written information, policies and procedures related to advance directives;

- *All sampled residents identified with orders or a condition (e.g., neuromuscular diseases, exacerbation of COPD, temporary swallowing or gastrointestinal tract issues) potentially related to provision of life-sustaining treatments such as artificial nutrition/hydration, artificial ventilation, dialysis, blood transfusions, or cardiopulmonary resuscitation. (NOTE: For the Quality Indicator Survey (QIS) process this review would be conducted during Stage 2 of the survey);*
- *Residents who refused medical or surgical treatment; or*
- *Is participating in an experimental research activity or project.*

Procedures

Briefly review the resident's record to determine if the resident has an advance directive, is participating in experimental research, refused medical or surgical treatment, received or is currently receiving life sustaining treatments. The surveyor(s) should conduct the following observations, interviews and record reviews.

Observations

Observe the selected resident care and treatments provided during various shifts. Note whether the care and services related to participation in experimental research, refusal of medical or surgical treatment, or provision of life-sustaining treatment are consistent with the care plan, progress notes and resident choices.

Interviews

Resident/Representative

Interview the resident and/or the resident's legal representative, as appropriate, regarding the following:

- *What the facility has done to determine the resident's choices regarding care and treatment;*
- *What the staff and practitioner have done to inform the resident or the resident's legal representative about the resident's medical condition and relevant health care issues;*
- *What the staff and practitioner have done to inform the resident or the resident's legal representative about treatment options and the relevance of those options to the resident's goals, wishes, medical condition and prognosis;*
- *What the staff and practitioner have done to help the resident or the resident's legal representative document treatment choices (e.g., advance directives or another format consistent with State and Federal law and regulation); and*

- *If the resident is participating in research, did the resident or the resident's legal representative receive information prior to the start of the project that: sufficiently explained the research for which he/she was being asked to give consent; made clear the risks and benefits of the research; and informed him/her of the right to refuse to participate?*

Facility staff

Interview staff who are involved in informing residents about treatment options and documenting resident wishes to determine:

- *How the facility determines whether the resident has an advance directive or other existing documentation related to life-sustaining treatment;*
- *What training staff receive regarding advance directives and their initiation;*
- *How the facility assessed the resident's capacity to make health care decisions and consent to participate in experimental research;*
- *How the practitioner and facility inform the resident or legal representative about his or her medical condition and relevant health care issues;*
- *How the practitioner and facility inform and educate the resident or legal representative about treatment options and the resident's right to refuse medical or surgical treatment, to formulate an advance directive and to refuse to participate in experimental research;*
- *How staff helps the resident or legal representative document treatment choices and formulate an advance directive;*
- *How documented choices and treatment decisions are communicated to the interdisciplinary team;*
- *How the practitioner and staff monitor and safeguarded the rights of the resident involved in experimental research;*
- *How staff know where to access the documented information on the resident's treatment choices and advance directives in the medical record, during both routine care and in an urgent or emergent situation; and*
- *How the facility ensures that practitioner orders and treatment decisions are consistent with the resident's documented choices and goals.*

Health care practitioners and professionals

Interview one or more health care practitioners and professionals as necessary (e.g., physician, nurse practitioners, physician assistants, charge nurse, director of nursing, social worker) who, by virtue of training and knowledge of the resident, should be able to provide information regarding:

- *How the facility seeks, identifies, and documents the resident's wishes regarding advance care planning and life-sustaining treatments;*
- *How the facility ensures that medical orders and treatments reflect the resident's choices and goals;*
- *The process by which the staff and practitioners are involved in advising the resident and the resident's legal representative about the right to refuse treatment (including life-sustaining treatments);*
- *How documented choices and treatment decisions are communicated to the interdisciplinary team;*
- *How the staff and practitioner obtain and document informed consent of the resident who is participating in experimental research;*
- *How the staff and practitioners proceed if the resident who is involved in experimental research is suspected of, or identified as, suffering adverse consequences related to his/her participation;*
- *How staff know where to access the documented information on the resident's treatment choices and advance directives in the medical record, during both routine care and in an urgent or emergent situation; and*
- *How the staff and practitioner periodically reassess the resident's condition and prognosis to identify whether existing advance directives remain pertinent and/or whether there is a need to review or possibly modify them.*

During the course of the review, the surveyor should consider contacting the attending physician or health care practitioner regarding questions related to the treatment 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 or health care practitioner for his/her review prior to responding to the surveyor's inquiries. If the attending physician or health care practitioner is unavailable, interview the medical director as appropriate.

Record Review

Depending on the issue of concern, review the resident's records for evidence of whether and how the facility determines the resident's capacity to understand and make decisions regarding the right to refuse treatment, to formulate an advance directive and/or refuse to participate in experimental research. Review whether information was provided in writing regarding these rights. Review whether the facility determined at admission if the resident had an existing advance directive and, if the resident did not have one, whether the facility offered the resident the option to formulate an advance directive. Review for any information regarding initiating, continuing, withholding, or withdrawing treatment.

Note whether the care plan considers the resident's choices.

Depending on the issue of concern, review information such as medical orders and interdisciplinary progress notes to determine:

- *Whether there is documentation of the rationale for recommendations and treatment decisions related to life-sustaining treatment options;*
- *Whether the practitioner's orders are consistent with the resident's documented choices and goals. Unless, in rare circumstances, where a physician needs more information about the residents decisional capacity, has a conscientious objection to the residents decision or other aspects of the case in order to be comfortable writing orders that are consistent with the resident's expressed wishes;*
- *The frequency and scope of monitoring the resident who is participating in experimental research activities for responses to and adverse consequences of any experimental treatments;*
- *Whether any treatments or interventions have been ordered (e.g., unplanned hospitalizations or placement of a feeding tube) that are inconsistent with the resident's documented treatment preferences or with any existing advance directives; and*
- *Whether the resident's advance directive, if formulated, has been incorporated into his or her active record, including in medical orders, progress notes, the resident care plan or other relevant means of communication to the interdisciplinary team.*

Review of Facility Practices

Depending on the issue of concern, the assigned surveyor should review, as indicated, the facility's policies, procedures, records related to determining and documenting resident wishes regarding advance care planning and implementing medical orders that reflect a resident's wishes. Related concerns may have been identified that would suggest the need for further review of facility practices. Examples of such activities may include a review of policies, staffing, staff training and/or functional responsibilities.

DETERMINATION OF COMPLIANCE

Criteria for Compliance

The facility is in compliance with 42 §CFR 483.10 (b)(4) and (8), if the facility has:

- *Established and implemented policies and procedures regarding the right to formulate advance directives, refuse medical and surgical treatment and other related interventions and to decline to participate in experimental research;*
- *Informed and educated the resident about these rights, including the facility's policies regarding exercising these rights;*

- *Determined whether the resident has an advance directive in place or has offered the resident the opportunity to develop an advance directive;*
- *Documented when the resident is determined not to have decision-making capacity and therefore decision-making is transferred to the health care agent or legal representative;*
- *Helped the resident to exercise these rights based on explaining risk and benefits of declining treatment;*
- *Incorporated the resident's choices into the medical record and orders related to treatment, care and services;*
- *Consistently maintained advance directives and resident goals and in the same section of the clinical record or other document filing system for all appropriate residents, where those documents are easily retrievable by staff during both routine and urgent or emergent situations; and*
- *Monitored the care and services given to the resident to ensure that they are consistent with the resident's documented choices and goals.*

If not, cite at F155.

IV. DEFICIENCY CATEGORIZATION (PART IV, APPENDIX P)

Once the 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.

The key elements for severity determination for F155 are as follows:

1. *Presence of harm/negative outcome(s) or potential for negative outcomes* *because of lack of appropriate care and services or lack of implementation of resident's right to refuse medical or surgical treatment, refuse to participate in experimental research and/or formulate an advance directive. Actual or potential harm/negative outcomes for F155 may include, but are not limited to:*

- *Resident was resuscitated despite a DNR order included in the resident's record;*
- *Resident suffered a life-threatening complication related to involvement in research activity in the absence of adequate consent of the resident or his/her legal representative;*
- *Resident was hospitalized contrary to his/her wishes; and*
- *Resident received treatment based on the consent of an individual who was not the resident or his/her representative, in accordance with State Law.*

2. Degree of harm (actual or potential) related to the noncompliance. Identify how the facility practices caused, resulted in, allowed, or contributed to the actual or potential for harm.

- If harm has occurred, determine if the harm is at the level of serious injury, impairment, death, compromise, or discomfort; and
- If harm has not yet occurred, determine how likely the potential is for serious injury, impairment, death, compromise or discomfort to occur to the resident.

3. The immediacy of correction required. Determine whether the noncompliance requires immediate correction in order to prevent serious injury, harm, impairment, or death to one or more residents.

The survey team must evaluate the harm or potential for harm based upon the following levels of severity. First, the team must rule out whether Severity Level 4 (immediate jeopardy to a resident's health or safety) exists by evaluating the deficient practice in relation to immediacy, culpability, and severity. (Follow the guidance in Appendix Q, Determining Immediate Jeopardy.)

Severity Level 4 Considerations: Immediate Jeopardy to Resident Health or Safety

Immediate jeopardy is a situation in which the facility's noncompliance with one or more requirements of participation:

- Has allowed, caused, or resulted in (or is likely to allow, cause, or result in) serious injury, harm, impairment, or death to a resident; and
- Requires immediate correction as the facility either created the situation or allowed the situation to continue by failing to implement preventative or corrective measures.

NOTE: The death or transfer of a resident, who was harmed as a result of facility practices, does not remove a finding of immediate jeopardy. The facility is required to implement specific actions to correct the deficient practices which allowed or caused the immediate jeopardy.

Examples of avoidable actual or potential resident outcomes that demonstrate severity at Level 4 may include, but are not limited to:

- As a result of the facility's failure to obtain and implement medical orders related to life-sustaining treatments, after the resident had documented choices, the resident was transferred to the hospital for an acute change of condition against his wishes, where he was resuscitated against his documented wishes, despite the facility's knowledge that the intervention was against the resident's wishes.

NOTE: *If Severity Level 4 (immediate jeopardy) has been ruled out based upon the evidence, then evaluate whether actual harm that is not immediate jeopardy exists at Severity Level 3 or the potential for more than minimal harm at Severity Level 2 exists.*

Severity Level 3 Considerations: Actual Harm that is Not Immediate Jeopardy

Severity Level 3 indicates noncompliance that resulted in actual harm that is not immediate jeopardy. The negative outcome can include but may not be limited to clinical compromise, decline, or the resident's inability to maintain and/or reach his/her highest practicable well-being.

Examples of avoidable resident outcomes that demonstrate severity at Level 3 may include, but are not limited to:

- *The facility failed to identify the medical orders that detailed the resident's wishes to forego lab work, IV antibiotic treatment and IV hydration for the resident's 7th episode of aspiration pneumonia. Furthermore, the nurses refused to allow the resident to attend his son's wedding, insisting that the resident remain in the nursing home so that a chest x-ray and blood work be done, which went against the resident's expressed wishes. The resident suffered emotional harm.*

NOTE: *If Severity Level 3 (actual harm that is not immediate jeopardy) has been ruled out based upon the evidence, then evaluate as to whether Severity Level 2 (no actual harm with the potential for more than minimal harm) exists.*

Severity Level 2 Considerations: No Actual Harm with Potential for More than Minimal Harm that is not Immediate Jeopardy

Severity Level 2 indicates noncompliance that resulted in a resident outcome of no more than minimal discomfort and/or had the potential to compromise the resident's ability to maintain or reach his or her highest practicable level of well being. The potential exists for greater harm to occur if interventions are not provided.

Examples of avoidable outcomes at Severity Level 2 include, but are not limited to:

- *As a result of the facility's failure to establish and implement policies and procedures regarding the rights to decline treatment and other related interventions, the resident and/or the resident's legal representative was unaware of the opportunities to decline medical treatment, although a situation involving the use of life-sustaining treatment options had not yet arisen in the resident's care; or*
- *As a result of the facility's failure to obtain medical orders that were consistent with the resident's documented wishes, the direct care staff was unaware of the resident's wishes, although a situation involving life-sustaining treatment options had not yet arisen in the resident's care.*

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

The failure of the facility to recognize and facilitate the exercising of the resident's right to refuse medical or surgical treatment, to refuse to participate in experimental research and to formulate an advance directive; and to maintain written policies and procedures regarding these rights, places the resident at risk for more than minimal harm. Therefore, Severity Level does not apply for this regulatory requirement

ENDNOTES:

¹ Adapted from: Emanuel, L.L., Danis, M., Pearlman, R.A., Singer, P.A. (1995). *Advance care planning as a process: structuring the discussions in practice. Journal of the American Geriatric Society*, 43, 440-6.

² TX Health and Safety Code Title 2, §166.002: *Definitions – Advance Directives Act. Available from: <http://www.statutes.legis.state.tx.us>; Accessed on December 3, 2010.*

³ Thomas, K.R. (Updated September 19, 2005). *The Right to Die: Constitutional and Statutory Analysis. Congressional Research Service Report for Congress*, 907-244A. (<http://www.policyarchive.org/handle/10207/bitstreams/363.pdf>)

⁴ Quinlan. (1976). 70 N.J. 10, 355 A.2d 647. (<http://www.libraryindex.com/pages/582/Court-End-Life-RIGHT-PRIVACY-KAREN-ANN-QUINLAN.html>">Court)

⁵ *Bartling v. Superior Court.* (1984). Dec 27:209:220-7. (<http://www.ncbi.nlm.nih.gov/pubmed/11648164>)

⁶ *Cruzan v. Director, Missouri Department of Health.* (1990). 497 U.S. 261. (http://www.oyez.org/cases/1980-1989/1989/1989_88_1503)

⁷ Atmore, C. & Naksook, C. (2007). *Respecting Patient Choices – Literature Review. Prepared by Health Issues Centre for the Respecting Patient Choices Project, Austin Health, La Trobe University, VIC, Australia.* (<http://www.healthissuescentre.org.au/documents/items/2008/04/205853-upload-00001.pdf>)

⁸ Emanuel, L.L., von Gunten, C.F., Ferris, F.D. (1991). *Education for Physicians at the End of Life (EPEC) Participant's Handbook -- Plenary 2, Legal Issues. Robert Wood Johnson Foundation.* (http://endoflife.northwestern.edu/legal_issues/module15.pdf)

⁹ *POLST Physician Orders for Life Sustaining Treatment Paradigm* (<http://www.ohsu.edu/polst/>)

¹⁰ Teno, J.M., Casey, V.A., Welch, L.C., Edgman – Levitan, S. (2001). *Patient-Focused, Family-Centered End-of-Life Medical Care: Views of the Guidelines and Bereaved Family Members. Journal of Pain and Symptom Management*, Vol. 22 No. 3.

F161

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§483.10(c)(7) Assurance of Financial Security

The facility must purchase a surety bond, or otherwise provide assurance satisfactory to the Secretary, to assure the security of all personal funds of residents deposited with the facility.

Definitions §483.10(c)(7)

A “surety bond” is an agreement between the principal (the facility), the surety (the insurance company), and the obligee (depending on State law, either the resident or the State acting on behalf of the resident), wherein the facility and the insurance company agree to compensate the resident (or the State on behalf of the resident) for any loss of residents’ funds that the facility holds, safeguards, manages, and accounts for.

Interpretive Guidelines §483.10(c)(7)

The purpose of the surety bond is to guarantee that the facility will pay the resident (or the State on behalf of the resident) for losses occurring from any failure by the facility to hold, safeguard, manage, and account for the residents’ funds, i.e., losses occurring as a result of acts or errors of negligence, incompetence or dishonesty.

Unlike other types of insurance, the surety bond protects the obligee (the resident or the State), not the principal (the facility), from loss. The surety bond differs from a fidelity bond, which covers no acts or errors of negligence, incompetence or dishonesty.

The surety bond is the commitment of the facility in an objective manner to meet the standard of conduct specified in §483.10(c)(2), that the facility will hold, safeguard, manage and account for the funds residents have entrusted to the facility. The facility assumes the responsibility to compensate the obligee for the amount of the loss up to the entire amount of the surety bond.

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

Reasonable alternatives to a surety bond must:

- Designate the obligee (depending on State law, the resident individually or in aggregate, or the State on behalf of each resident) who can collect in case of a loss;
- Specify that the obligee may collect due to any failure by the facility, whether by commission, bankruptcy, or omission, to hold, safeguard, manage, and account for the residents’ funds; and

- Be managed by a third party unrelated in any way to the facility or its management.

The facility cannot be named as a beneficiary.

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

Procedures §483.10(c)(7)

As part of Phase 2 *for the Traditional Survey Process*, if your team has any concerns about residents' funds, check the amount of the surety bond to make sure it is at least equal to the total amount of residents' funds, as of the most recent quarter.

If the State survey agency determines that individual circumstances associated with a facility's surety bond or its alternative are such that the survey agency cannot determine whether or not the facility is in compliance with the requirements at §483.10(c)(7), then it would be appropriate to make the referral to the State's fiscal department.

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

F202

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§483.12(a)(3) Documentation

When the facility transfers or discharges a resident under any of the circumstances specified in paragraphs (a)(2)(i) through (v) of this section, the resident's clinical record must be documented. The documentation must be made by--

(i) The resident's physician when transfer or discharge is necessary under paragraph (a)(2)(i) or paragraph (a)(2)(ii) of this section; and

(ii) A physician when transfer or discharge is necessary under paragraph (a)(2)(iv) of this section.

Interpretive Guidelines: §483.12(a)(2) and (3)

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 the appropriate assessment to determine if a new care plan would allow the facility to meet the

resident's needs. (See §483.20(b)(4)(iv), F274, for information concerning assessment upon significant change.)

Conversion from a private pay rate to payment at the Medicaid rate does not constitute non-payment.

Refusal of treatment would not constitute grounds for transfer, unless the facility is unable to meet the needs of the resident or protect the health and safety of others.

Documentation of the transfer/discharge may be completed by a physician extender unless prohibited by State law or facility policy.

If a nursing home discharges a resident or retaliates due to an existing resident's failure to sign or comply with a binding arbitration agreement, the State and Region may initiate an enforcement action based on a violation of the rules governing resident discharge and transfer. A current resident is not obligated to sign a new admission agreement that contains binding arbitration.

Procedures: §483.12(a)(2) and (3)

During closed record review, determine the reasons for transfer/discharge.

If the entity to which the resident was discharged is another long term care facility, evaluate the extent to which the discharge summary and the resident's physician justify why the facility could not meet the needs of this resident.

Probes: §483.12(a)(2) and (3)

Do records document accurate assessments and attempts through care planning to address resident's needs through multi-disciplinary interventions, accommodation of individual needs and attention to the resident's customary routines?

Did the resident's physician document the record if:

- o The resident was transferred/discharged for the sake of the resident's welfare and the resident's needs could not be met in the facility (e.g., a resident develops an acute condition requiring hospitalization)? or
- o The resident's health improved to the extent that the transferred/discharged resident no longer needed the services of the facility.

Did a physician document the record if residents were transferred because the health of individuals in the facility is endangered?

Do the records of residents transferred/discharged due to safety reasons reflect the process by which the facility concluded that in each instance transfer or discharge was necessary? Did the

survey team observe residents with similar safety concerns in the facility? If so, determine differences between these residents and those who were transferred or discharged.

Look for changes in source of payment coinciding with transfer. If you find such transfer, determine if the transfers were triggered by one of the criteria specified in §483.12(a)(2).

Ask the ombudsman if there were any complaints regarding transfer and/or discharge. If there were, what was the result of the ombudsman's investigation?

F208

(Rev. 127, Issued: 11-26-14, Effective: 11-26-14, Implementation: 11-26-14)

§483.12(d) Admissions Policy

(1) The facility must--

(i) Not require residents or potential residents to waive their rights to Medicare or Medicaid; and

(ii) Not require oral or written assurance that residents or potential residents are not eligible for, or will not apply for, Medicare or Medicaid benefits.

Interpretive Guidelines §483.12(d)(1)

This provision prohibits both direct and indirect request for waiver of rights to Medicare or Medicaid. A direct request for waiver, for example, requires residents to sign admissions documents explicitly promising or agreeing not to apply for Medicare or Medicaid. An indirect request for waiver includes requiring the resident to pay private rates for a specified period of time, such as two years ("private pay duration of stay contract") before Medicaid will be accepted as a payment source for the resident. Facilities must not seek or receive any kind of assurances that residents are not eligible for, or will not apply for, Medicare or Medicaid benefits.

Procedures §483.12(d)(1)

If concerns regarding admissions procedures arise during interviews, review admissions packages and contracts to determine if they contain prohibited requirements (e.g., "side agreements" for the resident to be private pay or to supplement the Medicaid rate).

Ask staff what factors lead to decisions to place residents in different wings or floors. Note if factors other than medical and nursing needs affect these decisions. Do staff know the source of payment for the residents they take care of?

Ask the ombudsman if the facility treats residents differently in transfer, discharge and covered services based on source of payment.

With respect to transfer and discharge, if the facility appears to be sending residents to hospitals at the time (or shortly before) their payment source changes from private-pay or Medicare to Medicaid, call the hospitals and ask their discharge planners if they have detected any pattern of dumping. Also, ask discharge planners if the facility readmits Medicaid recipients who are ready to return to the facility. During the tour, observe possible differences in services

- Observe if there are separate dining rooms. If so, are different foods served in these dining rooms? For what reasons? Are residents excluded from some dining rooms because of source of payment?
- Observe the placement of residents in rooms in the facility. If residents are segregated on floors or wings by source of payment, determine if the facility is providing different services based on source of payment. Be particularly alert to differences in treatment and services. For example, determine whether less experienced aides and nursing staff are assigned to Medicaid portions of the facility. Notice the condition of the rooms (e.g., carpeted in private-pay wings, tile in Medicaid wings, proximity to the nurses' station, quality of food served as evening snacks).

As part of closed record review, determine if residents have been treated differently in transfers or discharges because of payment status. For example, determine if the facility is sending residents to acute care hospitals shortly before they become eligible for Medicaid as a way of getting rid of Medicaid recipients.

Ask social services staff to describe the facility's policy and practice on providing services, such as rehabilitative services. Determine if services are provided based on source of payment, rather than on need for services to attain or maintain functioning.

§483.12(d)(2) The facility must not require a third party guarantee of payment to the facility as a condition of admission or expedited admission, or continued stay in the facility. However, the facility may require an individual who has legal access to a resident's income or resources available to pay for facility care to sign a contract, without incurring personal financial liability, to provide facility payment from the resident's income or resources.

Interpretive Guidelines §483.12(d)(2)

The facility may not require a third person to accept personal responsibility for paying the facility bill out of his or her own funds. However, he or she may use the resident's money to pay for care. A third party guarantee is not the same as a third party payor, e.g., an insurance company; and this provision does not preclude the facility from obtaining information about Medicare or Medicaid eligibility or the availability of private insurance. The prohibition against third-party guarantees applies to all residents and prospective residents in all certified long term care facilities, regardless of payment source.

§483.12(d)(3) In the case of a person eligible for Medicaid, a nursing facility must not charge, solicit, accept, or receive, in addition to any amount otherwise required to be paid

under the State plan, any gift, money, donation, or other consideration as a precondition of admission, expedited admission or continued stay in the facility. However,--

(i) A nursing facility may charge a resident who is eligible for Medicaid for items and services the resident has requested and received, and that are not specified in the State plan as included in the term “nursing facility services” so long as the facility gives proper notice of the availability and cost of these services to residents and does not condition the resident’s admission or continued stay on the request for and receipt of such additional services; and

(ii) A nursing facility may solicit, accept, or receive a charitable, religious, or philanthropic contribution from an organization or from a person unrelated to a Medicaid eligible resident or potential resident, but only to the extent that the contribution is not a condition of admission, expedited admission, or continued stay in the facility for a Medicaid eligible resident.

Interpretive Guidelines §483.12(d)(3)

This requirement applies only to Medicaid certified nursing facilities.

Facilities may not charge for any service that is included in the definition of “nursing facility services” and, therefore, required to be provided as part of the daily rate. Facilities may not accept additional payment from residents or their families as a prerequisite to admission or to continued stay in the facility. Additional payment includes deposits from Medicaid-eligible residents or their families, or any promise to pay private rates for a specified period of time.

***NOTE:** This regulation does not preclude a facility from charging a deposit fee to, or requiring a promissory note from, an individual whose stay is not covered by Medicaid. In instances where the deposit fee is refundable and remains as funds of the resident, the facility must have a surety bond that covers the deposit amount (§483.10(c)(7)).*

Permitted Charges for Medicaid Eligible Residents §483.12(d)(3)

A nursing facility is permitted to charge an applicant or resident whose Medicaid eligibility is pending, typically in the form of a deposit prior to admission and/or payment for services after admission. Medicaid eligibility will be made retroactive up to 3 months before the month of application if the applicant would have been eligible had he or she applied in any of the retroactive months.

In addition, the nursing facility must accept as payment in full the amounts determined by the state for all dates the resident was both Medicaid eligible and a nursing facility resident. Therefore, a nursing facility that charged a recipient for services between the first month of eligibility established by the state and the date notice of eligibility was received is obligated to refund any payments received for that period less the state's determination of any resident's share of the nursing facility's costs for that same period. A nursing facility must prominently display written information in the facility and provide oral and written explanation to applicants

or residents about applying for Medicaid, including how to use Medicaid benefits, and how to receive refunds for previous payments covered by such benefits.

Under the post-eligibility process, if the Medicaid-eligible resident has income and is required to make a monthly payment to the nursing facility (which is a portion of the Medicaid payment amount), then the nursing facility is permitted to retain the amount it is legally owed. However, the nursing facility must not charge any administrative fees.

A nursing facility may charge a Medicaid beneficiary for a service the beneficiary has requested and received, only if:

- That service is not defined in the State plan as a “nursing facility” service;
- The facility informs the resident and the resident’s representative in advance that this is not a covered service to allow them to make an informed choice regarding the fee; and
- The resident’s admission or continued stay is not conditioned on the resident's requesting and receiving that service.

Procedures §483.12(d)(3)

Review State covered services. Compare with the list of items for which the facility charges to determine if the facility is charging for covered services.

Determine if the facility requires deposits from residents. If you identify potential problems with discrimination, review the files of one or more residents selected for a focused or comprehensive review to determine if the facility requires residents to submit deposits as a precondition of admission besides what may be paid under the State plan.

If interviews with residents suggest that the facility may have required deposits from Medicaid recipients at admission, except those admitted when Medicaid eligibility is pending, corroborate by, for example, reviewing the facility's admissions documents or interviewing family members.

§483.12(d)(4) States or political subdivisions may apply stricter admissions standards under State or local laws than are specified in this section, to prohibit discrimination against individuals entitled to Medicaid.

F222

(Rev. 127, Issued: 11-26-14, Effective: 11-26-14, Implementation: 11-26-14)

Use Tag F222 for deficiencies concerning **chemical** restraints.

§483.13(a) Restraints

The resident has 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.

Intent §483.13(a)

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 restraints for discipline or convenience and limits restraint use to circumstances in which the resident has medical symptoms that warrant the use of restraints.

Definitions

“Chemical Restraints” is defined as any drug that is used for discipline or convenience and not required to treat medical symptoms.

“Convenience” is defined as any action taken by the facility to control a resident’s behavior or manage a resident’s behavior with a lesser amount of effort by the facility and 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.

“Medical Symptom” is defined as an indication or characteristic of a physical or psychological condition.

“Physical Restraints” are defined as any manual method or physical or mechanical device, material, or equipment attached or adjacent to the resident’s body that the individual cannot remove easily which restricts freedom of movement or normal access to one’s body (e.g. leg restraints, arm restraints, hand mitts, soft ties or vests, lap cushions, and lap trays the resident cannot remove easily).

“Removes easily” means that the manual method, device, material, or equipment can be removed intentionally by the resident in the same manner as it was applied by the staff (e.g., side rails are put down, not climbed over; buckles are intentionally unbuckled; ties or knots are intentionally untied; etc.) considering the resident’s physical condition and ability to accomplish objective (e.g., transfer to a chair, get to the bathroom in time).

Overview

Restraints may not be used for staff convenience. However, if the resident needs emergency care, restraints may be used for brief periods to permit medical treatment to proceed unless the facility has a notice indicating that the resident has previously made a valid refusal of the treatment in question. If a resident’s unanticipated violent or aggressive behavior places him/her

or others in imminent danger, the resident does not have the right to refuse the use of restraints. In this situation, the use of restraints is a measure of last resort to protect the safety of the resident or others and must not extend beyond the immediate episode. The facility may not use restraints in violation of the regulation solely based on a legal surrogate or representative's request or approval.

Finally, residents who are restrained may face a loss of autonomy, dignity and self-respect, and may show symptoms of withdrawal, depression, or reduced social contact.

Facility practices that meet the definition of a restraint include, but are not limited to:

- Using side rails that keep a resident from voluntarily getting out of bed;
- Tucking in or using velcro to hold a sheet, fabric, or clothing tightly so that a resident's movement is restricted;
- Using devices in conjunction with a chair, such as trays, tables, bars or belts, that the resident cannot remove easily, that prevent the resident from rising;
- Placing a resident in a chair that prevents a resident from rising; and
- Placing a chair or bed so close to a wall that the wall prevents the resident from rising out of the chair or voluntarily getting out of bed.

NOTE: An enclosed framed wheeled walker, with or without a posterior seat, would not meet the definition of a restraint if the resident could easily open the front gate and exit the device. If the resident cannot open the front gate (due to cognitive or physical limitations that prevent him or her from exiting the device or because the device has been altered to prevent the resident from exiting the device), the enclosed framed wheeled walker would meet the definition of a restraint since the device would restrict the resident's freedom of movement (e.g. transferring to another chair, to the commode, or into the bed). The decision on whether framed wheeled walkers are a restraint must be made on an individual basis.

Side Rails

Side rails sometimes restrain residents. The use of side rails as restraints is prohibited unless they are necessary to treat a resident's medical symptoms *or assist with physical functioning*. Residents who attempt to exit a bed through, between, over or around side rails are at risk of injury or death. The potential for serious injury is more likely from a fall from a bed with raised side rails than from a fall from a bed where side rails are not used. They also potentially increase the likelihood that the resident will spend more time in bed and fall when attempting to transfer from the bed.

As with other restraints, for residents who are restrained by side rails, it is expected that the process facilities employ to reduce the use of side rails as restraints is systematic and gradual to ensure the resident's safety while treating the resident's medical symptom.

The same device may have the effect of restraining one individual but not another, depending on the individual resident's condition and circumstances. For example, partial rails may assist one resident to enter and exit the bed independently while acting as a restraint for another.

Medical Symptom and Restraint Use

Objective findings derived from clinical evaluation and the resident's subjective symptoms should be considered to determine the presence of a medical symptom. The resident's subjective symptoms may not be used as the sole basis for using a restraint. In addition, the resident's medical symptoms should not be viewed in isolation; rather, the symptoms should be viewed in the context of the resident's condition, circumstances, and environment. Before a resident is restrained, the facility must determine the presence of a specific medical symptom that would require the use of restraints, and how *their* use would treat the medical symptom, protect the resident's safety, and assist the resident in attaining or maintaining his or her highest practicable level of physical and psychosocial well-being. This includes the facility's discussion with the resident, (and/or if indicated) their legal surrogate or representative of potential risks and benefits of all options under consideration including using a restraint, not using a restraint, and alternatives to restraint use.

Medical symptoms that warrant the use of restraints must be documented in the resident's medical record, ongoing assessments, and care plans. Surveyors should be aware that physical restraints as an intervention do not treat the underlying causes of medical symptoms and that they should be used temporarily and not be used without also seeking to identify and address the physical or psychosocial condition causing the medical symptom. While there must be a physician's order reflecting the presence of a medical symptom, CMS will hold the facility ultimately accountable for the appropriateness of that determination. The physician's order alone is not sufficient to warrant the use of the restraint. It is further expected, for those residents whose care plans indicate the need for restraints, that the facility engages in a systematic and gradual process toward reducing restraints (e.g., gradually increasing the time for ambulation and muscle strengthening activities). This systematic process would also apply to recently admitted residents for whom restraints were used in the previous setting.

NOTE: *Falls do not constitute self-injurious behavior or a medical symptom that warrants the use of a physical restraint. Although restraints have been traditionally used as a falls prevention approach, they have major, serious drawbacks and can contribute to serious injuries. There is no evidence that the use of physical restraints, including but not limited to side rails, 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).¹*

Orthotic Body Devices

Orthotic body devices may be used solely for therapeutic purposes to improve the overall functional capacity of the resident.

Assessment and Care Planning for Restraint Use

There are instances where, after assessment and care planning, a least restrictive restraint may be deemed appropriate for an individual resident to attain or maintain his or her highest practicable physical and psychosocial well-being. This does not alter the facility's responsibility to assess and care plan restraint use on an ongoing basis.

Before using a device for mobility or transfer, assessment should include a review of the resident's:

- Bed mobility (e.g., would the use of a device assist the resident to turn from side to side? Is the resident totally immobile and unable to change position without assistance?); and
- Ability to transfer between positions, to and from bed or chair, to stand and toilet (e.g., does the raised side rail add risk to the resident's ability to transfer?).

The facility must design its interventions not only to minimize or eliminate the medical symptom, but also to identify and address any underlying problems causing the medical symptom.

- Interventions that the facility might incorporate in care planning include:
 - Providing restorative care to enhance abilities to stand, transfer, and walk safely;
 - Providing a device such as a trapeze to increase a resident's mobility in bed;
 - Placing the bed lower to the floor and surrounding the bed with a soft mat;
 - Equipping the resident with a device that monitors his/her attempts to arise;
 - Providing frequent monitoring by staff with periodic assisted toileting for residents who attempt to arise to use the bathroom;
 - Furnishing visual and verbal reminders to use the call bell for residents who are able to comprehend this information and are able to use the call bell device; and/or
 - Providing exercise and therapeutic interventions, based on individual assessment and care planning, that may assist the resident in achieving proper body position, balance and alignment, without the potential negative effects associated with restraint use.

Procedures: §483.13(a)

Determine if the facility follows a systematic process of evaluation and care planning prior to using restraints. Since continued restraint use is associated with a potential for a decline in

functioning if the risk is not addressed, determine if the interdisciplinary team addressed the risk of decline at the time restraint use was initiated and that the care plan reflected measures to minimize a decline. Also determine if the plan of care was consistently implemented. Determine whether the decline can be attributed to a disease progression or inappropriate use of restraints.

For sampled residents observed as physically restrained during the survey or whose clinical records show the use of physical restraints within 30 days of the survey, determine whether the facility used the restraint for convenience or discipline, or a therapeutic intervention for specific periods to attain and maintain the resident's highest practicable physical, mental, or psychosocial well-being.

Probes: §483.13(a)

This systematic approach should answer these questions:

1. What are the medical symptoms that led to the consideration of the use of restraints?
2. Are these symptoms caused by failure to:
 - a. Meet individual needs in accordance with the resident assessments?
 - b. Use rehabilitative/restorative care?
 - c. Provide meaningful activities?
 - d. Manipulate the resident's environment, including seating?
3. Can the cause(s) of the medical symptoms be eliminated or reduced?
4. If the cause(s) cannot be eliminated or reduced, then has the facility attempted to use alternatives in order to avoid a decline in physical functioning associated with restraint use?
5. If alternatives have been tried and deemed unsuccessful, does the facility use the least restrictive restraint for the least amount of time? Does the facility monitor and adjust care to reduce the potential for negative outcomes while continually trying to find and use less restrictive alternatives?
6. Did the resident or legal surrogate make an informed choice about the use of restraints? Were risks, benefits, and alternatives explained?
7. Does the facility use the Care Area Assessments (CAAs) to evaluate the appropriateness of restraint use?

8. Has the facility re-evaluated the need for the restraint, made efforts to eliminate its use and maintained residents' strength and mobility?

¹ *American Geriatrics Society, British Geriatrics Society, and American Academy of Orthopaedic Surgeons Panel on Falls Prevention. Guideline for the prevention of falls in older persons. Journal of the American Geriatrics Society. 49(5):664-72, 2001 May.*
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F278

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§483.20(g) Accuracy of Assessment

The assessment must accurately reflect the resident's status.

Intent §483.20(g)

To assure that each resident receives an accurate assessment by staff that are qualified to assess relevant care areas and knowledgeable about the resident's status, needs, strengths, and areas of decline.

Interpretive Guidelines §483.20(g)

“The accuracy of the assessment” means that the appropriate, qualified health professional correctly documents the resident's medical, functional, and psychosocial problems and identifies resident strengths to maintain or improve medical status, functional abilities, and psychosocial status. The initial comprehensive assessment provides baseline data for ongoing assessment of resident progress.

Probes §483.20(g)

Based on your total review of the resident, is each portion of the assessment accurate?

§483.20(h) Coordination

A registered nurse must conduct or coordinate each assessment with the appropriate participation of health professionals.

Intent §483.20(h)

The registered nurse will conduct and/or coordinate the assessment, as appropriate. Whether conducted or coordinated by the registered nurse, he or she is responsible for certifying that the assessment has been completed.

Interpretive Guidelines §483.20(h)

According to the Utilization Guidelines for each State's RAI, the physical, mental and psychosocial condition of the resident determines the 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.

Probes §483.20(h)

Have appropriate health professionals assessed the resident? For example, has the resident's nutritional status been assessed by someone who is knowledgeable in nutrition and capable of correctly assessing a resident?

If the resident's medical status, functional abilities, or psychosocial status declined and the decline was not clinically unavoidable, were the appropriate health professionals involved in assessing the resident?

§483.20(i) Certification

(1) A registered nurse must sign and certify that the assessment is completed.

(2) Each individual who completes a portion of the assessment must sign and certify the accuracy of that portion of the assessment.

Interpretive Guidelines §483.20(i)

Whether the MDS assessments are manually completed, or computer generated following data entry, each individual assessor is responsible for certifying the accuracy of responses relative to the resident's condition and discharge or entry status. Manually completed forms are signed and dated by each individual assessor the day they complete their portion(s) of the MDS record.

Electronic Signatures

When MDS forms are completed directly on the facility's computer (e.g., no paper form has been manually completed), then each individual assessor signs and dates a computer generated hard copy, or provides an electronic signature, after they review it for accuracy of the portion(s) they completed.

Facilities may use electronic signatures on the MDS when permitted to do so by state and local law and when this is authorized by the long-term care facility's policy. Additionally, they must have written policies in place to ensure that they have proper security measures to protect use of an electronic signature by anyone other than to which the electronic signature belongs. The policy must also ensure that access to a hard copy of clinical records is made available to surveyors and others who are authorized access to clinical records by law.

Facilities that are not capable of maintaining the MDS signatures electronically must adhere to the current requirements addressing the need for either a hand-written copy or a computer-generated form. All state licensure and state practice regulations continue to apply to certified facilities.

NOTE: *Where state law is more restrictive than federal requirements, the provider needs to apply the state law standard.*

Backdating Completion Dates

Backdating completion dates is not acceptable – note that recording the actual date of completion is not considered backdating. For example, if an MDS was completed electronically and a hard copy was printed two days later, writing the date the MDS was completed on the hard copy is not considered backdating.

Probes §483.20(i)

Are the appropriate certifications in place, including the RN Coordinator’s certification of completion of an assessment or Correction Request, and the certification of individual assessors of the accuracy and completion of the portion(s) of the assessment or tracking record completed or corrected?

§483.20(j) Penalty for Falsification

(1) Under Medicare and Medicaid, an individual who willfully and knowingly--

(i) Certifies a material and false statement in a resident assessment is subject to a civil money penalty of not more than \$1,000 for each assessment; or

(ii) Causes another individual to certify a material and false statement in a resident assessment is subject to a civil money penalty or not more than \$5,000 for each assessment.

(2) Clinical disagreement does not constitute a material and false statement.

Interpretive Guidelines §483.20(j)

MDS information serves as the clinical basis for care planning and delivery. With the introduction of additional uses of MDS information such as for payment rate setting and quality monitoring, MDS information as it is reported impacts a nursing home’s payment rate and standing in terms of the quality monitoring process. A pattern within a nursing home of clinical documentation or of MDS assessment or reporting practices that result in higher RUG scores, untriggering CAA(s), or unflagging QI(s), where the information does not accurately reflect the resident’s status, may be indicative of payment fraud or avoidance of the quality monitoring process. Such practices may include but are not limited to a pattern or high prevalence of the following:

- Submitting MDS Assessments (including any reason(s) for assessment, routine or non-routine) or tracking *records*, where the information does not accurately reflect the resident’s status as of the ARD, or the Discharge or *Entry* date, as applicable;
- Submitting correction(s) to information in the *QIES ASAP system* where the corrected information does not accurately reflect the resident’s status as of the original ARD, or the original Discharge or Entry date, as applicable, or where the record it claims to correct does not appear to have been in error;

- Submitting Significant Correction Assessments where the assessment it claims to correct does not appear to have been in error;
- Submitting Significant Change in Status Assessments where the criteria for significant change in the resident's status do not appear to be met;
- Delaying or withholding MDS Assessments (including any reason(s) for assessment, routine or non-routine), Discharge or Entry Tracking information, or correction(s) to information in the *QIES ASAP system*.

When such patterns or practices are noticed, they should be reported by the State Agency to the proper authority.

F281

(Rev. 127, Issued: 11-26-14, Effective: 11-26-14, Implementation: 11-26-14)

§483.20(k)(3)

(3) The services provided or arranged by the facility must--

(i) Meet professional standards of quality and;

Intent §483.20(k)(3)(i):

The intent of this regulation is to assure that services being provided meet professional standards of quality (in accordance with the definition provided below) and are provided by appropriate qualified persons (e.g., licensed, certified).

Interpretive Guidelines §483.20(k)(3)(i):

“Professional standards of quality” means services that 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 of Health Care Policy and Research.

- Current professional journal articles.

If a 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 be cited under the appropriate quality of care or other relevant requirement.

Probes §483.20(k)(3):

Question only those practices which have a negative outcome or have a potential negative outcome. Ask the facility to produce references upon which the practice is based.

- Do nurses notify physicians, as appropriate, and show evidence of discussions of acute medical problems?
- Are residents with acute conditions who require intensive monitoring and hospital-level treatments that the facility is unable to provide, promptly hospitalized?
- Are there errors in the techniques of medication administration? (Cite actual medication errors at §483.25(m).)
- *Does the staff follow facility policies for assuring each resident has a sufficient supply of medications to meet the needs of residents and does the staff adhere to the facility's system for reordering medications?*
- Is there evidence of assessment and care planning sufficient to meet the needs of newly admitted residents, prior to completion of the first comprehensive assessment and comprehensive care plan?
- Are physicians' orders carried out, unless otherwise indicated by an advanced directive?

F286

(Rev. 127, Issued: 11-26-14, Effective: 11-26-14, Implementation: 11-26-14)

§483.20(d) Use

A facility must maintain all resident assessments completed within the previous 15 months in the resident's active record.

Intent: §483.20(d)

Facilities are required to maintain 15 months of assessment data in the resident's active clinical record.

Interpretive Guidelines §483.20(d)

The requirement to maintain 15 months of data in the resident's active clinical record applies regardless of form of storage to all MDS records, including the CAA Summary, Quarterly Assessment records, Identification Information and Entry, Discharge and Reentry Tracking Records and MDS Correction Requests (including signed attestation). MDS assessments must be kept in the resident's active clinical record for 15 months following the final completion date for all assessments and correction requests. Other assessment types require maintaining them in the resident's active clinical record for 15 months following:

- The entry date for tracking records including re-entry; and
- The date of discharge or death for discharge and death in facility records.

Facilities may maintain MDS data electronically regardless of whether the entire clinical record is maintained electronically and regardless of whether the facility has an electronic signature process in place. *This is in accordance with state and local law, and when this is authorized by the long-term care facility's policy.*

Facilities that maintain their MDS data electronically and do not utilize an electronic signature process must ensure that hard copies of the MDS assessment signature pages are maintained for every MDS assessment conducted in the resident's active clinical record for 15 months. (This includes enough information to identify the resident and type and date of assessment linked with the particular assessment's signature pages),

The information, regardless of form of storage (i.e., hard copy or electronic), must be kept in a centralized location and must be readily and easily accessible. This information must be available to all professional staff members (including consultants) who need to review the information in order to provide care to the resident. (This information must also be made readily and easily accessible for review by the State Survey agency and CMS.)

After the 15-month period, RAI information may be thinned from the clinical record and stored in the medical records department, provided that it is easily retrievable if requested by clinical staff, the State agency, or CMS.

F309

(Rev. 127, Issued: 11-26-14, Effective: 11-26-14, Implementation: 11-26-14)

§483.25 Quality of Care

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, in accordance with the comprehensive assessment and plan of care.

Intent: §483.25

The facility must ensure that the resident obtains optimal improvement or does not deteriorate within the limits of a resident's right to refuse treatment, and within the limits of recognized pathology and the normal aging process.

NOTE: Use guidance at F309 for review of quality of care not specifically covered by 42 CFR 483.25 (a)-(m). Tag F309 includes, but is not limited to, care such as *care of a resident with dementia*, end-of-life, diabetes, renal disease, fractures, congestive heart failure, non-pressure related skin ulcers, pain, and fecal impaction.

Review of Care and Services for a Resident with Dementia

Use this guidance for a resident with dementia. If the resident is receiving one or more psychopharmacological agents, also review the guidance at F329, Unnecessary Drugs.

There is no specific investigative protocol for care of a resident with dementia. For the traditional survey, the surveyor may use the surveyor checklist titled, “Review of Care and Services for a Resident with Dementia” to assist in investigating the care and services provided to a resident with a diagnosis of dementia. For the QIS survey, the surveyor will use the general CE pathway and may use the checklist as a guide to completing that pathway.

Definitions Related to Recognition and Management of Dementia

- *Behavioral interventions are individualized approaches (including direct care and activities) that are provided as part of a supportive physical and psychosocial environment, and are directed toward understanding, preventing, relieving, and/or accommodating a resident’s distress or loss of abilities.*
- *Person-Centered or Person-Appropriate Care is care that is individualized by being tailored to all relevant considerations for that individual, including physical, functional, and psychosocial aspects. For example, activities should be relevant to the specific needs, interests, culture, background, etc. of the individual for whom they are developed and medical treatment should be tailored to an individual’s risk factors, current conditions, past history, and details of any present symptoms.*
- *Behavioral or Psychological Symptoms of Dementia (BPSD) is a term used to describe behavior or other symptoms in individuals with dementia that cannot be attributed to a specific medical or psychiatric cause. The term “behaviors” is more general and may encompass BPSD or responses by individuals to a situation, the environment or efforts to communicate an unmet need.*

Overview of Dementia and Behavioral Health

What is Behavior?

Human behavior is the response of an individual to a wide variety of factors. Behavior is generated through brain function, which is in turn influenced by input from the rest of the body. Specific behavioral responses depends on many factors, including personal experience and past learning, inborn tendencies and genetic traits, the environment and response to the actions and reactions of other people. A condition (such as dementia) that affects the brain and the body may affect behavior.

What is Dementia?

Dementia is not a specific disease. It is a descriptive term for a collection of symptoms that can be caused by a number of disorders that affect the brain. People with dementia have significantly impaired intellectual functioning that interferes with normal activities and relationships. They also lose their ability to solve problems and maintain emotional control, and they may experience personality changes and behavioral problems, such as agitation, delusions, and hallucinations. While memory loss is a common symptom of dementia, memory loss by itself does not mean that a person has dementia. Doctors diagnose dementia only if two or more brain functions - such as memory and language skills -- are significantly impaired without loss of consciousness.

Some of the diseases that can cause symptoms of dementia are Alzheimer's disease, vascular dementia, Lewy body dementia, fronto-temporal dementia, Huntington's disease, and Creutzfeldt-Jakob disease. Doctors have identified other conditions that can cause dementia or dementia-like symptoms including reactions to medications, metabolic problems and endocrine abnormalities, nutritional deficiencies, infections, poisoning, brain tumors, anoxia or hypoxia (conditions in which the brain's oxygen supply is either reduced or cut off entirely), and heart and lung problems. Although it is common in very elderly individuals, dementia is not a normal part of the aging process.

Some individuals with dementia may have coexisting symptoms or psychiatric conditions such as depression or bipolar affective disorder, paranoia, delusions or hallucinations. Progressive dementia may exacerbate these and other symptoms.

Behavioral or psychological symptoms are often related to the brain disease in dementia; however behavior and other symptoms may also be caused or exacerbated by environmental triggers. Behavior often represents a person's attempt to communicate an unmet need, discomfort or thoughts that they can no longer articulate. Knowing detailed cultural, medical and psychosocial information about a person can help caregivers identify potential environmental or other triggers in order to prevent or reduce, to the extent possible, behavior or other expressions of distress.² Because behavioral symptoms may be caused by medical conditions such as delirium, medication side effects, and psychiatric symptoms such as delusions or hallucinations, these should be considered as possible causes in addition to environmental triggers.

What is Delirium?

A resident may have undiagnosed delirium, which is an acute confusional state that includes symptoms very similar to those of dementia and psychiatric disorders. The diagnostic criteria for delirium include a fluctuating course throughout the day, inattention as evidenced by being easily distracted, cognitive changes, and perceptual disturbances³.

Delirium develops rapidly over a short time period, such as hours or days, and is associated with an altered level of consciousness. Delirium has an underlying physiologic cause that can generally be identified through a diagnostic evaluation. Potential causes include, but are not

limited to, infection, fluid/electrolyte imbalance, medication, or multiple factors. Specific diagnostic criteria are outlined in the DSM IV-TR or the Confusion Assessment Method^{3,4}.

Classic delirium is often characterized as hyperactive (e.g., extreme restlessness, climbing out of bed); but more commonly delirium is hypoactive often leading to the misdiagnosis of dementia or a psychiatric disorder. 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.

Delirium and dementia are now recognized as being related. Individuals with dementia are at higher risk for developing delirium and it now appears that delirium increases the risk of developing dementia over time⁵. Recognizing delirium is critical, as failure to act quickly to identify and treat the underlying causes may result in poor health outcomes, hospitalization or even death⁶.

Therapeutic Interventions or Approaches

The use of any approach must be based on a careful, detailed assessment of physical, psychological and behavioral symptoms and underlying causes as well as potential situational or environmental reasons for the behaviors. Caregivers and practitioners are expected to understand or explain the rationale for interventions/approaches, to monitor the effectiveness of those interventions/approaches, and to provide ongoing assessment as to whether they are improving or stabilizing the resident's status or causing adverse consequences. Describing the details and possible consequences of resident behaviors helps to distinguish expressions such as restlessness or continual verbalization from potentially harmful actions such as kicking, biting or striking out at others. This description alone does not suggest that a specific intervention is or is not indicated; however, it is important information that may assist the care team (including the resident and/or family or representative) in decision-making and in matching selected interventions to the individual needs of each resident.

Identifying the frequency, intensity, duration and impact of behaviors, as well as the location, surroundings or situation in which they occur may help staff and practitioners identify individualized interventions or approaches to prevent or address the behaviors. Individualized, person-centered interventions must be implemented to address behavioral expressions of distress in persons with dementia. In many situations, medications may not be necessary; staff/practitioners should not automatically assume that medications are an appropriate treatment without a systematic evaluation of the resident. Examples of techniques or environmental modifications that may prevent certain behavior related to dementia may include (but are not limited to):

- Arranging staffing to optimize familiarity with the resident (e.g., consistent caregiver assignment);*
- Identifying, to the extent possible, factors that may underlie the resident's expressions of distress, as well as applying knowledge of lifelong patterns, preferences, and interests for daily activities to enhance quality of life and individualize routine care.*

- *Understanding that the resident with dementia may be responding predictably given the situation or surroundings. For example, being awakened at night in his/her bedroom by staff and not recognizing the staff could elicit an aggressive response; and*
- *Matching activities for a resident with dementia to his/her individual cognitive and other abilities and the specific behaviors in that individual based on the assessment.*

Medication Use in Dementia (see also F329)

It has been a common practice to use various types of psychopharmacological medications in nursing homes to try to address behavioral or psychological symptoms of dementia (BPSD)^{7,8} without first determining whether there is an underlying medical, physical, functional, psychosocial, emotional, psychiatric, or environmental cause of the behaviors. Medications may be effective when they are used appropriately to address significant, specific underlying medical and psychiatric causes or new or worsening behavioral symptoms. However, medications may be ineffective and are likely to cause harm when given without a clinical indication, at too high a dose or for too long after symptoms have resolved and if the medications are not monitored. All interventions including medications need to be monitored for efficacy, risks, benefits and harm.

These agents must only be used if the steps in the care process below and as outlined in F329 have been followed.

When antipsychotic medications are used without an adequate rationale, or for the sole purpose of limiting or controlling behavior of an unidentified cause, there is little chance that they will be effective, and they commonly cause complications such as movement disorders, falls, hip fractures, cerebrovascular adverse events (cerebrovascular accidents and transient ischemic events) and increased risk of death.^{9,10,11,12} The FDA Black Box Warning Regarding Atypical Antipsychotics in Dementia states, “Elderly patients with dementia-related psychosis treated with atypical antipsychotic drugs are at an increased risk of death compared to placebo.” The FDA issued a similar Black Box Warning for conventional antipsychotic drugs. (Additional information on the FDA black box warning is available at <http://www.fda.gov/Drugs/default.htm>.)

Recent studies suggest that certain antipsychotic medications may have greater risks than others in that same class of medications.^{13,14} Other classes of psychopharmacological agents may carry significant risks as well.

NOTE: *If a concern is identified during a survey that an antipsychotic medication may potentially be administered for discipline, convenience and/or is not being used to treat a medical symptom, consider reviewing F222 - 483.3(a) Restraints, for the right to be free from any chemical restraints.*

Resident and/or Family/Representative Involvement:

CMS expects that the resident and family/representatives, to the extent possible, are involved in helping staff to understand the potential underlying causes of behavioral distress and to participate in the development and implementation of the resident’s care plan. Residents have

the right to be informed about their medical condition, care and treatment; they have the right to refuse treatment and the right to participate in the care plan process. (See F154, F155, F242, F279, F280)

Facilities should be able to identify how they have involved residents/families/representatives in discussions about potential approaches to address behaviors and about the potential risks and benefits of a psychopharmacological medication (e.g., FDA black box warnings), the proposed course of treatment, expected duration of use of the medication, use of individualized approaches, plans to evaluate the effects of the treatment, and pertinent alternatives. The discussion should be documented in the resident's record. (See F154)

NOTE: *some states have specific laws/licensing rules regarding the provision of informed consent. The State Agency determines and directs the surveyors regarding the review for those provisions under their State licensing authority. If non-compliance with the State regulation is identified, the surveyors may only cite this non-compliance at F492 when the Federal, State or local authority having jurisdiction has both made a determination of non-compliance AND has taken a final adverse action.*

The facility should document attempts to include the family/representative, to the extent possible, in the decision-making process. If the family/representative is unable to participate in person, were further attempts made to include the family/representative in the discussions/development of the care planning through alternative methods, such as by phone or electronic methods?

If the resident lacks decision-making capacity and lacks an effective family/representative support, contact the facility social worker to determine what type of social services or referrals have been attempted to assist the resident. (See F250)

During interviews with the family/representative, surveyors should ask if families have observed staff implementing the individualized care plan interventions that were developed. (See F282)

Care Process for a Resident with Dementia

Fundamental principles of care for persons with dementia include an interdisciplinary team approach that focuses holistically on the needs of the resident as well as the needs of the other residents in the nursing home. It is important for the facility to have systems and procedures in place to assure that assessments are timely and accurate; interventions are described, consistently implemented, monitored, and revised as appropriate in accordance with current standards of practice.

It is expected that a facility's approach to care for a resident with dementia follows a systematic care process in order to gather and analyze information necessary to provide appropriate care and services, and that the resident and/or family or representative is engaged throughout the process. It is expected that the resident's record reflects the implementation of the following care processes:

A. Recognition and Assessment;

- B. Cause Identification and Diagnosis;*
- C. Development of Care Plan;*
- D. Individualized Approaches and Treatment;*
- E. Monitoring, Follow-up and Oversight; and*
- F. Quality Assessment and Assurance (QAA).*

See Additional Resources section below for some suggested resources that facilities may consult in developing their dementia care policies.

The following guidance aggregates requirements in a number of other F-tags such as comprehensive assessment, activities, resident rights, unnecessary medications and others, bringing that guidance together into a framework for evaluating care of individuals with dementia.

A. Recognition and Assessment:

This step includes collecting detailed information about a resident. The resident's record should reflect comprehensive information about the person including, but not limited to: past life experiences, description of behaviors, preferences such as those for daily routines, food, music, exercise and others; oral health, presence of pain, medical conditions; cognitive status and related abilities and medications. When reviewing the comprehensive assessment (see F272), the Care Area Assessment (CAA) Resources, particularly those related to Activities and Behavioral Symptoms, found in the Long-Term Care Facility Resident Assessment Instrument User's Manual, Version 3.0 may be helpful.

It is important to determine whether the record reflects the evaluation of, but is not limited to:

- How the resident typically communicates physical needs such as pain, discomfort, hunger or thirst, as well as emotional and psychological needs such as frustration or boredom; or a desire to do or express something that he/she cannot articulate;*
- The resident's usual and current cognitive patterns, mood and behavior, and whether these present a risk to the resident or others;*
- How the resident typically displays personal distress such as anxiety or fatigue.*

This and other information enables an understanding of the individual and provides a basis for cause identification (based on knowing the whole person and how the situation and environment may trigger behaviors) and individualized interventions. If the resident expresses distress, staff should specifically describe the behavior (including potential underlying causes, onset, duration, intensity, precipitating events or environmental triggers, etc.) and related factors (such as appearance and alertness) in the medical record with enough detail of the actual situation to

permit cause identification and individualized interventions. (See F54) For example, noting that the resident is generally “violent,” “agitated” or “aggressive” does not identify the specific behavior exhibited by the resident. Noting instead that the resident responds in crowded, busy group activities by yelling or throwing furniture reflects not only a potential safety issue but should result in the resident being provided alternative activities to meet his/her needs.

B. Cause Identification and Diagnosis:

This step uses the information collected about an individual to help identify the physical, functional, psychosocial, environmental, and other potential causes of behavior and related symptoms, including how they interact with each other. Staff, in collaboration with the practitioner, should identify possible risk and causal/contributing factors for behaviors, such as:

- Presence of co-existing medical or psychiatric conditions, including acute/chronic pain, constipation, delirium and others, or worsening of mental function; and/or*
- Adverse consequences related to the resident’s current medications. (See F329)*

Staff must make an ongoing effort to identify and document the new onset or worsening behavioral symptoms, including whether or not the behavior presents a significant risk for adverse consequences to the resident and/or others.

The attending physician is responsible for supervising each resident’s medical care. In addition, the facility must immediately consult with the resident’s physician when there is a significant change in the resident’s physical, mental, or psychosocial status. (See F157) If the behaviors observed represent a change or worsening from the baseline, the attending physician/practitioner and staff are expected to consider potential underlying medical, physical, psychosocial, or environmental causes of the behaviors (See F385). If the resident has experienced two or more areas of decline or improvement, including a change related to behavior, a Significant Change in Clinical Status Assessment (SCSA) should be considered (see F274).

If medical causes are ruled out, the facility should attempt to establish other root causes of behavior using individualized, holistic knowledge about the person and when possible, information from the resident, family or previous caregivers, and direct care staff. This includes conducting a systematic analysis and consideration of possible causes, including but not limited to:

- Boredom; lack of meaningful activity or stimulation during customary routines and activities;*
- Anxiety related to changes in routines such as shift changes, unfamiliar or different caregivers, change of (or relationship with) roommate, inability to communicate;*
- Care routines (such as bathing) that are inconsistent with a person’s preferences;*

- *Personal needs not being met appropriately or sufficiently, such as hunger, thirst, constipation;*
- *Fatigue, lack of sleep or change in sleep patterns which may make the person more likely to misinterpret environmental cues resulting in anxiety, aggression or confusion.*
- *Environmental factors, for example noise levels that could be causing or contributing to discomfort or misinterpretation of noises such as over-head pages, alarms, etc. causing delusions and/or hallucinations.*
- *Mismatch between the activities or routines selected and the resident's cognitive and other abilities to participate in those activities/routines. For example, a resident who has progressed from mid to later stages of dementia may become frustrated and upset if he/she is trying but unable to do things that she previously enjoyed, or unable to perform tasks such as dressing or grooming.*

C. Development of Care Plan:

This step identifies the approaches, interventions, therapies, medications, etc. for a specific resident. The care plan should include a well-defined problem-statement and should outline the goals of care. It should include measurable objectives and timetables for individualized interventions. It should also identify the responsibilities of various staff to implement the approaches effectively. The care plan should reflect:

- *Baseline and ongoing details (e.g., frequency, intensity, and duration) of common behavioral expressions and expected response to interventions (See F279);*
- *Specific goals for and monitoring of all interventions for effectiveness in responding to target behaviors/expressions of distress (See F279); and*
- *For any medications, indication/rationale for use, specific target behaviors and expected outcomes, dosage, duration, monitoring for efficacy and/or adverse consequences and (when applicable) plans for gradual dose reduction (GDR) if an antipsychotic medication is used (See F329).*

In developing the plan of care, the interdisciplinary team, in collaboration with the resident or family/representative, reviews the results of the assessment and cause identification above in order to develop individualized, person-centered interventions. Staff should determine, in collaboration with the practitioner, resident, and family/resident representative if and why behaviors should be addressed (e.g., severely distressing to resident and unrelieved by other approaches or interventions). Individualized, person-centered approaches should be implemented to address expressions of distress. These may include:

- *Non-pharmacological approaches. Section 483.25 (l)(2)(ii) - F329, requires that "Residents who use antipsychotic drugs receive gradual dose reductions and*

behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs.”

The guidance at F248, §483.15(f)(1), Activities, provides examples of non-pharmacological approaches for several types of distressed behavior such as constant walking, yelling, going through others’ belongings, etc. Certain behavior may be anticipated and sometimes may be preventable based on understanding the underlying causes and possible triggers for each individual.

Current published clinical guidelines^{5,6,7,8,9} recommend use of non-pharmacological interventions for BPSD.

Utilizing a consistent process to address behaviors that focuses on the resident’s individual needs and tries to understand their behaviors as a form of communication may help to reduce behavioral expressions of distress in those residents.

Several techniques are also outlined in the CMS DVD series for nursing assistant training, “Hand in Hand,” distributed to all U.S. nursing homes in 2012, and other materials available on the Advancing Excellence website: <http://www.nhqualitycampaign.org>.

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

- *Pharmacological interventions: In certain cases, residents may benefit from the use of medications. For example, a person who has a persistent, frightening delusion that she has left her children unattended and that they are in danger is inconsolable most of the day or night despite a number of staff and family approaches to address this fear. If other potential causes are ruled out, the team may determine that a trial of a low dose antipsychotic medication is warranted.*

If a psychopharmacologic medication is initiated or continued, review the guidance at F329, and interview staff about:

- *What was the person trying to communicate through their behavior;*
- *What were the possible reasons for the person’s behavior that led to the initiation of the medication;*
- *What other approaches and interventions were attempted prior to the use of the antipsychotic medication;*
- *Was the family or representative contacted prior to initiating the medication;*

- *Was the medication clinically indicated and/or necessary to treat a specific condition and target symptoms as diagnosed and documented in the record;*
- *Was the medication adjusted to the lowest possible dosage to achieve the desired therapeutic effects;*
- *Were gradual dose reductions planned and behavioral interventions, unless clinically contraindicated, provided in an effort to discontinue the medication;*
- *Was the interdisciplinary team, including the primary care practitioner, involved in the care planning process; and*
- *How does the staff monitor for the effectiveness and possible adverse consequences of the medication.*

If the resident experienced a decline in function, an increased or worsening behavior, or less than anticipated level of improvement in response to interventions, or refused or resisted the interventions, the care plan approaches should be reviewed and revised/updated as appropriate. (See F280)

D. Individualized Approaches and Treatment:

This step implements the care plan interventions to address the needs of a resident with dementia. It includes addressing the causes and consequences of the resident's behavior and staff communication and interactions with residents and families to try to prevent potentially distressing behaviors or symptoms. It is important to conduct sufficient observations in order to determine if the care plan is being implemented as written. Observations should focus on whether staff:

- *Identify and document specific target behaviors, expressions of distress and desired outcomes (See F279 and F514); and*
- *Implement appropriate, individualized, person-centered interventions and document the results (See F240, F309, F329 and F514);*
- *Communicate and consistently implement the care plan, over time and across various shifts (See F282 and F498).*

Staffing and Staff Training

During observations, determine whether there are sufficient numbers of staff to consistently implement the care plan. (See F353) The nursing home must provide staff, both in terms of quantity (direct care as well as supervisory staff) and quality to meet the needs of the residents as determined by resident assessments and individual plans of care. The facility must strive to staff in a way that optimizes familiarity with residents. The principles for quality include, but are not limited to, the facility ensuring that nursing assistants are able to demonstrate competency in skills and techniques necessary to care for residents' needs as identified through resident assessments, and as described in the plan of care. (See F498) Surveyors should focus on

observations of staff interactions with residents who have dementia to determine whether staff consistently applies basic principles for quality in the provision of care.

Nursing assistants must receive a performance review at least once every 2 months and receive regular in-service education based on the outcome of the reviews. (See F497) In addition, the facility must provide training in care of individuals with dementia and related behaviors to nursing assistants when initially hired and annually thereafter.

Research on caregivers of people with dementia suggests that caregiver stress can have a significant impact on outcomes and behavioral expressions of distress in the individual with dementia. This may be true for family, community or institutional caregivers. Some facilities may have systems in place to assist their staff in identifying, addressing and supporting staff who may exhibit “caregiver stress.” See the Additional Resources section here for an example of tools to assess caregiver stress.

Involvement of the Medical Team

During observations and record review, if potential medical causes of behavior or other symptoms (such as those indicating possible delirium or infection) were identified, determine whether the attending physician was contacted promptly and a workup and/or treatment were initiated. (See F157 and F385) Residents who exhibit new or worsening BPSD should have an evaluation by the interdisciplinary team, including the physician and knowledgeable staff, in order to identify and address, to the extent possible, treatable medical, physical, emotional, psychiatric, psychological, functional, social, and environmental factors that may be contributing to behaviors, in order to develop a comprehensive plan of care to address expressions of distress. If a medication(s) was ordered, determine if the staff and practitioner identified and the medical record reflected documentation of the appropriate indication(s) for use. (See F329, Table 1 and F428) For a resident who is receiving any type of psychopharmacologic medication, staff must attempt non-pharmacological interventions, unless clinically contraindicated. (See F329 and F428)

None of the guidance to surveyors should be construed as evaluating the practice of medicine. Surveyors are instructed to evaluate the process of care, including the communication among the prescriber/practitioner, pharmacist, interdisciplinary team, resident or family/representative, and the review of the nursing home practice to prevent unnecessary use of psychopharmacological medications and to closely monitor those medications when they are used. Interviews with the attending physician or other primary care provider (e.g., NP, PA, CNS), medical director, behavioral health specialist and other team members help clarify the reasons for using a psychopharmacological medication or any other interventions for a specific resident. In addition, interviewing the medical director with regard to policies and procedures for behavioral health and psychopharmacological medication use is strongly encouraged.

F. Monitoring and Follow-up:

It is important that surveyors evaluate whether or not a facility used the steps identified above to develop the plan of care. To meet requirements related to monitoring and follow-up of care plan implementation, surveyors evaluate whether or not the interdisciplinary team reviewed a resident’s progress towards defined goals, adjusted interventions as needed, and identified when

care objectives were met. Monitoring and follow-up of care plan implementation includes, but is not limited to, the following:

- Staff monitors and documents (See F514) the implementation of the care plan, identifies effectiveness of interventions relative to target behaviors and/or psychological symptoms and changes in a resident's level of distress or emergence of adverse consequences.*
- In collaboration with the practitioner, staff adjusts the interventions based on the effectiveness and/or adverse consequences related to treatment. (See F280, F329, F428)*
- If concerns are identified related to the effectiveness or potential or actual adverse consequences of a resident's medication regimen, staff must notify the physician and the physician must respond and, as necessary, initiate a change to the resident's care. (F157, F385, F428)*
- If the physician does not provide a timely and appropriate response to the notification, staff must contact the medical director for further review, and if the medical director was contacted, he/she must respond and intervene as needed. (See F501)*

G. Quality Assessment and Assurance (QAA):

NOTE: *Refer to F520 Quality Assessment and Assurance for guidance regarding information that is obtainable from the QAA committee.*

This guidance addresses the evaluation of a facility's systemic approaches to deliver care and services for a resident with dementia. The medical director and the quality assessment and assurance committee can help the facility evaluate existing strategies for coordinating the care of a resident with dementia and ensure that facility policies and procedures are consistent with current standards of practice.

During interviews with the staff responsible for the QAA functions, determine whether the QAA committee has identified and corrected, as indicated, any quality deficiencies related to the care of residents with dementia. In addition, determine whether the QAA committee has monitored and overseen the following areas related to dementia care:

- Whether resident care policies reflect the facility's overall approach to the care of residents with dementia including a clearly outlined process for their care (see also F501);*
- How the facility monitors whether staff follow related policies and procedures in choosing and implementing individualized interventions for the care of each resident with dementia;*
- Whether the facility has trained staff (such as nursing, dietary, therapy or rehabilitation staff, social workers) in how to communicate with and address behaviors in residents with dementia and were the trainings evaluated for*

effectiveness, including initial and annual dementia care training for CNAs (See F495 and F497);

- Whether there is sufficient staff to implement the care plan for residents with dementia, so that medication is not used instead of pertinent non-pharmacological interventions, unless clinically contraindicated (See F353 and F222);*
- Whether staff collect and analyze data to monitor the pharmacological and non-pharmacological interventions used to care for residents with dementia; and*
- How the committee helps the facility monitor responses to the issues and concerns identified through the consultant pharmacist medication regimen review. (See F329 and F428)*

Criteria for Compliance (F309)

Compliance at F309, care for persons with dementia, is based upon a set of key principles. For a resident with dementia, the facility is in compliance with F309, care for persons with dementia, if they:

- 1. Obtained details about the person's behaviors (nature, frequency, severity, and duration) and risks of those behaviors, and discussed potential underlying causes with the care team and (to the extent possible) resident, family or representative;*
- 2. Excluded potentially remediable (medical, medication-related, psychiatric, physical, functional, psychosocial, emotional, environmental) causes of behaviors and determined if symptoms were severe, distressing or risky enough to adversely affect the safety of residents;*
- 3. Implemented environmental and other approaches in an attempt to understand and address behavior as a form of communication and modified the environment and daily routines to meet the person's needs;*
- 4. Implemented the care plan consistently and communicated across shifts and among caregivers and with the resident or family/representative (to the extent possible); and*
- 5. Assessed the effects of the approaches, identified benefits and complications in a timely fashion, involved the attending physician and medical director as appropriate, and adjusted treatment accordingly.*

If not, cite F309.

(For residents with dementia for whom antipsychotic or other medications were prescribed, surveyors must also assess for compliance using guidance at F329, Unnecessary Medications).

DEFICIENCY CATEGORIZATION (Part IV, Appendix P)

Once the team has completed its investigation, analyzed the data, reviewed the regulatory requirements, and *identified any deficient practice(s)* that *demonstrate* that noncompliance *with the regulation at F309* exists, the team must determine the severity of each deficiency, based on the *resultant* harm or potential for harm to the resident. *(Note: some of the examples here involving residents with dementia who receive an antipsychotic medication may also be cited at F329. Surveyors should evaluate compliance at each tag separately).*

Severity Level 4 Considerations: Immediate Jeopardy to Resident Health or Safety

Immediate Jeopardy is a situation in which the facility's noncompliance with one or more requirements of participation:

- Has allowed, caused, or resulted in, or is likely to allow, cause, or result in serious injury, harm, impairment, or death to a resident; and
- Requires immediate correction, as the facility either created the situation or allowed the situation to continue by failing to implement preventative or corrective measures.

NOTE: If immediate jeopardy has been ruled out based upon the evidence, then evaluate whether actual harm that is not immediate jeopardy exists at Severity Level 3.

Severity Level 3 Considerations: Actual Harm that is **Not** Immediate Jeopardy

Level 3 indicates noncompliance that resulted in actual harm, and may include, but is not limited to, clinical compromise, decline, or the resident's inability to maintain and/or reach his/her highest practicable well-being.

NOTE: If Severity Level 3 (actual harm that is not immediate jeopardy) has been ruled out based upon the evidence, then evaluate as to whether Severity Level 2 (no actual harm with the potential for more than minimal harm) exists.

Severity Level 2 Considerations: No Actual Harm with Potential for More Than Minimal Harm that is Not Immediate Jeopardy

Level 2 indicates noncompliance that results in a resident outcome of no more than minimal discomfort and/or has the potential to compromise the resident's ability to maintain or reach his or her highest practicable level of well-being. The potential exists for greater harm to occur if interventions are not provided.

The following examples illustrate the differences among compliance and non-compliance at levels 4, 3 and 2 for F309 Review of a Resident with Dementia. This is only one example; surveyors must investigate each case as the specific situation will vary and may lead to different conclusions based on the evidence.

F309 – Review of a Resident with Dementia – Compliance Example

A resident with dementia was admitted after hospitalization for a hip fracture she sustained while showering at home. The social worker's note, the nurses' notes and the care plan all included information from the family: they had reported on admission that the resident was now very fearful of showers. The RAI indicated choosing the method she was bathed was "very important" and the resident's daughter stated she preferred sponge baths due to her fear of showers. The interventions in the care plan were implemented consistently across all shifts and levels of staff. The nurses and social workers documented ongoing discussions with family and reassessments to ensure the resident's needs were being met and that no new issues had been identified. The criteria for compliance were met.

F309 – Review of a Resident with Dementia - Level 4 Severity Non-compliance Example

A resident with dementia was admitted after hospitalization for a hip fracture she sustained while showering at home. The social worker's note, the nurses' notes and the care plan all included information from the family: they had reported on admission that the resident was now very fearful of showers. The RAI indicated choosing the method the resident was bathed was "very important" and her daughter stated she preferred sponge baths due to her fear of showers.

In addition to the basic facts noted above in the level 4 severity non-compliance example:

- The surveyor observed an occurrence of bathing for the resident described above during the survey. The resident displayed substantial distress and fearfulness, calling out "help me," crying, striking out and grabbing at the staff, and made repeated attempts to get out of the shower chair.*
- The staff member present called for a second staff member to help her complete the shower. Despite the resident's cries for help, no other staff members intervened or attempted to determine whether or not her distress warranted a different approach to the bathing routine/schedule.*
- Significant psychological distress was noted during the bathing and for the remainder of the day and was documented in the nurse's notes.*
- The surveyor observed that no other staff members intervened to assess the resident's situation or consult the care plan during or after the bathing.*
- The surveyor interviewed direct care staff and nurses on the unit. One licensed nurse stated, "That resident always yells out during her shower" and attributed this to her dementia. Neither CNA interviewed was aware that the resident had sustained a hip fracture during a shower prior to admission.*
- The resident's fear of bathing was noted in the care plan; however during interviews/observations, direct care staff could not articulate this information about the resident.*

- *The staff admitted they had not considered alternative routines/approaches for bathing this resident, despite the fact that the family had reported the resident's fear of showers and despite repeated episodes of distress.*
- *In addition to the staff being unaware of the resident's fear of showers, they also failed to investigate for other causes of the behavior.*
- *Upon further investigation related to quality assurance, there was no evidence that a physician attends QA&A meetings regularly.*
- *In reviewing staff training records, it appears that nursing assistants have not received training on how to care for residents with dementia.*

What is the evidence for non-compliance?

- *Resident exhibits adverse reaction to showers with verbal distress, combative behavior, and continuous struggling to get out of the chair.*
- *Facility failed to consider and rule out possible causes such as pain related to hip fracture while sitting in a shower chair or possible discomfort with the approach being used to bathe. Facility also failed to recognize the risk of a fall or injury due to combative behavior that required two staff members.*
- *Facility failed to develop and attempt alternate interventions.*
- *No staff member intervened despite the staff member present calling for help and hearing resident's cries for help and her obvious distress.*
- *Facility failed to develop a care plan intervention related to trying to reduce or eliminate extreme reactions to showers;*
- *Staff had appropriate care plan but failed to communicate across shifts and caregivers; and/or*
- *Facility failed to assess the effects of the interventions and try to modify interventions based on those assessments.*

Why is this Immediate Jeopardy?

See Decision-Making Grid with Components of Immediate Jeopardy below. Based on the severity of the resident's reaction, there was evidence that the resident experienced actual psychological harm. In addition, there was immediacy since the repeated attempts at showering the resident resulted in resident-to-staff altercations and placed her at risk for serious physical harm.

Furthermore, there was no evidence of physician participation in the QA&A committee and no evidence that nurse aides received required training in caring for and communicating with residents with dementia. This suggests a lack of effective systems and processes for the assessment and treatment of a resident with dementia. If so, these systems failures place this and potentially other residents with dementia at risk for serious harm. The facility is culpable for a deficient practice that must be addressed immediately in order to prevent further harm to this

and other residents (surveyors may wish to consider whether or not there is a need to expand the sample).

Components of Immediate Jeopardy

Harm	
a. Actual - Was there an outcome of harm? Does the harm meet the definition of Immediate Jeopardy, e.g., has the provider's noncompliance caused serious injury, harm, impairment, or death to an individual?	Yes. Repeated, extreme reaction to attempts to bathe with visible anguish, crying and yelling out reflects actual psychological harm with no attempts to alter the care plan.
b. Potential – Is there a likelihood of potential harm? Does the potential harm meet the definition of Immediate Jeopardy; e.g., is the provider's noncompliance likely to cause serious injury, harm, impairment, or death to an individual?	Yes. Repeated risk of a serious fall on an already injured or vulnerable area due to the struggle related to attempted showering.
Immediacy	
Is the harm or potential harm likely to occur in the very near future to this individual or others in the entity, if immediate action is not taken?	Yes. Potential for subsequent harm (a fall or other injury, psychological harm) exists as the facility did not attempt to identify causes or modify alternate interventions related to showers. Other residents with dementia may also be at risk, as staff had not received training in caring for individuals with dementia including how to understand the communication efforts of residents with dementia. There was no evidence of physician participation with the QA&A committee.
Culpability	
Did the facility know about the situation? If so when did the facility first become aware?	Yes, it had happened repeatedly and the social worker and nurses had been informed on admission of the resident's fear and preferences. While the information was in the care plan, the team had not passed the information along to the direct care staff and staff did not review the care plan. Staff did not intervene during these episodes despite the resident's cries for help. These behaviors were attributed to her dementia and were not considered remediable.
Should the facility have known about the situation?	Yes. There were recurrent episodes and the family had reported similar behavior at home related to showers.

A resident with dementia was admitted after hospitalization for a hip fracture she sustained while showering at home. The social services note, the nurses' notes and the care plan all included information from the family: they had reported on admission that the resident was now very fearful of showers. The RAI indicated choosing the method she was bathed was "very important" and her daughter stated she preferred sponge baths due to her fear of showers.

In addition to the basic facts noted above in the level 3 severity non-compliance example:

- The information about the resident's fear of bathing was in the care plan; however during interviews/observations, direct care staff could not articulate this information.*
- The surveyor determined that the resident was taken to the shower room three times in the three weeks since admission. Staff interviews revealed that each time the staff attempted to provide her with a shower, the resident immediately started to call out, "help me, help me." With each of the three attempts, the shower was stopped, the staff member documented "shower was refused" and the resident was given a sponge bath instead. On those days, the resident was noted to be anxious and fretful, wringing her hands and crying on and off for the rest of the day. These behaviors are not noted on other days.*
- No further investigation occurred after each incident. Neither the physician nor the family was involved in discussions regarding the resident's response to the shower and no change in the plan of care was evident after the attempts to shower the resident.*

Why is this Level 3 Severity?

There is evidence of actual psychosocial harm to this resident, with no attempts by the facility to identify the underlying cause of her expressions of distress. However this case does not meet the criteria for immediacy, since the staff did not attempt to actually place the resident into the shower once she started to resist. While staff failed to rule out underlying causes of the resident's behavior, they did provide an alternative when the resident resisted.

F309 – Review of a Resident with Dementia - Level 2 Severity Non-compliance Example

A resident with dementia was admitted after hospitalization for a hip fracture she sustained while showering at home. It was documented in the social service and nurses' notes that the family had reported on admission that the resident was now very fearful of showers and preferred sponge baths. However, this information was not communicated to other staff nor was it incorporated into the care plan. The care plan stated that the resident would receive weekly showers.

In addition to the basic facts noted above in the level 2 severity example:

- The resident's daughter insisted on bathing her mother herself for a period of time after admission, and provided sponge baths to the resident several times a week. The staff did not attempt to provide showers to the resident for several weeks after admission.*

- *At the next care plan meeting, the daughter discovered that her mother’s care plan included “provide weekly showers,” and was upset that the information about her mother’s fear of showers had not been identified and addressed in the care plan.*

Why is this Level 2 Severity?

There is potential for more than minimal harm since significant psychological distress was reported by the family to occur consistently with attempts to shower the resident. In addition, the potential for serious physical harm exists if showers are attempted and the resident resists by trying to get up out of the shower chair or becoming combative with staff. This is Level 2 because actual harm did not occur.

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Additional Resources

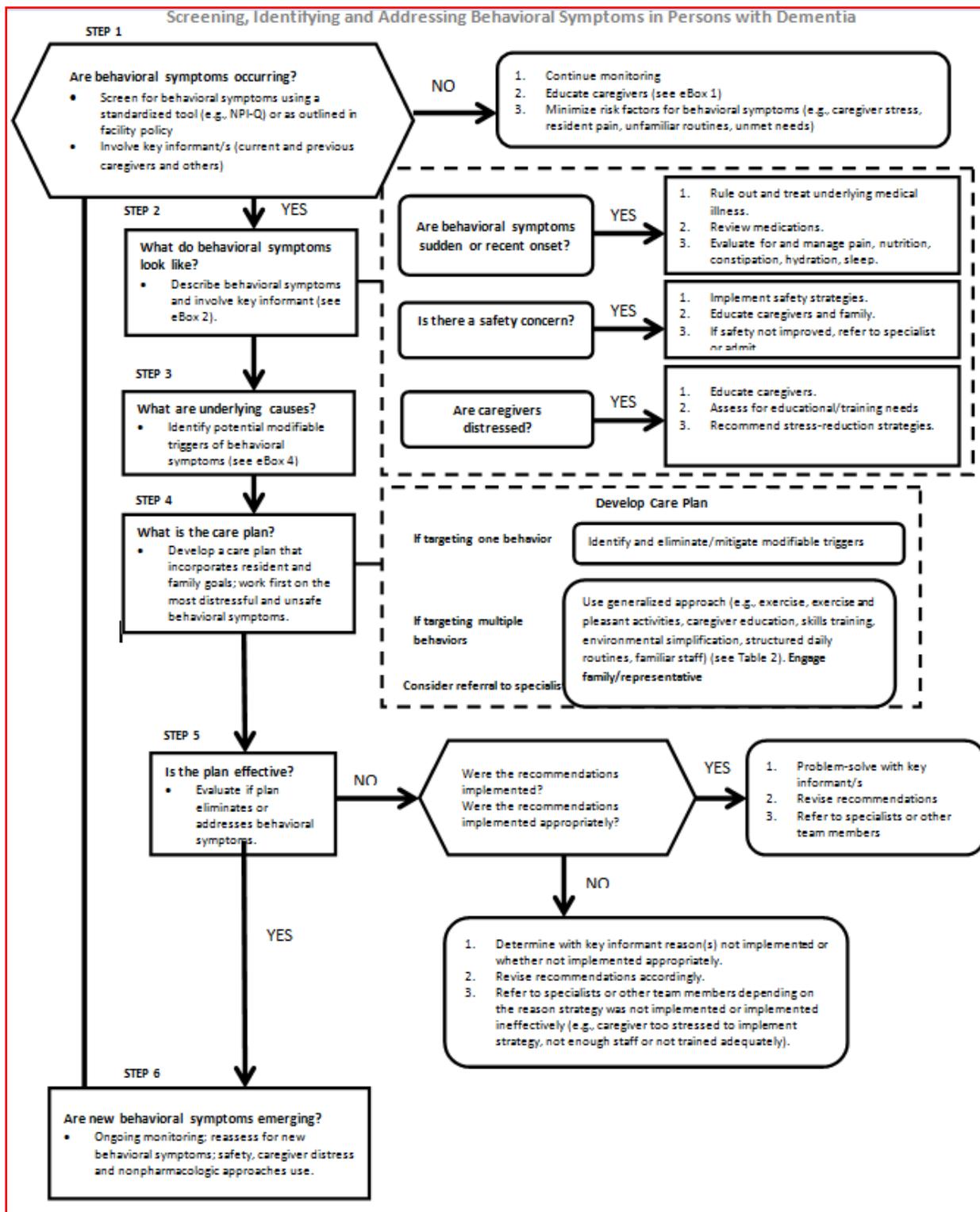
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Some clinical resources that identify the challenges and basic principles of dementia care include, but are not limited to:

- *Advancing Excellence in America's Nursing Homes.* <http://www.nhqualitycampaign.org>
- *Diagnostic and Statistical Manual of Mental Disorders DSM IV-TR Fourth edition.* 2000 American Psychiatric Association.
- Gitlin LN, Kales HC, Lyketsos CG. Nonpharmacologic Management of Behavioral Symptoms in Dementia. *JAMA* 202; 308(9): 2020-2029.
- *Hand in Hand.* For information, to download the training modules or inquire about receiving a copy or replacement copies of the Hand in Hand Toolkit please visit <http://www.cms-handinhandtoolkit.info/Index.aspx>

- *Lyketsos, C., Lipsey, J., Rabins, P., and Slavney, P. Psychiatric Aspects of Neurological Diseases. New York: Oxford University Press, 2008. Print*
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- *Excerpt adapted from: Gitlin LN, Kales HC, Lyketsos CG. Nonpharmacologic Management of Behavioral Symptoms in Dementia. JAMA, November 2, 202; 308(9): 2020-2029. © 202 American Medical Association. All rights reserved.*

Screening, Identifying and Addressing Behavioral Symptoms in Persons with Dementia



List of Boxes

Box – Key Considerations Caregivers Need to Know to Help Prevent Behavioral Symptoms

Box 2 – Informal Assessment: Brief Questions to Guide Describing Behavioral Symptoms

Box 3 – Checklist of Factors to Consider to Identify Potential Causes of Behavioral Symptoms

Box – *Key Considerations Caregivers Need to Know to Help Prevent Behavioral Symptoms*

Effectively communicate:

- *Use calm voice*
- *Offer no more than two choices*
- *Do not use open-ended questions*
- *Keep it simple – do not over explain or discuss events happening in the future*

Attend to resident's nonverbal communications:

- *Grimacing may be a sign of pain*
- *Ringing hands may be a sign of anxiety, feelings of insecurity*

Relax the rules - there is no right or wrong way to perform an activity if resident is safe

Establish a structured daily routine for resident that is predictable

Keep resident engaged in activities of interest and that match capabilities

Use cueing strategies (e.g., touch, verbal directions) to help people with executive dysfunction initiate, sequence, and execute daily activities

Understand behaviors are not intentional or done “in spite” but are a consequence of erosion in person's ability to initiate or comprehend steps of a task or its purpose

Inform physician immediately of changes in behavior as they occur (e.g., sleep disruptions, withdrawal, increased confusion)

Take care of self as a caregiver/team member:

- *Exercise regularly*
- *Involve other staff and family/representative in care responsibilities as appropriate*
- *Discuss stressful situations with colleagues and supervisors and brainstorm about potential solutions*
- *Use stress reduction techniques (see Hand in Hand, CMS video series available in nursing home, or other resources for suggestions)*

Box 2 - Informal Assessment: Brief Questions to Guide Describing Behavioral Symptoms

- What is the behavior? Can you describe the behavior?*
 - *What did he/she do?*
 - *What did he/she say?*
 - *What did you do and say?*
- Why is this behavior a problem? What about it really gets to you or makes you upset?*
- When does the behavior occur?*
 - *What time of day?*
 - *What day(s) of the week?*
- How often did the behavior happen in the past week? Past month?*
- Where does the behavior occur?*
 - *Is there a particular room/setting within the facility where the behavior occurs (e.g., during activities, in dining room, in person's own room with daily care routines)?*
- Can you recognize any patterns?*
 - *Does the behavior happen at the same time every day?*
- What happens right before the behavior occurs?*
- Who is around when the behavior occurs and how do they react?*

- What is the environment like where the behavior occurs?*
 - Is there a lot of stimulation (television, noise, people)?*
- How would you like this behavior to change? When would you consider the problem “solved”?*

Note: Adapted from randomized trials and the NIH Resources for Enhancing Alzheimer’s Caregiver Health (REACH I and II).

Box 3 – Checklist of Factors to Consider to Identify Potential Causes of Behavioral Symptoms

1. Resident-based Factors

- Altered emotional status (feelings of insecurity, sadness, anxiety, or loneliness)*
- Lack of daily routines*
- Sensory deficits (hearing, sight)*
- Basic physical needs (hydration, constipation, body temperature)*
- Interests and preferences not being met*
- Level of stimulation (under or over) not appropriate*
- Health issues (underlying infection)*
- Impact of other illness or conditions*
- Pain*
- Medications (changes in, dosage, polypharmacy, failure to take, inappropriate medication administration)*
- Ambulation and/or difficulty finding one’s way (getting lost)*
- Challenges performing daily activities of living (bathing, dressing, using the toilet, grooming, eating)*
- Sleep cycle disruptions*

2. Caregiver-based Factors

- Communications too complex*
- Emotional tone is harsh*
- High level of distress*
- Lack of availability (staffing issues)*
- Poor health status*
- Expectations are too high or too low*
- Cultural expectations and care values and beliefs that are not good fit with dementia care needs*
- Style of caregiving not good fit*
- Poor relationship with resident*
- Lack of education about disease and behaviors*
- Lack of supportive network or system within facility for dementia care*
- Limited opportunities for respite*
- Strained financial situation influencing work performance*
- Employment and other family care responsibilities*

3. *Environmental-based factors*

- Level of physical and/or social stimulation (too much or too little)*
- Room arrangements*
 - Amount of clutter*
 - Needed items are out-of-sight or not in where person can see them*
- Lack of appropriate visual cues*
- Safety risk*
- Too hot or too cold*

Lack of needed adaptive equipment (grab bars in bathroom)

Poor lighting

F322

(Rev. 127, Issued: 11-26-14, Effective: 11-26-14, Implementation: 11-26-14)

§483.25(g) Naso-Gastric Tubes

Based on the comprehensive assessment of a resident, the facility must ensure that --

(1) A resident who has been able to eat enough alone or with assistance is not fed by naso-gastric tube unless the resident's clinical condition demonstrates that use of a naso-gastric tube was unavoidable; and

(2) A resident who is fed by a naso-gastric or gastrostomy tube receives the appropriate treatment and services to prevent aspiration pneumonia, diarrhea, vomiting, dehydration, metabolic abnormalities, and nasal-pharyngeal ulcers and to restore, if possible, normal eating skills.

Intent: (F322) §483.25(g)(1) and (2)

The intent of this regulation is that:

- The feeding tube is utilized only after adequate assessment determines that the resident's clinical condition makes this intervention medically necessary;*
- A feeding tube is utilized in accordance with current clinical standards of practice and services are provided to prevent complications to the extent possible; and*
- Services are provided to restore normal eating skills to the extent possible.*

***NOTE:** For the purpose of the interpretative guidelines at F tag 322 the regulatory title “§483.25(g) Naso-gastric tubes” is considered to include any feeding tube used to provide enteral nutrition to a resident by bypassing oral intake. Since the regulation was promulgated, use of naso-gastric tubes has become extremely rare, and use of other types of enteral feeding tubes (such as those listed in the definitions section) has become prominent.*

DEFINITIONS

“Avoidable/Unavoidable use of a feeding tube”

- “Avoidable” means there is not a clear indication for using a feeding tube or there is insufficient evidence that it provides a benefit that outweighs associated risks.*
- “Unavoidable” means there is a clear indication for using a feeding tube or there is sufficient evidence that it provides a benefit that outweighs associated risks.*

“Bolus feeding” is the administration of a limited volume of enteral formula over brief periods of time.

“Continuous feeding” is the uninterrupted administration of enteral formula over extended periods of time.

“Enteral nutrition” (a.k.a. “tube feeding”) is the delivery of nutrients through a feeding tube directly into the stomach, duodenum, or jejunum.

“Feeding tube” refers to a medical device used to provide enteral nutrition to a resident by bypassing oral intake.

“Gastrostomy tube” (“G-tube”) is a tube that is placed directly into the stomach through an abdominal wall incision for administration of food, fluids, and medications. The most common type is a percutaneous endoscopic gastrostomy (PEG) tube.

“Jejunostomy tube” (a.k.a. “percutaneous endoscopic jejunostomy” (PEJ) or “J-tube”) is a feeding tube placed directly into the small intestine.

“Nasogastric feeding tube” (“NG tube”) is a tube that is passed through the nose and down through the nasopharynx and esophagus into the stomach.

“Transgastric jejunal feeding tube” (“G-J tube”) is a feeding tube that is placed through the stomach into the jejunum and that has dual ports to access both the stomach and the small intestine.

“Tube feeding” (a.k.a. “enteral feeding”) is the delivery of nutrients through a feeding tube directly into the stomach, duodenum, or jejunum.

OVERVIEW

A decision to use a feeding tube has a major impact on a resident and his or her quality of life. It is important that any decision regarding the use of a feeding tube be based on the resident’s clinical condition and wishes as well as applicable federal and state laws and regulations for decision making about life-sustaining treatments.¹²³⁴⁵

The use of feeding tubes varies widely within and among states. Reasons for this variability are unclear, but they may include diverse opinions about the benefits and risks of non-oral nutrition, and variable facility policies and usual practices.

NOTE: Refer to §483.0(b)(4) and (b)(8), Notice of Rights and Services, Right to Refuse Treatment and Experimental Research and to Formulate Advance Directives; and §483.5(b), Self-Determination and Participation, in order to determine if the use of a feeding tube is consistent with the wishes and instructions of the resident, if known (e.g., verbal or handwritten instructions, advance directive or living will) or the instructions of the resident’s legal representative, if the resident is unable to make his or her wishes known.

RESOURCES

- *The American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.) is dedicated to improving patient care by advancing the science and practice of nutrition support therapy. A.S.P.E.N. maintains a Guidelines and Standards Library. The Guidelines and Standards make specific practice recommendations. <http://www.nutritioncare.org/Library.aspx>*
- *The Alzheimer's Association offers a fact sheet regarding care and patient rights: Ethical Issues in Alzheimer's Disease, Assisted Oral Feeding and Tube Feeding. http://www.alz.org/alzwa/documents/alzwa_Resource_EOL_FS_Oral_Feeding.pdf*

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CONSIDERATIONS REGARDING THE USE OF FEEDING TUBES

The regulations at §483.25(g) require that the resident's clinical condition demonstrates the use of a feeding tube to be unavoidable. A feeding tube may be considered unavoidable only if no other viable alternative to maintain adequate nutrition and/or hydration is possible and the use of the feeding tube is consistent with the clinical objective of trying to maintain or improve nutritional and hydration parameters.⁶

Several factors may be involved in the decision to use a feeding tube including medical conditions that impair the resident's ability to maintain appropriate nutritional parameters (e.g., cerebrovascular accident, esophageal cancer, delirium, reconstructive facial or oral surgery), the need to improve the resident's nutritional status or level of comfort, or the desire to prolong the resident's life. The duration of use of a feeding tube may vary, depending on the clinical situation.

The interdisciplinary team, with support and guidance from the physician, is responsible for assuring the ongoing review, evaluation and decision-making regarding the continuation or discontinuation of all treatments, devices or approaches implemented to care for the resident. Involving the resident, family, and/or the resident's legal representative in discussions about the indications, use, potential benefits and risks of tube feeding, types of approaches, and alternatives helps support the resident's right to make an informed decision to use or not use artificial nutrition and hydration.

A clinically pertinent rationale for using a feeding tube includes, but is not limited to:

- *An assessment of the resident's nutritional status, which may include usual food and fluid intake, pertinent laboratory values, appetite, and usual weight and weight changes;*
- *An assessment of the resident's clinical status, which may include the ability to chew, swallow, and digest food and fluid; underlying conditions affecting those abilities (e.g., coma, stroke, esophageal stricture, potentially correctable malnutrition that cannot be*

improved sufficiently by oral intake alone); factors affecting appetite and intake (e.g., medications known to affect appetite, taste, or nutrition utilization); and prognosis;

- *Relevant functional and psychosocial factors (e.g., inability to sufficiently feed self, stroke or neurological injury that results in loss of appetite, psychosis that prevents eating); and*
- *Interventions prior to the decision to use a feeding tube and the resident's response to them. (Refer to F325 for discussion and examples of interventions to improve and restore normal nutritional parameters.)*

NOTE: *Refer to §483.20 Resident Assessment and the Assessment Section of the General Investigative Protocol at Quality of Care (F309) for discussion of the comprehensive evaluation that comprises an assessment.*

The use of a feeding tube may potentially benefit or may adversely affect a resident's clinical condition and/or psychosocial well-being. Examples of some possible benefits of using a feeding tube may include:

- *Addressing malnutrition and dehydration;*
- *Promoting wound healing; and*
- *Allowing the resident to gain strength, receive appropriate interventions that may help restore the resident's ability to eat and, perhaps, return to oral feeding.*

Examples of some possible adverse effects of using a feeding tube may include:

- *Diminishing socialization, including, but not limited to, the close human contact associated with being assisted to eat or being with others at mealtimes;*
- *Not having the opportunity to experience the taste, texture, and chewing of foods;*
- *Causing tube-associated complications; and*
- *Reducing the freedom of movement related to efforts to prevent the resident from pulling on the tube or other requirements related to the tube or the tube feeding.*

In order to assure that the resident being fed by a feeding tube maintains the highest degree of quality of life possible, it is important to minimize possible social isolation or negative psychosocial impact to the degree possible (e.g., continuing to engage in appropriate activities, socializing in the dining room). Because of the possible side-effects and discomfort associated with the use of nasogastric tubes, there should be clinically pertinent documentation for extended use of nasogastric tubes (e.g., greater than 30 days).

Nutrition and feeding issues and their underlying causes in the resident with advanced dementia or other chronic neurological disorders such as Parkinson's disease present a particular set of issues and considerations that are discussed in F325. The extended use of enteral feeding tubes in individuals with advanced dementia remains controversial. The literature regarding enteral feeding of these individuals suggests that there is little evidence that enteral feeding improves clinical outcomes (e.g., prevents aspiration or reduces mortality).^{7 8 9 10 11 12}

Resident Rights

The regulations at 483.0(d)(2) state that the resident has the right to be fully informed in advance about care and treatment and of any changes in the care or treatment that may affect the resident's well-being. In addition, the regulations at 483.0(b)(4) state that the resident has the right to refuse treatment and to formulate an advance directive.

If a resident has had a feeding tube placed prior to admission or in another setting while residing in the facility, the physician and interdisciplinary care team review the basis (e.g., precipitating illness or condition change) for the initial placement of the feeding tube and the resident's current condition to determine if there is a continued rationale for its use and to ensure that its continued use is consistent with the resident's treatment goals and wishes. Decisions to continue or discontinue the use of a feeding tube are made through collaboration between the resident (or a legal representative for a resident who lacks capacity to make and communicate such decisions), the physician, and the interdisciplinary care team. This includes a discussion of the relevance of a feeding tube to attaining a resident's goals (e.g., whether the nutritional intervention is likely to have a significant impact on the individual's underlying condition or overall status).

TECHNICAL AND NUTRITIONAL ASPECTS OF FEEDING TUBES

It is important that staff providing care and services to the resident who has a feeding tube are aware of, competent in, and utilize facility protocols regarding feeding tube nutrition and care. These protocols are required to be developed with the medical director in order to assure staff implement and provide care and services according to resident needs and clinical standards of practice.

Technical Aspects of Feeding Tubes

Facility procedures regarding the technical aspects of feeding tubes include, but are not limited to, the following:

Location of the feeding tube. *Direction to staff regarding how to monitor and check that the feeding tube is in the right location (e.g., stomach or small intestine, depending on the tube) or verify that placement was checked, such as:*

- *Techniques to verify that tube placement is appropriate before beginning a feeding and before administering medications; and*

- *The frequency with which staff should monitor for proper location of the feeding tube to assure that the enteral retention device is properly approximated to the abdominal wall and the surrounding skin is intact.*

Care of the feeding tube. *Direction to staff on how to provide care such as:*

- *Securing a feeding tube externally;*
- *Providing needed personal, skin, oral, and nasal care to the resident;¹³*
- *Examining and cleaning the insertion site in order to identify, lessen or resolve possible skin irritation and local infection;*
- *Using infection control precautions and related techniques to minimize the risk of contamination; for example, in connecting the tube and the tube feeding; and*
- *Defining the frequency of and volume used for flushing, including flushing for medication administration, and when a prescriber's order does not specify.*

Feeding tube replacement. *Direction for staff regarding the conditions and circumstances under which a tube is to be changed, such as:*

- *When to replace and/or change a feeding tube (generally replaced either as planned/scheduled or as needed such as when a long-term feeding tube comes out unexpectedly or a tube is worn or clogged);*
- *How and when to examine a feeding tube and the infusion plug to identify splits or cracks that could produce leakage;*
- *Instances when a tube can be replaced within the facility and by whom;*
- *Instances when a tube must be replaced in another setting (e.g., hospital, ambulatory surgery center); and*
- *Notification of the practitioner when the need for a tube change arises unexpectedly.*

Nutritional Aspects of Feeding Tubes

When a resident is receiving nutrition via a feeding tube, the practitioner and the interdisciplinary team identify the resident's nutritional needs and facility procedures that direct staff in providing care and services to the resident. The practitioner's orders related to tube feeding typically include the following components: kind of feeding and its caloric value; volume, duration, and mechanism of administration (e.g., gravity or pump); and frequency of flush.

Facility procedures regarding the nutritional aspects of feeding tubes include, but are not limited to:

Enteral nutrition. *Direction to staff regarding the nutritional product and meeting the resident's nutritional needs such as:*

- *Types of enteral nutrition formulas available for use;*
- *How to determine whether the tube feedings meet the resident's nutritional needs and when to adjust them accordingly;*
- *How to balance essential nutritional support with efforts to minimize complications related to the feeding tube;*
- *Ensuring that the selection and use of enteral nutrition is consistent with manufacturer's recommendations;*
- *Ensuring that the administration of enteral nutrition is consistent with and follows the practitioner's orders; and*
- *Ensuring that the product has not exceeded the expiration date.*^{14 15}

Flow of feeding. *Direction for staff regarding how to manage and monitor the rate of flow, such as:*

- *Use of gravity flow;*
- *Use of a pump;*
- *Periodic evaluation of the amount of feeding being administered for consistency with practitioner's orders;*
- *Calibration of enteral feeding pumps to ensure that pump settings accurately provide the rate and volume consistent with the resident's care plan; and*
- *Periodic maintenance of feeding pumps consistent with manufacturer's instructions to ensure proper mechanical functioning.*

Complications Related to the Feeding Tube

An enteral feeding tube may be associated with significant complications, including aspiration, leaking around the insertion site, abdominal wall abscess, or erosion at the insertion site including the nasal areas. Feeding tubes can perforate the stomach or small intestine, with resultant peritonitis. Esophageal complications of feeding tubes may also occur including esophagitis, ulcerations, strictures, and tracheoesophageal fistulas. The use of tubes not designed or intended for enteral feeding may increase the risk of complications.^{16 17}

Tubes may clog for various reasons, including plugging by formula, pill fragments, or the precipitation of medications incompatible with the formula.¹⁸ Flushing feeding tubes regularly and in association with medication administration, as indicated by current clinical standards of practice and provided in the resident care policies, can help reduce the risk of clogging.

Complications Related to the Administration of the Enteral Nutrition Product

The administration of an enteral nutrition product may be associated with other complications including, but not limited to, nausea, vomiting, diarrhea, abdominal cramping, inadequate nutrition and aspiration. Additionally, interactions between the formula and various medications can affect the absorption and/or effectiveness of the medication. For example, the effectiveness of phenytoin sodium may be reduced by the drug binding with the enteral feeding's protein component, leading to less free drug availability and possibly inadequate therapeutic levels.

Metabolic complications related to tube feeding may include inadequate calorie or protein intake, altered hydration, hypo- or hyperglycemia, and altered electrolyte and nutrient levels. These risks may be reduced by calculating the nutritional needs of the resident, taking into account comorbid conditions and medications that affect these balances, monitoring for adequate nutritional status and complications, and adjusting the tube feeding accordingly.

While a feeding tube may be initiated with the intent to address certain medical conditions, the use of a feeding tube does not necessarily decrease the risk of aspiration for individuals with other risk factors, such as moderate or less severe swallowing abnormalities. Aspiration risk may potentially be affected by factors such as diminished level of consciousness, improper positioning of the resident during administration of the feeding, and failure to assure the feeding tube is correctly positioned within the stomach or intestine. The evidence is inconsistent and conflicting regarding any connection between gastric residual volume and the risk or occurrence of aspiration.¹⁹

Risk of aspiration should be assessed individually and appropriate interventions (e.g., proper positioning, rate of flow) implemented accordingly. There may be situations where other coexisting factors influence decisions about elevating the head of the bed; for example, a resident being fed by a tube who may be at risk for shearing by sliding down the sheets when the head of the bed is elevated to a recommended angle.

Complications Management

The facility is expected to identify and address actual or potential complications related to the feeding tube or tube feeding and to notify and involve the practitioner in evaluating and managing care to address these complications and risk factors.²⁰

INVESTIGATIVE PROTOCOL FOR FEEDING TUBES

Objectives

- *To determine if a feeding tube is utilized only after adequate assessment determines that the resident's clinical condition makes this intervention medically necessary;*
- *To determine if a feeding tube is utilized in accordance with current clinical standards of practice and if services are provided to prevent complications to the extent possible; and*
- *To determine if services are provided to restore normal eating skills to the extent possible.*

Use

Use this protocol for a resident who has a feeding tube.

Procedures

The surveyor(s) should conduct the following observations, interviews and record reviews. If there are concerns regarding the facility's use and care of feeding tubes, review facility policies and practices with regard to the use and care of feeding tubes.

Observations

During various shifts, observe staff interactions with the resident and provision of care including: initiation, continuation, and termination of feedings; care of the tube site and equipment; and medication administration via the feeding tube, if possible. Use the observations to determine whether staff follow clinical standards of practice, facility policy, the resident care plan, and prescriber's orders and if they try to minimize the risk for complications including but not limited to:

- *Implementing interventions to minimize the negative psychosocial impact that may occur as a result of tube feeding;*
- *Providing mouth care, including teeth, gums, and tongue;*
- *Checking that the tubing remains in the correct location;*
- *Properly positioning the resident consistent with the resident's individual needs;*
- *Using universal precautions and clean technique and following the manufacturer's recommendations when stopping, starting, flushing, and giving medications through the feeding tube;*
- *Ensuring the cleanliness of the feeding tube, insertion site, dressing (if present) and nutritional product; and*

- *Providing the type, rate, volume and duration of the feeding as ordered by the practitioner and consistent with the manufacturer's recommendations.*

Note staff response if there is evidence of possible complications, such as diarrhea, nausea, vomiting, abdominal discomfort, nasal discomfort (if a nasogastric tube is being used); evidence of leakage and/or skin irritation at the tube insertion site; or risk of inadvertent removal of the tube.

Interviews

Resident/Representative

Interview the resident and/or resident's legal representative (as appropriate) regarding involvement in development of the care plan including goals and approaches; whether the interventions reflect the resident's choices and preferences; and the resident's response to the tube feeding, including the following:

- *Whether staff provided assistance to the resident to increase the food intake, prior to inserting a feeding tube (e.g., identifying underlying causes of anorexia; hand feeding; changing food consistency, texture, form; offering alternate food choices; and/or providing assistive devices);*
- *Whether the resident and/or the resident's legal representative (as appropriate) was informed about the relevant benefits and risks of tube feeding, and involved in discussing alternatives and making the decision about using a feeding tube;*
- *Whether the resident has had any significant new or worsening physical, functional or psychosocial changes; whether the resident informed the staff; and how the problems were addressed;*
- *Whether there has been a reassessment and discussion with the resident or the resident's legal representative regarding the continued appropriateness/necessity of the feeding tube.*

NOTE: *Prior to inserting a feeding tube, the prescriber reviews the resident's choices/instructions and goals, including all relevant information that may be identified in advance directives (See F155, F156 and F242).*

Facility staff

Interview staff that provide direct care on various shifts to determine:

- *How staff and practitioner determined the cause(s) of decreased oral intake/weight loss or impaired nutrition and attempted to maintain oral intake prior to the insertion of a feeding tube, such as did staff collaborate with the physician to identify medical causes of decreased appetite or try to help the resident eat enough food (e.g., cueing or hand*

feeding; changing food consistency, texture, form; seeking and addressing causes of anorexia; providing assistive devices);

- *What the specific care needs for the resident are (e.g., special positioning, personal care, insertion site care, amount of feeding taken in);*
- *How the staff determined the resident's nutritional status was being met such as periodically weighing the resident and how they decide whether the tube feeding is adequate to maintain acceptable nutrition parameters;*
- *Whether the resident has voiced any complaints or exhibited any physical or psychosocial complications that may be associated with the tube feeding (e.g., nausea or vomiting, diarrhea, pain associated with the tube, abdominal discomfort, depression, withdrawal); and how these problems have been addressed;*
- *To whom a staff member has reported the resident's signs or symptoms; and*
- *Whether there has been a periodic reassessment and discussion with the resident or his/her legal representative regarding the continued appropriateness/necessity of the feeding tube; and whether the care plan has been revised and implemented as necessary.*

Health care practitioners and professionals

The assigned surveyor should review, as indicated, the facility's policies, procedures, records of incidents and corrective actions related to feeding tubes; documentation of staff knowledge and skills related to the aspects of administering tube feeding; and should, as necessary, interview facility staff with responsibility for overseeing or training in this aspect of care to determine:

- *How the facility identified the resident at risk for impaired nutrition, identified and addressed causes of impaired nutrition, and determined that use of a feeding tube was unavoidable;*
- *How staff calculated nutritional needs for the resident and how they ensure that the resident receives close to the calculated amount of nutrition daily;*
- *How staff monitor the resident for the benefits and risks related to a feeding tube, and address adverse consequences of the feeding tube use (e.g., altered mood, nausea and vomiting, pain, or restraint use to try to prevent the resident from removing the feeding tube);*
- *How staff are trained and directed regarding management of feeding tubes and tube feedings in general, and in addressing any specific issues related to this individual resident;*

- *Whether the physician and staff attempted to identify the circumstances that led to the placement of the feeding tube (e.g., when the tube was placed in another facility); and*
- *Whether the resident was periodically reassessed for the continued appropriateness/necessity of the feeding tube; and whether the care plan was revised and implemented, as necessary, with input from the resident or his/her legal representative, to the extent possible.*

***NOTE:** During the course of the review, if the surveyor needs to contact the attending physician regarding questions related to the treatment 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. If the attending physician is unavailable, interview the medical director, as appropriate.*

Record Review

Review information such as physician orders, tube feeding records, multidisciplinary progress notes, RAI/MDS and any available assessment regarding the rationale for feeding tube insertion and the potential to restore normal eating skills, including the interventions tried (to avoid using the feeding tube before its insertion, restore oral intake after tube insertion, and prevent potential complications). In order to identify concerns or to further investigate identified concerns about tube feedings, review to determine:

- *How the staff verify that the feeding tube is properly placed;*
- *That staff are assigned responsibilities for various aspects of enteral feedings consistent with their position and training (e.g., administering the feeding, determining and verifying correct formula; calculating the amount of formula, feeding intervals, flow rate);*
- *How staff have monitored a resident for possible complications (e.g., depression, nutritional deficits, withdrawal, aspiration, aspiration pneumonia, dehydration, metabolic abnormalities, diarrhea, nausea, vomiting, abdominal discomfort, nasal discomfort, nasal-pharyngeal ulcer, etc.) related to a feeding tube and the tube feeding, and have identified and addressed such complications; and*
- *That the resident was periodically reassessed and the care plan was revised and implemented, as necessary with input from the resident or his/her legal representative, to the extent possible.*

Review of Facility Practices

Related concerns may have been identified that would suggest the need for a review of facility practices. Examples of such activities may include a review of policies, staffing, and staff training, functional responsibilities, and interviews with staff (including facility management). If

there is a pattern of residents who have issues related to the indications, utilization, complications, process or performance issues with feeding tubes, determine whether the facility has incorporated into its quality assurance activities a review of appropriateness and management of tube feedings.

DETERMINATION OF COMPLIANCE

Synopsis of Regulation (F322)

The feeding tube requirement has two aspects. The first aspect requires that the facility utilizes a feeding tube only after it determines that a resident's clinical condition demonstrates this intervention was unavoidable. The second aspect requires that the facility provides to the resident who is fed by a tube, services to prevent complications, to the extent possible, and services to restore normal eating skills, if possible.

Criteria for Compliance

The facility is in compliance with 42 CFR §483.25(g), if staff:

- Use a feeding tube to provide nutrition and hydration only when the resident's clinical condition makes this intervention necessary based on adequate assessment and after other efforts to maintain or improve the resident's nutritional status have failed;*
- Manage all aspects of a feeding tube and enteral feeding consistent with current clinical standards of practice in order to meet the resident's nutritional and hydration needs and to prevent complications; and*
- Identify and address the potential risks and /or complications associated with feeding tubes, and provide treatment and services to restore, if possible, adequate oral intake.*

If not, cite at F322.

Noncompliance for F322

After completing the Investigative Protocol, analyze the data in order to determine whether noncompliance with the regulation exists. Noncompliance for F322 may include, but is not limited to, failure to do one or more of the following:

- Appropriately assess a resident's nutritional status and needs, and identify a clinically pertinent rationale for the use of a feeding tube;*
- Identify nutritional requirements for a resident fed by a feeding tube and ensure that a tube feeding meets those needs;*

- *Adequately address the nutritional aspects of enteral feeding and the management of the feeding tube, including prevention of related complications; or*
- *Use and monitor a feeding tube per facility protocol and pertinent clinical standards of practice, provide services to attempt to restore, if possible, normal eating skills, or identify and manage tube-related or enteral feeding-related complications.*

Potential Tags for Additional Investigations

If an additional concern has been identified, the surveyor must investigate the identified concern. Do not cite any related or associated requirements before first conducting an investigation to determine compliance or non-compliance with the related or associated requirements. Some examples include, but are not limited to, the following:

42CFR §483.10(b)(3);(d)(2), F154, Right to Be Fully Informed

- *Determine if the facility has fully informed the resident of his or her total health status and has provided the resident with information about the use of a feeding tube (including risks, benefits and alternatives) so that an informed decision can be made.*

42 CFR §483.10(b)(4)(8), F155, Notice of Rights and Services, Right to Refuse Treatment and Experimental Research and to Formulate Advance Directives, Maintenance and Provision of Written Policies of These Rights

- *Determine if the facility has given the resident or legal representative the opportunity to participate in the decision about tube feeding and informed the resident of the right to make advance directives and to decline life-sustaining treatments including artificial nutrition and hydration;*
- *Determine if the facility maintains written policies and procedures regarding advance directives; and*
- *Determine if the facility informs and provides written information to all adult residents concerning the right to accept or refuse medical treatment and formulate advance directives.*

42 CFR §483.10(b)(11), F157, Notification of Changes

- *Determine if staff notified:*
 - *The physician when they suspected or identified inability to maintain adequate oral intake or complications related to use of the feeding tube; and*

- *The resident and the resident's legal representative (if known) of significant changes in the resident's condition in relation to the feeding tube or inability to take nutrition orally;*

42 CFR §483.15(a), F241, Dignity

- *Determine whether the staff provided respectful care for the resident being tube fed to maintain and enhance the resident's dignity;*

42 CFR §483.15(b), F242, Self-determination and Participation

- *Determine whether staff provided the resident with relevant information and choices regarding feeding tubes;*

42 CFR §483.20(b), F272, Comprehensive Assessments

- *Determine if the resident's comprehensive assessment reflects the resident's nutritional status, including factors that may have contributed to inadequate oral intake, and evaluates the resident's response to the implementation of tube feeding, including nutritional and psychosocial aspects;*

42 CFR §483.20(g), F278, Accuracy of Assessments

- *Determine whether the assessment accurately reflects the resident's status;*

42 CFR §483.20(k), F279, Comprehensive Care Plans

- *Determine if the resident's comprehensive care plan includes measurable objectives, time frames, and specific interventions consistent with the resident's specific nutritional status, risks, needs, and current clinical standards of practice. This includes interventions prior to the insertion of the feeding tube to attempt to avoid tube feeding and after the insertion of the tube to prevent tube-related and tube-feeding related complications and restore, if possible, adequate oral intake;*

42 CFR §483.20(k)(2)(iii), F280, Comprehensive Care Plan Revision

- *Determine if the care plan was periodically reviewed and revised by appropriate staff, in conjunction with the practitioner and with input from the resident or his/her legal representative, to try to meet the resident's nutritional and hydration needs; reduce, prevent, or address potential complications; and attempt to restore normal eating skills, if possible;*

42 CFR §483.20(k)(3)(i), F281, Services Provided Meet Professional Standards of Quality

- *Determine if staff provided care in accordance with accepted professional standards of quality to maintain or restore adequate oral intake, if possible, and to manage the feeding tube to maintain or improve nutrition and prevent complications, to the extent possible;*

42 CFR §483.20(k)(3)(ii), F282, Care Provided by Qualified Persons in Accordance with the Plan of Care

- *Determine whether care of the resident with a feeding tube is being provided by qualified staff and/or whether the care plan is adequately and/or correctly implemented;*

42 CFR §483.25(i), F325, Nutrition

- *Determine if the facility has managed the resident's nutritional interventions to meet the resident's nutritional needs, while using a feeding tube;*

42 CFR §483.25(l), F329, Unnecessary Drugs

- *Determine if the facility has reviewed the resident's medication regimen for medications that may have caused or contributed to a decline in oral intake, or ability to chew and/or swallow, that may have contributed to the decision to place a feeding tube or affected the efforts to restore normal eating;*

42 CFR §483.30, F353, Nursing Services

- *Determine if the facility has sufficient nursing staff that is qualified to provide necessary care and services to the resident being fed by a feeding tube;*

42 CFR §483.40(a), F385, Physician Supervision

- *Determine if a physician is supervising the medical aspects of the tube feedings including assessment of causes of impaired nutritional status, development of a treatment regimen consistent with current clinical standards of practice, monitoring, and response to notification of change in the resident's medical status;*

42 CFR §483.60, F425, Pharmacy Services

- *Determine if the policies were developed and implemented for the safe administration of medications for a resident with a feeding tube;*

42 CFR §483.65, F441, Infection Control

- *Determine if the facility established and maintained an infection control policies for safe and sanitary care and services for a resident being fed by a tube;*

42 CFR §483.75(i), F501, Medical Director

- *Determine whether the medical director helped the facility develop and implement policies addressing the assessment and management of individuals with impaired or at-risk nutrition and hydration status and recognizing, addressing, and preventing complications related to tube feedings;*

42 CFR §483.75(l), F514, Clinical Records

- *Determine whether the clinical record:*
 - *Accurately, completely and, in accordance with current clinical standards, documents: the resident's status (including changes in condition), care and services provided to the resident with a feeding tube, response to treatment and the resident's goals; and*
 - *Provides the basis for determining the continued need for tube feeding and whether changes in treatment are necessary.*

DEFICIENCY CATEGORIZATION (PART IV, APPENDIX P)

Once the 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.

The key elements for severity determination for F322 are as follows:

1. Presence of harm/negative outcome(s) or potential for negative outcomes because of lack of appropriate care and services. *Actual or potential harm/negative outcomes for F322 may include but are not limited to:*

- *Failure to adequately assess a resident's nutritional status and the care and services needed to maintain or improve the resident's nutritional status and/or to identify why the use of a feeding tube was medically unavoidable;*
- *Failure to adequately identify nutritional requirements for a resident fed by a feeding tube and ensure that the tube feeding met those needs (if clinically feasible), resulting in the resident experiencing malnutrition and dehydration;*
- *Failure to verify the location of the tube in accordance with current clinical standards, facility protocols, and resident condition; therefore increasing the risk for complications such as aspiration; and*

- *Failure to use and monitor a feeding tube per facility protocol and current clinical standards of practice or to identify and manage feeding tube-related or tube-feeding related complications, thereby allowing the complication to continue without appropriate intervention.*
2. ***Degree of harm (actual or potential) related to the noncompliance.*** *Identify how the facility practices caused, resulted in, allowed, or contributed to the actual or potential for harm.*
- *If harm has occurred, determine if the harm is at the level of serious injury, impairment, death, compromise, or discomfort; and*
 - *If harm has not yet occurred, determine how likely the potential is for serious injury, impairment, death, compromise or discomfort to occur to the resident.*
3. ***The immediacy of correction required.*** *Determine whether the noncompliance requires immediate correction in order to prevent serious injury, harm, impairment, or death to one or more residents.*

The survey team must evaluate the harm or potential for harm based upon the following levels of severity. First, the team must rule out whether Severity Level 4 (immediate jeopardy to a resident's health or safety) exists by evaluating the deficient practice in relation to immediacy, culpability, and severity. (Follow the guidance in Appendix Q, Determining Immediate Jeopardy.)

Severity Level 4 Considerations: Immediate Jeopardy to Resident Health or Safety

Immediate jeopardy is a situation in which the facility's noncompliance with one or more requirements of participation:

- *Has allowed, caused, or resulted in (or is likely to allow, cause, or result in) serious injury, harm, impairment, or death to a resident; and*
- *Requires immediate correction as the facility either created the situation or allowed the situation to continue by failing to implement preventative or corrective measures.*

NOTE: *The death or transfer of a resident, who was harmed as a result of facility practices, does not remove a finding of immediate jeopardy. The facility is required to implement specific actions to correct the deficient practices which allowed or caused the immediate jeopardy.*

Examples of avoidable actual or potential resident outcomes that demonstrate severity at Level 4 may include, but are not limited to:

- *The facility failed to train staff about how to ensure proper placement of a feeding tube, and/or to ensure that staff were checking for tube placement consistently and correctly.*

As a result of staff failure to verify tube placement, a resident got peritonitis (infection of the lining of the abdominal cavity) and died following the administration of tube feeding; or

- *As a result of the facility routinely keeping a resident lying almost flat in bed while administering the resident's tube feeding, the resident aspirated some of the tube feeding and acquired aspiration pneumonia.*

NOTE: *If Severity Level 4 (immediate jeopardy) has been ruled out based upon the evidence, then evaluate whether actual harm that is not immediate jeopardy exists at Severity Level 3 or the potential for more than minimal harm at Severity Level 2 exists.*

Severity Level 3 Considerations: Actual Harm that is Not Immediate Jeopardy

Severity Level 3 indicates noncompliance that resulted in actual harm that is not immediate jeopardy. The negative outcome can include but may not be limited to clinical compromise, decline, or the resident's inability to maintain and/or reach his/her highest practicable well-being.

Examples of avoidable, actual resident outcomes that demonstrate severity at Level 3 may include, but are not limited to:

- *The facility failed to monitor for complications related to a resident's feeding tube and tube feeding. As a result, the resident experienced significant but not life-threatening tube feeding-related complications; or*
- *As a result of facility failure to assess the resident's nutritional needs and to continue to administer, monitor, and adjust tube feeding accordingly, a resident experienced significant weight loss that cannot be otherwise attributed to a medically unavoidable cause.*

NOTE: *If Severity Level 3 (actual harm that is not immediate jeopardy) has been ruled out based upon the evidence, then evaluate whether Severity Level 2 (no actual harm with the potential for more than minimal harm) exists.*

Severity Level 2 Considerations: No Actual Harm with Potential for More than Minimal Harm that is Not Immediate Jeopardy

Severity Level 2 indicates noncompliance that resulted in a resident outcome of no more than minimal discomfort and/or had the potential to compromise the resident's ability to maintain or reach his or her highest practicable level of well-being. The potential exists for greater harm to occur if interventions are not provided.

Examples of avoidable outcomes at Severity Level 2 include, but are not limited to:

- *As a result of staff failure to anchor a feeding tube properly, the resident had leakage and irritation around the tube insertion site that required topical treatment and resolved without complications;*
- *As a result of staff failure to manage a tube feeding pump properly, the resident did not receive the calculated amount of tube feeding, without resulting in significant weight loss or other GI complications; or*
- *As a result of staff failure to consistently flush a resident's feeding tube as ordered, the tube clogged and had to be replaced, but there were no other complications.*

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

The failure of the facility to provide appropriate care and services for feeding tubes, places the resident at risk for more than minimal harm. Therefore, Severity Level 1 does not apply for this regulatory requirement.

ENDNOTES

¹ *Teno, J.M, Mitchell, S.L., Gozalo, P.L., et al. (2010). Hospital characteristics associated with feeding tube placement in nursing home residents with advanced cognitive impairment. Journal of the American Medical Association, 303: 544-550.*

² *Lopez, R.P., Amella, E.J., Strumpf, N.E., et al. (2010). The influence of nursing home culture on the use of feeding tubes. Archives of Internal Medicine, 170: 83-88.*

³ *Finucane, T.E., Christmas, C., Leff, B.A. (2007). Tube feeding in dementia: how incentives undermine health care quality and patient safety. Journal of American Medical Directors Association, 8: 205-208. (<http://www.ncbi.nlm.nih.gov/pubmed/17498602>)*

⁴ *Mitchell, S.L., Teno, J.M., Roy, J., et al. (2003). Clinical and organizational factors associated with feeding tube use among nursing home residents with advanced cognitive impairment. Journal of the American Medical Association, 290: 73-80.*

⁵ *Mitchell, S.L., Kiely, D.K., Gillick, M.R. (2003). Nursing home characteristics associated with tube feeding in advanced cognitive impairment. Journal of American Geriatric Society, 51:75-79. (<http://www.ncbi.nlm.nih.gov/pubmed/125348499>)*

⁶ *Pearce, C.B. & Duncan, H.D. (2002) Enteral feeding. Nasogastric, nasojejunal, percutaneous endoscopic gastrostomy, or jejunostomy: its indications and limitations. Postgraduate Medical Journal (a UK journal), 78: 199-203. (<http://pmj.bmj.com/content/78/918/198.abstract>)*

⁷ *Genao, L., White, H., Twersky, J. (2010). The clinical course of advanced dementia. New England Journal of Medicine, 362: 363-364.*

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F329

(Rev. 127, Issued: 11-26-14, Effective: 11-26-14, Implementation: 11-26-14)

§483.25(l) Unnecessary Drugs

Antipsychotic medications	
<p>All classes, e.g.,</p> <p>First generation (conventional) agents, e.g.</p> <ul style="list-style-type: none"> • chlorpromazine • fluphenazine • haloperidol • loxapine • mesoridazine • molindone • perphenazine • promazine • thioridazine • thiothixene • trifluoperazine • triflupromazine <p>Second generation (atypical) agents, e.g.</p> <ul style="list-style-type: none"> • <i>asenapine</i> • aripiprazole • clozapine • <i>iloperidone</i> • <i>lurasidone</i> • <i>olanzapine</i> • <i>paliperidone</i> • <i>quetiapine</i> • <i>risperidone</i> • <i>ziprasidone</i> 	<p>Indications <i>for Use</i>:</p> <p><i>A. Conditions Other than Dementia</i></p> <p>An antipsychotic medication should <i>generally</i> be used only for the following conditions/diagnoses as documented in the record and as meets the definition(s) in the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Training Revision (DSM-IV TR) or subsequent editions):</p> <ul style="list-style-type: none"> ○ Schizophrenia ○ Schizo-affective disorder ○ <i>Schizophreniform disorder</i> ○ <i>Delusional disorder</i> ○ <i>Mood disorders (e.g. bipolar disorder, severe depression refractory to other therapies and/or with psychotic features)</i> ○ <i>Psychosis in the absence of dementia</i> ○ <i>Medical illnesses with psychotic symptoms (e.g., neoplastic disease or delirium) and/or treatment related psychosis or mania (e.g., high-dose steroids)</i> ○ <i>Tourette’s Disorder</i> ○ <i>Huntington disease</i> ○ <i>Hiccups (not induced by other medications)</i> ○ <i>Nausea and vomiting associated with cancer or chemotherapy</i> <p><i>B. Behavioral or Psychological Symptoms of Dementia (BPSD)</i></p> <p><i>(Use this guidance in conjunction with guidance at §483.25 F309 Quality of Care, Review of Care and</i></p>

Services for a Resident with Dementia. Also consider §483.10(d)(2) F154, Right to be informed in advance about care and treatment; F155, Right to refuse treatment; and §483.10(d)(3) F280, Right to participate in planning care and treatment.)

Antipsychotic medications are only appropriate for elderly residents in a small minority of circumstances (unless the antipsychotic is prescribed to treat previously diagnosed mental illness such as schizophrenia or possibly other conditions listed above). All antipsychotic medications carry a Food and Drug Administration (FDA) Black Box Warning. Since June 6, 2008, FDA warned healthcare professionals that both conventional and atypical antipsychotics are associated with an increased risk of death in elderly patients treated for dementia-related psychosis.

Addition information is available at:

<http://www.fda.gov/Drugs/default.htm>.

(A black box warning means that medical studies indicate that the drug carries a significant risk of serious or even life-threatening adverse effects. It is the strongest warning that the U.S. Food and Drug Administration can require a pharmaceutical company to place on the labeling of a prescription drug, or in the product literature describing it. The intent of 483.25(l) is that each resident's entire medication regimen be managed and monitored to promote or maintain the resident's highest practicable mental, physical, and psychosocial well-being.)

Antipsychotic medications may be considered for elderly residents with dementia but only after medical, physical, functional, psychological, emotional psychiatric, social and environmental causes have been identified and addressed. Antipsychotic medications must be prescribed at the lowest possible dosage for the shortest period of time and are subject to gradual dose reduction and re-review.

Inadequate Indications:

Antipsychotic medications in persons with dementia should not be used if the only indication is one or more of the following:

- wandering*
- poor self-care*
- restlessness*
- impaired memory*
- mild anxiety*

- *insomnia*
- *inattention or indifference to surroundings*
- *sadness or crying alone that is not related to depression or other psychiatric disorders*
- *fidgeting*
- *nervousness*
- *uncooperativeness (e.g. refusal of or difficulty receiving care).*

Criteria:

All of the above highlight conditions/diagnoses where antipsychotic medications may possibly be appropriate, but diagnoses alone do not warrant the use of an antipsychotic unless the following criteria are also met:

- *The behavioral symptoms present a danger to the resident or others*

AND one or both of the following:

- *The symptoms are identified as being due to mania or psychosis (such as: auditory, visual, or other hallucinations; delusions, paranoia or grandiosity);*

OR

- *Behavioral interventions have been attempted and included in the plan of care, except in an emergency.*

Additional Criteria:

Acute Situations/Emergency

When an antipsychotic 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 one or more of the aforementioned conditions/diagnoses, *the use must meet the above criteria* and all of the following additional requirements:

1. *The acute treatment period is limited to seven days or less; AND*
2. *A clinician in conjunction with the interdisciplinary team must evaluate and document the situation within 7 days to identify and address any contributing and underlying causes of the acute condition and verify the continuing need for an antipsychotic medication.*
3. *If the behaviors persist beyond the emergency situation, pertinent non-pharmacological interventions must be attempted, unless*

clinically contraindicated, and documented following the resolution of the acute psychiatric event.

Additional Criteria:

Enduring Conditions

Antipsychotic medications may be used to treat an enduring (i.e., non-acute; chronic or prolonged) condition, if the clinical condition/diagnosis meets the criteria in Section B above.

In addition, before initiating or increasing an antipsychotic medication for enduring conditions, the target behavior/s must be clearly and specifically identified and documented. Monitoring must ensure that the behavioral symptoms are:

1. *Not due to a medical condition or problem (e.g., pain, fluid or electrolyte imbalance, infection, obstipation, medication side effect or polypharmacy) that can be expected to improve or resolve as the underlying condition is treated or the offending medication(s) are discontinued;*

AND

2. *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;*

AND

3. *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

4. *Persistent. In this case, there must be clear documented evidence in the medical record that the situation or condition continues or recurs over time (persists) and that other approaches that have been attempted have failed to adequately address the behavioral/psychological symptoms and that the resident's quality of life is negatively affected by the behaviors/symptoms as described above.*

New Admissions:
Many residents are admitted to a SNF/NF already on an antipsychotic medication. The medication may have been started in the hospital or the community, which can make it challenging for the facility and clinical team to identify the indication for use. However, the facility is responsible for:

- Preadmission screening for mentally ill and intellectually disabled individuals, and;*
- Obtaining physician’s orders for the resident’s immediate care.*

This PASRR screening (F285) should provide pertinent information including appropriate clinical indications for the use of an antipsychotic.
For residents who do not require PASRR screening and are admitted on an antipsychotic medication, the facility must re-evaluate the use of the antipsychotic medication at the time of admission and/or within two weeks of admission (at the time of the initial MDS assessment) and consider whether or not the medication can be reduced (tapered) or discontinued).

Dosage:
When dosing an antipsychotic, the treatment should be at the lowest possible dose to improve the target symptoms being monitored. It is important to note that doses for acute indications (e.g. delirium or acute psychosis) may differ from those used for long-term treatment of various conditions.

The table below is provided only as a general guide for residents with dementia who have met all of the criteria outlined above. Orders for doses greater than those that appear in the table warrant closer review for adverse effects and risk/benefit evaluation. However, also note that in some cases, residents may require lower doses than those listed on the table. This is an individual, clinical decision based on a number of complex factors. Surveyors are strongly advised to speak with the practitioner/prescriber and/or consultant pharmacist in cases where an antipsychotic medication is prescribed for an elderly resident with dementia.

Daily Dose Thresholds for Antipsychotic Medications Used to Treat Residents with BPSD

Generic <i>Name</i>	Maximum Total Dosage
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	(mg) per day
<i>First Generation or Typical Agents</i>	
chlorpromazine	75
fluphenazine	4
haloperidol	2
loxapine	10
molindone	10
perphenazine	8
thioridazine	75*
thiothixene	7
trifluoperazine	8
<i>Second Generation or Atypical</i>	
aripiprazole	10
clozapine	50
olanzapine	5
quetiapine	150
risperidone	2
ziprasidone	**
<i>paliperidone</i>	**
<i>asenapine</i>	**
<i>iloperidone</i>	**
<i>lurasidone</i>	**
<p>* <i>Due to additional black box warnings of QTC prolongation, its use should be avoided.</i></p> <p>** <i>No studies have been conducted or have results available to assess the drug's safety or efficacy in older adults with dementia.</i></p>	
<p>Duration:</p> <p><i>Refer to Section V – Tapering of a Medication Dose/Gradual Dose Reduction (GDR) in the guidance.</i></p>	

Monitoring:

When monitoring antipsychotics, it is important to not only evaluate ongoing effectiveness and potential adverse consequences, as discussed below, but also to evaluate the use of any other psychopharmacological medications (e.g. mood stabilizers, benzodiazepines) being given to the resident. Specifically, surveyors should review the record to determine whether the facility can explain the rationale for adding, or switching from an antipsychotic to another category (or categories) of psychopharmacological agents; otherwise, both may potentially be unnecessary medications. Surveyors should investigate further in cases where more than one antipsychotic agent has been prescribed. Surveyors should investigate further in cases where more than one antipsychotic agent has been prescribed, or where an antipsychotic has been discontinued and a medication such as a mood stabilizer has been added.

Effectiveness:

After initiating or increasing the dose of an antipsychotic medication, the behavioral symptoms must be reevaluated periodically (at least during quarterly care plan review, but often more frequently, depending on the resident's response to the medication) to determine the effectiveness of the antipsychotic and the potential for reducing or discontinuing the dose based on target symptoms and any adverse effects or functional impairment.

Potential Adverse Consequences:

The facility assures that residents are being adequately monitored for adverse consequences such as:

- General: anticholinergic effects (see Table II), falls, excessive sedation*
- Cardiovascular: cardiac arrhythmias, orthostatic hypotension*
- Metabolic: increase in total cholesterol and triglycerides, unstable or poorly controlled blood sugar, weight gain*
- Neurologic: akathisia, neuroleptic malignant syndrome (NMS), parkinsonism, tardive dyskinesia, cerebrovascular event (e.g., stroke,*

	<p><i>transient ischemic attack (TIA)) in individuals with dementia</i></p> <p><i>If the antipsychotic medication is identified as probably causing or contributing to adverse consequences as identified above, the facility must act upon this. In some cases, the benefits of treatment will still be considered to outweigh the risks or burdens of treatment, so the medication may be continued; however, the facility and prescriber must document the rationale for the decision and also that the resident, family member or legal representative is aware of and involved in the decision to continue the medication.</i></p>
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IV. DEFICIENCY CATEGORIZATION (Part IV, Appendix P)

Once the team has completed its investigation, analyzed the data, reviewed the regulatory requirement, and identified any deficient practice(s) that demonstrate that noncompliance with the regulation at F329 exists, the team must determine the severity of each deficiency, based on the resultant harm or potential for harm to the resident.

The key elements for severity determination for F329 are as follows:

1. Presence of potential or actual harm/negative outcome(s) due to a failure related to unnecessary medications.

Examples of actual or potential harm/negative outcomes for F329 may include, but are not limited to:

- Potential for life-threatening toxicity from excessive dose or lack of indication for the use of digoxin.*
- Complications (such as diarrhea with life threatening fluid loss, nephrotoxicity, hearing loss, or anaphylactic shock) from use of an antibiotic when no clear indication for use has been established or response to the use has not been monitored.*
- Fractures or falls with injury resulting from the continuing use of medications (e.g., hypnotics/sedatives, antipsychotics, antidepressants, antihypertensives) in the presence of predisposing risks or adverse consequences such as persistent dizziness or recurrent falling without intervening or reevaluating the need for and dose of the medication believed to be the cause of the gait instability.*

2. Degree of potential or actual harm/negative outcome(s) due to a failure related to unnecessary medications.

Identify how the facility practices caused, resulted in, allowed, or contributed to the actual or potential for harm:

- If harm has occurred, determine if the harm is at the level of serious injury, impairment, death, compromise, or discomfort; or*
- If harm has not yet occurred, determine how likely is the potential for serious injury, impairment, death, compromise, or discomfort to occur to the resident.*

3. The immediacy of correction required.

Determine whether the noncompliance requires immediate correction in order to prevent serious injury, harm, impairment, or death to one or more residents.

The survey team must evaluate the harm or potential for harm based upon the following levels of severity for tag F329. First, the team must rule out whether Severity Level 4, Immediate Jeopardy to a resident's health or safety, exists by evaluating the deficient practice in relation to immediacy, culpability, and severity. (Follow the guidance in Appendix Q.)

NOTE: *The death or transfer of a resident who was harmed or injured as a result of facility noncompliance does not remove a finding of immediate jeopardy. The facility is required to implement specific actions to remove the jeopardy and correct the noncompliance which allowed or caused the immediate jeopardy.*

Severity Level 4 Considerations: Immediate Jeopardy to Resident Health or Safety

Immediate Jeopardy is a situation in which the facility's noncompliance with one or more requirements of participation:

- Has allowed, caused, or resulted in, or is likely to allow, cause, or result in serious injury, harm, impairment, or death to a resident; and*
- Requires immediate correction, as the facility either created the situation or allowed the situation to continue by failing to implement preventative or corrective measures.*

Examples may include, but are not limited to:

- Failure to assess or respond appropriately for a resident taking warfarin who had an elevated INR of 9 or greater with or without bleeding, or the elevated INR persisted without assessment/follow-up.*
- Failure to monitor PT/INR for a resident on anticoagulant therapy in accordance with current standards of practice and to recognize and/or respond to a life threatening adverse consequence related to anticoagulation.*
- Failure to recognize developing serotonin syndrome (e.g., confusion, motor restlessness, tremor) in a resident receiving a SSRI, 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 gastrointestinal bleeding, 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.*

NOTE: *If immediate jeopardy has been ruled out based upon the evidence, then evaluate whether actual harm that is not immediate jeopardy exists at Severity Level 3.*

Severity Level 3 Considerations: Actual Harm that is Not Immediate Jeopardy

Level 3 indicates noncompliance that resulted in actual harm, and may include, but is not limited to, clinical compromise, decline, or the resident's inability to maintain and/or reach his/her highest practicable well-being. Examples may include, but are not limited to:

- Facility failure to take appropriate action (e.g., suspending administration of the anticoagulant) in response to an INR greater than 4 and less than 9 for a resident who is*

receiving warfarin until spontaneous bruising or frank bleeding occurs, resulting in the need to transfuse or hospitalize the resident.

- Facility failure to evaluate the medication regimen as a potential cause of seizure activity resulting in the addition of anticonvulsants to treat recent-onset seizures that can be adverse consequences of medications.*
- Facility failure to implement a GDR that was not contraindicated in a resident receiving prolonged, continuous antipsychotic therapy resulting in functional decline, somnolence, lethargy, tremors, increased falling, or impaired ambulation.*

***NOTE:** If Severity Level 3 (actual harm that is not immediate jeopardy) has been ruled out based upon the evidence, then evaluate as to whether Severity Level 2 (no actual harm with the potential for more than minimal harm) exists.*

Severity Level 2 Considerations: No Actual Harm with Potential for More Than Minimal Harm that is Not Immediate Jeopardy

Level 2 indicates noncompliance that resulted in a resident outcome of no more than minimal discomfort and/or has the potential to compromise the resident's ability to maintain or reach his or her highest practicable level of well-being. The potential exists for greater harm to occur if interventions are not provided. Examples may include, but are not limited to:

- Facility failure to take appropriate action (e.g., change or suspend administration of the warfarin dose) for a resident who has an INR greater than 4 and less than 9 without any bleeding.*
- Failure to monitor INR for a resident who has been stabilized on warfarin, but who has not had bleeding.*
- Facility failure to identify and act upon minor symptoms of allergic response to medications, such as a rash.*
- Facility failure to monitor for response to therapy or for the emergence or presence of adverse consequences before the resident has experienced an adverse consequence or decline in function (e.g., monitoring periodically for symptoms of behavioral distress in someone receiving psychopharmacological medication; monitoring thyroid function at least annually in an individual receiving thyroid hormone replacement; and monitoring hydration status and basic metabolic profile for a resident receiving diuretics or ACE inhibitors, who had a change in mental status after the onset of diarrhea).*

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

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. Therefore, Severity Level 1 does not apply for this regulatory requirement.

F329 - Additional Example under Investigative Protocol

The following example illustrates the differences between compliance, and non-compliance at severity levels 4, 3 and 2 related to the use of antipsychotic medication when circumstances and outcomes change:

F329 – Compliance Example

An 89 year old male was re-admitted to the nursing home from the hospital. Upon readmission, diagnoses included pneumonia, CHF, and dementia with moderate cognitive decline and delirium with psychotic features. The history from the hospital indicated the resident was treated with antibiotics, fluid replacement, and was placed on an antipsychotic due to the sudden development, one day after admission, of delirium with psychotic features. The resident had a change in cognition, disorientation and was less alert for prolonged periods and had attempted to remove the IV fluids and crawl out of bed. After the resident's infection stabilized, he was discharged back to the nursing home.

Upon readmission to the nursing home, the nurse practitioner contacted the hospitalist by telephone to review the case. They agreed that if the resident did not exhibit signs/symptoms of acute delirium over the next week, it would be reasonable to taper and discontinue the antipsychotic medication. The nurse practitioner communicated this information to the nursing staff and consultant pharmacist – the nursing staff included this information in the plan of care. After a week, no target behaviors were observed. The medication was tapered and discontinued, with ongoing monitoring in place for the potential recurrence of symptoms. The facility has met the criteria for compliance.

F329 - Level 4 Severity Non-compliance Example

An 89 year old male was re-admitted to the nursing home from the hospital. Admitting diagnoses included pneumonia, CHF, and dementia with moderate cognitive decline and delirium with psychotic features. The history from the hospital indicated the resident was treated with antibiotics, fluid replacement, and was placed on an antipsychotic due to the sudden development, one day after admission, of delirium with psychotic features. The resident had a change in cognition, disorientation and was less alert for prolonged periods and had attempted to remove the IV fluids and crawl out of bed. After the resident's infection stabilized, he was discharged back to the nursing home.

Approximately 4 months after nursing home readmission, the resident was still receiving the antipsychotic medication. Staff was monitoring for the identified target behaviors; however, documentation revealed that the resident had not exhibited any of the target behaviors for over 3 months. The facility failed to evaluate and/or consider gradual dose reductions, and had not attempted alternative approaches in an effort to discontinue the medication. The consultant pharmacist had recommended gradual dose reductions, but the physician had indicated that the medication was to be continued.

The record indicated that the resident was exhibiting orthostatic hypotension and was at high risk for falling. In addition, he was no longer attending group activities as he was sleeping off and on throughout the day. Staff had identified that the resident, who had been ambulatory with one staff person at admission, was no longer ambulating, was weaker and was in a recliner in his room during the day and evening. The resident had several areas on his hips and coccyx which were identified as Stage III pressure ulcers; he was losing weight due to decreased appetite and was drinking insufficient amounts of fluids.

When interviewed, staff stated that they believed the resident's decline was related to his dementia. They had not considered reducing or discontinuing the medication and failed to recognize that the medication had been initially ordered for delirium in the hospital, a condition that could potentially be time-limited and in many cases resolves completely.

The facility failed to evaluate for the ongoing indication of use of the antipsychotic after symptoms were no longer present, had not monitored for the presence of adverse consequences, had not attempted gradual dose reductions nor implemented any behavioral interventions. The facility staff had not contacted the medical director to evaluate the resident's response and consider discussing the case with the attending physician. Following additional investigation, it was determined that the quality assessment and assurance (QAA) committee did not conduct any oversight or monitoring of residents who were receiving antipsychotics to assure that there were appropriate clinical indications for use and that behavioral interventions and gradual dose reductions were attempted.

Why is this Immediate Jeopardy?

This resident is now so compromised (he has developed pressure ulcers, has reduced food and fluid intake, is experiencing blood pressure fluctuations and is at risk for falls) that immediate action is required to prevent a serious illness or injury. While immediate jeopardy may exist when only one resident is affected, in this case the lack of systems and processes for review of psychopharmacological medications in residents with dementia indicates that other residents on these medications could potentially be at risk for serious harm as well.

F329 - Level 3 Severity Non-compliance Example

An 89 year old male was re-admitted to the nursing home from the hospital. Admitting diagnoses included pneumonia, heart failure, dementia with moderate cognitive decline and delirium with psychotic features. The history from the hospital indicated the resident was treated with antibiotics, fluid replacement, and was placed on an antipsychotic due to the sudden development, one day after admission, of delirium with psychotic features. The resident had a change in cognition, disorientation and was less alert for prolonged periods and had attempted to remove the IV fluids and crawl out of bed. After the resident's infection stabilized, he was discharged back to the nursing home.

Approximately 3 months after nursing home readmission, the resident was still receiving the antipsychotic medication. The record indicated that the resident was now having difficulty with mobility and was more dependent on staff for ADLs such as bed mobility and transfers. Staff had identified that the resident was in a recliner in his room during the day and evening and was drowsy more often throughout the day. Staff documented that the resident had a small stage II pressure ulcer.

Staff was monitoring the identified target behaviors and documentation revealed the resident had not exhibited the target behaviors for the past 3 months. However, the facility failed to evaluate and/or consider gradual dose reductions, and had not attempted behavioral interventions in an effort to discontinue the medication. Staff failed to recognize that the medication had initially been ordered for delirium in the hospital, a condition that could potentially be time-limited and in many cases resolves completely.

Why is this level 3 Severity?

The staff had not identified/evaluated the causal factors for the ongoing use of the medication, nor the potential that the medication could have been contributing to the resident's decline in ADLs, alertness and skin condition. Staff failed to recognize that the medication had initially been ordered for delirium in the hospital, a condition that could potentially be time-limited and in many cases resolves completely. The facility failed to consider a gradual dose reduction. The resident had actual harm (ADL decline, stage II pressure ulcer) that could have been related to the medication. However, this is not a level 4 severity because the requirement for immediacy is not met.

Level 2 Severity

An 89 year old male was re-admitted to the nursing home sub-acute unit from the hospital. Admitting diagnoses included pneumonia, heart failure, dementia with moderate cognitive decline and delirium with psychotic features. The history from the hospital indicated the resident was treated with antibiotics, fluid replacement, and was placed on an antipsychotic due to the sudden development, one day after admission, of delirium with psychotic features. The resident had a change in cognition, disorientation and was less alert for prolonged periods and had attempted to remove the IV fluids and crawl out of bed. After the resident's infection stabilized, he was discharged back to the nursing home.

Approximately 3 months after admission, the resident was still receiving the antipsychotic medication and staff was monitoring for target behaviors and for the presence of adverse consequences. The record revealed that the resident had not had any adverse consequences and was no longer exhibiting the target behaviors. However, the facility failed to evaluate and/or consider gradual dose reductions, and had not attempted behavioral interventions in an effort to discontinue the medication. Staff failed to recognize that the medication had been initially ordered for delirium in the hospital, a condition that could potentially be time-limited and in many cases resolves completely.

Why is this level 2 Severity?

While the resident is at risk for potential for more than minimal harm from ongoing use of an antipsychotic medication without a clear clinical indication, the staff did not document any actual harm.

This is only one example. Specific evidence may differ in actual situations and surveyors should evaluate each situation individually as no one example applies to every situation.

F332 and F333

(Rev. 127, Issued: 11-26-14, Effective: 11-26-14, Implementation: 11-26-14)

§483.25(m) Medication Errors

The facility must ensure that--

[F332] §483.25(m)(1) It is free of medication error rates of 5 percent or greater; and

[F333] §483.25(m)(2) Residents are free of any significant medication errors.
Interpretive Guidelines §483.25(m) (1) and (2)

Definitions §483.25(m)(1) and (2)

“**Medication Error**” the observed preparation or administration of *medications* or biologicals which is not in accordance with:

1. *The prescriber’s* order;
2. Manufacturer’s specifications (not recommendations) regarding the preparation and administration of the *medication* or biological;
3. Accepted professional standards and principles which apply to professionals providing services. Accepted professional standards and principles include the various practice regulations in each State, and current commonly accepted health standards established by national organizations, boards, and councils.

“**Significant medication error**” means one which causes the resident discomfort or jeopardizes his or her health and safety. Criteria for judging significant medication errors as well as examples are provided under significant and non-significant medication errors. Discomfort may be a subjective or relative term used in different ways depending on the individual situation. (Constipation that is unrelieved by an ordered laxative that results in a *medication* error that is omitted for one day may be slightly uncomfortable or perhaps not uncomfortable at all. When the constipation persists for greater than three days, the constipation may be more significant. Constipation causing obstruction or fecal impaction can jeopardize the resident’s health and safety.)

“**Medication error rate**” is determined by calculating the percentage of medication errors observed during a medication administration observation. The numerator in the ratio is the total number of errors that the survey team observes, both significant and non-significant. The denominator consists of the total number of observations or “opportunities for errors” and includes all the doses the survey team observed being administered plus the doses ordered but not administered. The equation for calculating a medication error rate is as follows:

Medication Error Rate = Number of Errors Observed divided by the Opportunities for Errors (doses given plus doses ordered but not given) X 100.

The error rate must be 5% or greater in order to cite F332. Rounding up of a lower rate (e.g., 4.6%) to a 5% rate is not permitted. A medication error rate of 5% or greater may indicate that the facility has systemic problems with its medication distribution system.

NOTE: *Significant and non-significant medication errors observed at 5% or greater during the Medication Administration Observation task should continue to be cited at F332. However, any **significant** medication error included in the F332 (5% or greater) citation should also be cited at F333. If concerns are identified related to the*

administration of medications at F332-Medication Errors,, then additional requirements may also be considered and investigated such as F425 - Pharmacy Services.

Significant and Non-significant Medication Errors

Determining Significance

The relative significance of medication errors is a matter of professional judgment. Follow three general guidelines in determining whether a medication error is significant or not:

- Resident Condition - The resident's condition is an important factor to take into consideration. For example, a fluid pill erroneously administered to a dehydrated resident may have serious consequences, but if administered to a resident with a normal fluid balance may not. If the resident's condition requires rigid control, a single missed or wrong dose can be highly significant.
- Drug Category - If the *medication* is from a category that usually requires the resident to be titrated to a specific blood level, a single medication error could alter that level and precipitate a reoccurrence of symptoms or toxicity. This is especially important with a *medication* that has a Narrow Therapeutic Index (NTI) (i.e., a *medication* in which the therapeutic dose is very close to the toxic dose). Examples of *medications* with NTI are as follows: Anticonvulsant: phenytoin (Dilantin), carbamazepine (Tegretol), Anticoagulants: warfarin (Coumadin) Antiarrhythmic (digoxin) Lanoxin) Antiasthmatics: theophylline (TheoDur) Antimanic Drugs: lithium salts (Eskalith, Lithobid).
- Frequency of Error - If an error is occurring with any frequency, there is more reason to classify the error as significant. For example, if a resident's *medication* was omitted several times, as verified by reconciling the number of tablets delivered with the number administered, classifying that error as significant would be more in order. This conclusion should be considered in concert with the resident's condition and the *medication* category.

Significant medication errors are cited in the following circumstances:

- *When observed during the medication administration observation. A significant medication error observed during a medication administration observation should be cited, regardless of whether the facility error rate is 5% or greater;*
- *When identified during the course of a resident record review, including a revisit survey or a complaint investigation. A surveyor may cite a deficiency at F333 based upon either a resident record review and/or an observation of a medication preparation or administration. Surveyors must conduct any follow up investigation to obtain corroborating information regarding the error, such as interviews with the nurse, Director of Nursing, or the pharmacist, and document that information and facts as*

required by the Principles of Documentation. Also, it may be necessary to apply the past non-compliance protocol when determining a deficient practice or citation.

Examples of Significant and Non-Significant Medication Errors

Some of these errors are identified as significant. This designation is based on expert opinion without regard to the status of the resident. Most experts concluded that the significance of these errors, in and of themselves, have a high potential for creating problems for the typical long term care facility resident. Those errors identified as non-significant have also been designated primarily on the basis of the nature of the *medication*. Resident status and frequency of error could classify these errors as significant.

Examples of Medication Errors

In the following tables, S=Significant; NS=Not Significant.

Omissions Examples (*Medication* ordered but not administered at least once):

Medication Order	Significance
Quinidine 200mg TID	S
Nitrol Oint. one inch	S
Haldol 1mg BID	NS
Motrin 400mg TID	NS
Tearisol Drops 2 both eyes TID	NS
Metamucil one packet BID	NS
Multivitamin one daily	NS
Mylanta Susp. one oz., TID AC	NS

Unauthorized *Medication* Examples (*Medications* administered without a physician's order):

Medication Order	Significance
Coumadin 4mg	S
Feosol	NS
Zyloprim 100mg	NS
Tylenol 5 gr	NS
Motrin 400mg	NS

Wrong Dose Examples:

Medication Order	Administered	Significance
Digoxin 0.125mg everyday	0.25mg	S
Dilantin 125 SUSP 12ml	2ml	S
Timoptic 0.25% one drop in the left eye TID	Three drops in each eye	NS
Amphojel 30ml QID	15ml	NS

Wrong Route of Administration Examples:

Medication Order	Administered	Significance
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Medication Order	Administered	Significance
Cortisporin Ear Drops 4 to 5 left ear QID	Left Eye	S

Wrong Dosage Form Examples:

Medication Order	Administered	Significance
Dilantin Kapseals 100 mg three Kapseals p.o. HS	Prompt Phenytoin 100 mg three capsules p.o. HS	S*
Colace Liquid 100mg BID	Capsule	NS
Mellaril Tab 10mg	Liquid Concentrate	NS (<i>if correct dose was given</i>)

* Parke Davis Kapseals have an extended rate of absorption. Prompt phenytoin capsules do not.

Wrong Medication Examples:

Medication Order	Administered	Significance
Vibramycin	Vancomycin	S
Tums	Oscal	NS

Wrong Time Examples:

Medication Order	Administered	Significance
Percocet 2 Tabs 20 min. before painful treatment	2 Tabs given after treatment	S
Digoxin 0.25mg daily at 8 a.m.	At 9:30 am	NS

Medication Errors Due to Failure to Follow Manufacturers Specifications or Accepted Professional Standards

Failure to “Shake Well”

The failure to “shake” a *medication* that is labeled “shake well” may lead to an under dose or over dose depending on the product and the elapsed time since the last “shake.” The surveyor should use common sense in determining the adequacy of the shaking of the medication. Some *medications*, for example *phenytoin*, are more critical to achieve correct dosage delivery than others.

- Insulin Suspensions: Also included under this category is the failure to “mix” the suspension without creating air bubbles. Some individuals “roll” the insulin suspension to mix it without creating air bubbles. Any motion used is acceptable so long as the suspension is mixed and does not have air bubbles in it prior to the administration.

Crushed Medications

The crushing of tablets or capsules for which the manufacturer instructs to “do not crush” requires further investigation. Some exceptions to the “Do Not Crush” instruction include:

- If the prescriber orders a *medication* to be crushed which the manufacturer states should not be crushed, the prescriber or the pharmacist must explain, in the clinical record, why crushing the medication will not adversely affect the resident. Additionally, the pharmacist should inform the facility staff to observe for pertinent adverse effects.
- If the facility can provide literature from the *medication* manufacturer or from a reviewed health journal to justify why modification of the dosage form will not compromise resident care.

Giving Adequate Fluids with Medications

Administering medications without adequate fluid when the manufacturer specifies that adequate fluids be taken with the medication *requires further investigation*. If the resident refuses to take adequate fluid, the facility should not be at fault so long as they made a good faith effort to offer fluid, and provided any assistance that may be necessary to drink the fluid. Surveyors should also be aware if a resident is on a fluid restriction, and not apply this standard to residents who are fluid restricted. For example, the surveyor should count fluids consumed during meals or snacks (such as coffee, juice, milk, soft drinks, etc.) as fluids taken with the medication, as long as they have consumed within a reasonable time of taking the medication (e.g., within approximately 30 minutes).

Medications that are recommended to be given with adequate fluid include, but are not limited to:

- Bulk laxatives (e.g., Metamucil, Fiberall, Serutan, Konsyl, Citrucel);
- Nonsteroidal Anti-Inflammatory Drugs (NSAIDs) should be administered with adequate fluid. Adequate fluid is not defined by the manufacturer but is usually four to eight ounces; and
- Potassium supplements (solid or liquid dosage forms) such as: Kaochlor, Klorvess, Kaon, K-Lor, K-Tab, K-Dur, K-Lyte, Slow K, Klotrix, Micro K, or Ten K should be administered with or after meals with a full glass (e.g., approximately 4 - 8 ounces of water or fruit juice). This will minimize the possibility of gastrointestinal irritation and saline cathartic effect. If the resident refuses to take adequate fluid, the facility should not be at fault so long as they made a good faith effort to offer fluid, and provided any assistance that may be necessary to drink the fluid. It is important that the surveyor not apply this rule to residents who are fluid restricted.

Medications that *must be taken with food or antacids*

The administration of medications without food or antacids when the manufacturer specifies that food or antacids be taken with or before the medication is considered a medication error. The

most commonly used *medications* that should be taken with food or antacids are the Nonsteroidal Anti-Inflammatory Drugs (NSAIDs). There is evidence that elderly, debilitated persons are at greater risk of gastritis and GI bleeds, including silent GI bleeds. Determine if the time of administration was selected to take into account the need to give the medication with food.

Examples of commonly used NSAIDs are as follows:

Generic Name	Brand Name
Diclofenac	Voltaren, Cataflam
Diflunisal	Dolobid
Etodolac	Lodine
Fenoprofen	Nalfon
Ibuprofen	Motrin, Advil
Indomethacin	Indocin
Ketoprofen	Orudis, Oruvail
Mefenamic Acid	Ponstel
Nabumetone	Relafen
Naproxen	Naprosyn, Aleve
Piroxicam	Feldene
Sulindac	Clinoril
Tolmetin	Tolectin

Medications Administered Via Enteral Feeding Tubes

The placement of the feeding tube should be confirmed in accordance with the facility's policy.

NOTE: *If the placement of the tube is not checked, it is not a medication error, but should be evaluated under F322, §483.25(g)(1) and (2) – Nasogastric Tubes.*

Determine if the staff member administers each medication separately and flushes the tubing between each medication. An exception would be if there is a physician's order that specifies a different flush schedule because of a fluid restriction. For a resident who requires fluid regulation, the physician's order should include the amount of water to be used for the flushing and administration of medications.

NOTE: *Failure to flush before and in between each medication administration is considered a single medication error and would be included in the facility's medication error rate calculation.*

The administration of enteral nutrition formula and administration of phenytoin (Dilantin) should be separated to minimize interaction. The surveyor should look for appropriate documentation and monitoring if the two are administered simultaneously. If the facility is not aware that there is a potential for an interaction between the two when given together, and is not monitoring for outcome of seizures or unwanted side effects of phenytoin, then the surveyor should consider simultaneous administration a medication error.

Nutritional and Dietary Supplements

Nutritional Supplements are medical foods that are used to complement a resident's dietary needs. Examples of these are total parenteral products, enteral products, and meal replacement products (e.g., Ensure, Glucerna and Promote.)

Herbal and alternative products are considered to be dietary supplements. They are not regulated by the Food and Drug Administration (e.g., they are not reviewed for safety and effectiveness like medications) and their composition is not standardized (e.g., the composition varies among manufacturers). If a dietary supplement that is given to a resident between meals and has a vitamin(s) as one or more of its ingredients, it should be documented and evaluated as a dietary supplement, rather than a medication. For clinical purposes, it is important to document a resident's intake of such substances elsewhere in the clinical record and to monitor their potential effects, as they can interact with other medications.

NOTE: *Because nutritional and dietary supplements are not considered to be medications for purposes of the medication administration observation, noncompliance with the administration of these products should not be included in the calculation of the facility's medication error rate at F332 or as a significant medication error at F333. Medication errors involving vitamins and/or minerals should be documented at F332 and counted towards the error rate calculation. Medication errors involving vitamins and minerals would not be considered to be a significant medication error unless the criteria at F333 were met.*

It is expected that the facility staff, along with the prescriber and consulting pharmacist, are aware of, review for, and document any potential adverse consequences between medications, nutritional supplements, and dietary supplements that a resident is receiving.

Medications Instilled into the Eye

When observing the administration of eye drops, confirm that the medication makes full contact with the conjunctival sac, so that the medication is washed over the eye when the resident closes eyelid. The eye drop must contact the eye for a sufficient period of time before the next eye drop is instilled. The time for optimal eye drop absorption is approximately 3 to 5 minutes. (It should be encouraged that when the procedures are possible, systemic effects of eye medications be reduced by pressing the tear duct for one minute after eye drop administration or by gentle eye closing for approximately three minutes after the administration.)

Sublingual Medications

If the resident persists in swallowing a sublingual tablet (e.g., nitroglycerin) despite efforts to train otherwise, the facility should endeavor to seek an alternative dosage form for this *medication*.

Metered Dose Inhalers (MDI)

Ensuring that a device is administered correctly is vital to optimizing inhalation therapy. The surveyor would observe the administration of MDIs for the following:

- o Shake the container well;
- o Position the inhaler in front of or in the resident's mouth. Alternatively a spacer *or valved holding chamber* may be used;
- o For cognitively impaired residents, many clinicians believe that the closed mouth technique is easier for the resident and more likely to be successful. However, the open mouth technique often results in better and deeper penetration of the medication into the lungs, when this method can be used.
- o If more than one puff is required (whether the same medication or a different medication), *follow the manufacturer's product information for administration instructions including the acceptable wait time between inhalations.*

NOTE: If the person administering the *medication* follows all the procedures outlined above, and there is a failure to administer the medication because the resident can't cooperate (for example, a resident with dementia may not understand the procedure), this should not be counted as a medication error. The surveyor should evaluate the facility's responsibility to assess the resident's circumstance, and possibly attempt other dosage forms such as oral dosage forms or nebulizers.

Determining Medication Errors

Timing Errors

If a *medication* is ordered before meals (AC) and administered after meals (PC), always count this as a medication error. Likewise, if a *medication* is ordered PC and is given AC, count as a medication error. Count a wrong time error if the *medication* is administered 60 minutes earlier or later than its scheduled time of administration, **BUT ONLY IF THAT WRONG TIME ERROR CAN CAUSE THE RESIDENT DISCOMFORT OR JEOPARDIZE THE RESIDENT'S HEALTH AND SAFETY.** Counting a *medication* with a long half-life (e.g., digoxin) as a wrong time error when it is 15 minutes late is improper because this *medication* has a long half-life (beyond 24 hours) and 15 minutes has no significant impact on the resident. The same is true for many other wrong time errors (except AC AND PC errors).

To determine the scheduled time, examine the facility's policy relative to dosing schedules. The facility's policy should dictate when it administers a.m. doses, or when it administers the first dose in a 4-times-a-day dosing schedule.

Prescriber's Orders

The latest recapitulation of *medication* orders is sufficient for determining whether a valid order exists provided the prescriber has signed the "recap." The signed "recap," if the facility uses the "recap" system and subsequent orders constitute a legal authorization to administer the *medication*.

Omitted Dose

One of the most frequent types of errors is an omitted dose, *i.e. a dose of medication that is ordered but not given*. If a surveyor detects an omitted dose, investigate the omission further:

- Ask the person administering *medications*, if possible, to describe the system for administering the *medications* given. Occasionally, a respiratory therapist may administer inhalers, a designated treatment person may only administer topical treatments, a hospice nurse may administer hospice medications, another person may administer eye drops or as needed *medications*, etc.
- Sometimes people may share medication carts. Under these circumstances, these individuals should be interviewed about the omitted dose, if they were involved, if possible.
- When persons that were actually responsible for administering the *medications* are not available, ask their supervisor for clarification.

Procedures §483.25(m) (1) and (2)

Medication *Administration Observation* Methodology

The survey team should observe the administration of *medications*, on several different *medication* "passes," when necessary. Record what is observed; and reconcile the record of observation with the prescriber's *medication* orders to determine whether or not medication errors have occurred.

Do not rely solely on a paper review to determine medication errors. Detection of blank spaces on a medication administration record does not constitute the detection of actual medication errors. Paper review only identifies possible errors in most cases. In some cases paper review can help identify actual errors but research has shown that the procedure is time consuming for the number of actual errors detected.

Observation Technique

The survey team must know without doubt, what *medications*, in what strength, and dosage forms, are being administered. This is accomplished prior to *medication* administration and may be done in a number of ways depending on the *medication* distribution system used (e.g. unit dose, vial system, punch card). *Refer to Medication Administration Observation and Pharmacy Services in Appendix P for additional information related to the Medication Administration Observation.*

1. Identify the *medication*. There are two principal ways to do this. In most cases, they are used in combination:
 - Identify the *medication* by its size, shape, and color. Many *medications* are identifiable by their distinctive size, shape, or color. This technique is problematic because not all *medications* have distinctive sizes, shapes, or color.
 - Identify the *medication* by observing the label. When the punch card or the unit dose system is used, the survey team can usually observe the label and adequately identify the *medication*. When the vial system is used, observing the label is sometimes more difficult. Ask the nurse to identify the medication being administered.
2. Observe and record the administration of *medications* (“pass”). Follow the person administering *medications* and observe residents receiving *medications* (e.g., actually swallowing oral dosage forms). Be neutral and as unobtrusive as possible during this process.
 - Make every effort to observe residents during several different *medication* “passes,” if possible, so the survey team will have an assessment of the entire facility rather than one staff member on one *medication* pass.
 - Identifying residents can present a problem. The surveyor should ask appropriate staff to explain the facility policy or system for the identification of residents.
 - *Multiple tablets or capsules required to deliver a dose of medication count as one observation;*
 - *Observe infection prevention practices by staff administering medications, including the procedures used for insulin pens and single dose vial use. If the caregiver fails to observe appropriate infection control and prevention standards of practice, it should also be evaluated under F441, Preventing the Spread of Infection/Indirect Transmission.*
3. Reconcile the surveyor’s record of observation with physician’s orders. Compare the record of observation with the most current orders for *medications*. This comparison involves two distinct activities:
 - For each *medication* on the surveyor’s list: Was it administered according to the prescriber’s orders? For example, in the correct strength, by the correct route? Was there a valid order for the *medication*? Was the *medication* the correct one?

- For *medications* not on the surveyor's list: Are there orders for *medications* that should have been administered, but were not? Examine the record for *medication* orders that were not administered and should have been. Such circumstances may represent omitted doses, one of the most frequent types of errors.

Do not rely solely on a paper review of the *Medication Administration Record (MAR)* to determine medication errors. Detection of blank spaces on a *MAR* does not constitute the detection of actual medication errors. Paper review only identifies possible errors in most cases.

The surveyor should now have a complete record of what was observed and what should have occurred according to the prescribers' orders. Determine the number of errors by adding the errors on each resident. Before concluding for certain that an error has occurred, discuss the apparent error with the person who administered the *medications* if possible. There may be a logical explanation for an apparent error. For example, the surveyor observed that a resident had received Lasix 20 mg, but the order was for 40 mg. This was an apparent error in dosage. But the nurse showed the surveyor another more recent order which discontinued the 40 mg order and replaced it with a 20 mg order.

4. Reporting Errors -- Describe to the facility each error that the survey team detects (e.g., Mary Jones received digoxin in 0.125 instead of 0.25 mg). The survey team is not required to analyze the errors and come to any conclusions on how the facility can correct them. Do not attempt to categorize errors into various classifications (e.g., wrong dose, wrong resident). Stress that an error occurred and that future errors must be avoided.
5. Observe Many Individuals Administering Medications. Strive to observe as many individuals administering medications as possible. This provides a better picture of accuracy of the facility's entire *medication* distribution system.

Dose Reconciliation Technique Supplement to the Observation Technique -- When an omission error has been detected through the observation technique, the dose reconciliation technique can sometimes enable the survey team to learn how frequently an error has occurred in the past. Learning about the frequency of an error can assist in judging the significance of the error. (See Significant and Non-Significant Medication Errors above.) The dose reconciliation technique requires a comparison of the number of doses remaining in a supply of *medications* with the number of days the *medication* has been in use and the directions for use. For example, if a *medication* were in use for 5 days with direction to administer the *medication* 4 times a day, then 20 doses should have been used. If a count of the supply of that *medication* shows that only 18 doses were used (i.e., two extra doses exist) and no explanation for the discrepancy exists (e.g., resident refused the dose, or resident was hospitalized), then two omission errors may have occurred.

Use the dose reconciliation technique in facilities that indicate the number of *medications* received, and the date and the specific "pass" when that particular *medication* was started. Unless this information is available, do not use this technique. If this information is not available, there is no Federal authority under which the survey team may require it, except for controlled drugs.

F371

(Rev. 127, Issued: 11-26-14, Effective: 11-26-14, Implementation: 11-26-14)

§483.35(i) - Sanitary Conditions

The facility must –

§483.35(i)(1) - Procure food from sources approved or considered satisfactory by Federal, State or local authorities; and

§483.35(i)(2) - Store, prepare, distribute and serve food under sanitary conditions

INTENT: (Tag F371) 42 CFR 483.35(i) Sanitary Conditions

The intent of this requirement is to ensure that the facility:

- Obtains food for resident consumption from sources approved or considered satisfactory by Federal, State or local authorities; and
- 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.

DEFINITIONS

Definitions are provided to clarify terms related to sanitary conditions and the prevention of foodborne illness.

- **“Cross-contamination”** refers to 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”** refers to 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”** refers to storing/maintaining dry foods (canned goods, flour, sugar, etc.) and supplies (disposable dishware, napkins, and kitchen cleaning supplies).
- **“Food Contamination”** refers to the unintended presence of potentially harmful substances, including, but not limited to microorganisms, chemicals or physical objects in food. ²

- **“Food Preparation”** refers to the series of operational processes involved in getting foods ready for serving, such as: washing, thawing, mixing ingredients, cutting, slicing, diluting concentrates, cooking, pureeing, blending, cooling, and reheating.
- **“Food Service/Distribution”** refers to the processes involved in getting food to the resident. This may include holding foods hot on the steam table or under refrigeration for cold temperature control, dispensing food portions for individual residents, family style and dining room service, or delivering trays to residents’ rooms or units, etc.
- **“Foodborne Illness”** refers to illness caused by the ingestion of contaminated food or beverages.
- **“Highly Susceptible Population”** refers to persons who are more likely than the general population to experience foodborne illness because of their susceptibility to becoming ill if they ingest microorganisms or toxins. Increased susceptibility may be associated with immuno-compromised health status, chronic disease and advanced age. *The Food and Drug Administration’s Food Code (Section 3-801.11) includes nursing facilities in its definition of a “highly susceptible population.”*
- **“Pathogen”** refers to an organism capable of causing a disease (e.g., pathogenic bacteria or viruses).
- **“Potentially Hazardous Food (PHF)”** or “Time/Temperature Control for Safety (TCS) Food” refers to food that requires time/temperature control for safety to limit the growth of pathogens or toxin formation.
- **“Ready-to-Eat Food”** refers to food that is edible with little or no preparation to achieve food safety. It includes foods requiring minimal preparation for palatability or culinary purposes, such as mixing with other ingredients (e.g., meat type salads such as tuna, chicken, or egg salad).
- **“Storage”** refers to the retention of food (before and after preparation) and associated dry goods.
- **“Toxins”** refer to poisonous substances that are produced by living cells or organisms (e.g., pathogenic bacteria) that cause foodborne illness when ingested.

OVERVIEW

Nursing home residents risk serious complications from foodborne illness as a result of their compromised health status. Unsafe food handling practices represent a potential source of pathogen exposure for residents. Sanitary conditions must be present in health care food service settings to promote safe food handling. *CMS recognizes the U.S. Food and Drug Administration’s (FDA) Food Code and the Centers for Disease Control and Prevention’s (CDC) food safety guidance as national standards to procure, store, prepare, distribute and serve food in long term care facilities in a safe and sanitary manner.*

Effective food safety systems involve identifying hazards at specific points during food handling and preparation, and identifying how the hazards can be prevented, reduced or eliminated. It is important to focus attention on the risks that are associated with foodborne illness by identifying critical control points (CCPs) in the food preparation processes that, if not controlled, might result in food safety hazards. Some operational steps that are critical to control in facilities to

prevent or eliminate food safety hazards are thawing, cooking, cooling, holding, reheating of foods, and employee hygienic practices.

Web sites for additional information regarding safe food handling to minimize the potential for foodborne illness include:

- National Food Safety Information Network's Gateway to Government Food Safety Information at <http://www.FoodSafety.gov>;
- United States Food & Drug Administration Food Code Web site at <http://www.cfsan.fda.gov/~dms/primecon.html>;
- United States Food & Drug Administration Hazard Analysis Critical Control Point <http://www.cfsan.fda.gov/~dms/hret2toc.html>, (Operator's Manual) and <http://www.cfsan.fda.gov/~dms/hret3toc.html> (Regulator's manual).

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

TYPES OF FOOD CONTAMINATION

Food contaminants fall into 3 categories: biological, chemical, and physical.

Biological Contamination

Biological contaminants 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.

- **Pathogenic Bacteria** - Not all bacteria in food cause illness in humans. For example, live cultures of Lactobacillus bacteria are added to yogurt to enhance digestion. However, some bacteria can be pathogenic and thus may cause illness or death (e.g., some strains of Escherichia Coli). It is vital to control the growth of bacteria during food storage and preparation because raw or uncooked food may naturally contain pathogenic organisms (e.g., Salmonella in poultry).

Several factors which may influence the growth of bacteria include:

- 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, inhibits bacterial growth;

- o Water percentage of the food. Foods that have a high level of water (e.g., fruits and vegetables) encourage bacterial growth; and
- o 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, refried beans, grilled sautéed onions, or baked potatoes).

- **Viruses** - Viruses cannot reproduce without a living host (animal or human). While they cannot reproduce in or on food, viruses may survive long enough in or on a food to be transmitted to a new host. Two viruses that are well known for being spread by poor food handling practices are Hepatitis A and Norovirus (formerly known as Norwalk virus).
- **Toxins** - Toxins are poisonous substances that come from a variety of sources. Some pathogens (e.g., *Staphylococcus aureus* and *Clostridium botulinum*) produce toxins as a byproduct of their growth. Most toxins are not destroyed by high temperatures. A PHF/TCS food that is allowed to remain in the danger zone long enough for the bacteria to produce toxins will become unsafe to eat.
- **Spores** - A spore is an inactive form of an organism that is highly resistant to extreme temperatures, acidity, and dehydration. The organism is reactivated once conditions become favorable for its growth. Two common spore-forming pathogens are *Bacillus cereus* and *Clostridium botulinum*. Temperature control is the way to minimize the danger associated with spore-forming organisms.

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. It is recommended that chemical products including, but not limited to cleaning supplies, be stored separately from food items.

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 of bones.

FACTORS IMPLICATED IN FOODBORNE ILLNESSES

Many pathogens contribute to foodborne outbreaks in facilities. Several factors that cause pathogen growth include, but are not limited to:

- Poor Personal Hygiene - Employee health and hygiene are significant factors in preventing foodborne illness. This has been demonstrated in the population at large³, commercial food service establishments⁴, and in nursing facilities⁵. Foodborne illness in nursing homes has been associated with Norovirus. Because "infectious" individuals (persons capable of transmitting an infection or communicable disease whether they be colonized or infected) are a source of Norovirus, proper hand washing techniques and exclusion of infectious workers from handling food are critical for prevention of foodborne illness.
- Inadequate Cooking and Improper Holding Temperatures - Poorly cooked food promotes the growth of pathogens that may cause foodborne illness. The PHF/TCS foods require adequate cooking and proper holding temperatures to reduce the rapid and progressive growth of illness producing microorganisms, such as Salmonellae and Clostridium botulinum.
- 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 - Unsafe food sources are sources not approved or considered satisfactory by Federal, State, or local authorities. Nursing homes are not permitted to use home-prepared or home-preserved (e.g., canned, pickled) foods for service to residents⁶.

NOTE: The food procurement requirements for facilities are not intended to restrict resident choice. All residents have the right to accept food brought to the facility by any visitor(s) for any resident.

Pathogenic Microorganisms and Strategies for their Control

The table below illustrates the more commonly identified ingestible items which have been associated with the listed illness-producing organisms. The primary agents are the organisms

that have been associated with the ingestible food source⁷. Further, the primary control strategies list the preventive actions to inhibit the growth of these organisms.

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, raw or unpasteurized	<ul style="list-style-type: none"> • Salmonella 	<ul style="list-style-type: none"> • PHF/TCS • Cook <i>until all parts of the egg are completely firm</i> • Prevention of cross-contamination to ready-to-eat 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 ready-to-eat 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 ready-to-eat 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 ready-to-eat foods
	<ul style="list-style-type: none"> • Staphylococcus aureus 	<ul style="list-style-type: none"> • PHF/TCS • Proper hand-washing procedures • Avoid bare-hand contact with ready-to-eat foods
B. Hazards that may occur as a result of adulteration of food products, and for which good food handling practices are needed to minimize the potential for foodborne illness transmission.		
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 prior to use (unless pre-washed) • 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 according to manufacturers' guidelines

PREVENTION OF FOODBORNE ILLNESS

Food Handling and Preparation

Proper food preparation, storage, and handling practices are essential in preventing foodborne illness. Education, training, and monitoring of all staff and volunteers involved in food service, as well as establishing effective infection control and quality assurance programs help maintain safe food handling practices.

Approaches to create a homelike environment or to provide accessible nourishments may include a variety of unconventional and non-institutional food services. Meals or snacks may be served at times other than scheduled meal times and convenience foods, ready-to-eat foods, and pre-packaged foods may be stored and microwave heated on the nursing units. Whatever the approach, it is important that staff follow safe food handling practices.

Employee Health

Employees who handle food must be free of communicable diseases and infected skin lesions. (See the requirement at 42 CFR 483.65(b) (2) regarding preventing the spread of infection.) Bare hand contact with foods is prohibited.

Hand Washing, Gloves, and Antimicrobial Gel

Since the skin carries microorganisms, it is critical that staff involved in food preparation consistently utilize good hygienic practices and techniques. Staff should have access to proper hand washing facilities with available soap (regular or anti-microbial), hot water, and disposable towels and/or heat/air drying methods. Antimicrobial gel (hand hygiene agent that does not require water) cannot be used in place of proper hand washing techniques in a food service setting⁸.

The appropriate use of utensils such as gloves, tongs, deli paper and spatulas is essential in preventing foodborne illness. Gloved hands are considered a food contact surface that can get contaminated or soiled. Failure to change gloves between tasks can contribute to cross-contamination. Disposable gloves are a single use item and should be discarded after each use.

NOTE: The use of disposable gloves is not a substitute for proper hand washing with soap and water.

Hair Restraints/Jewelry/Nail Polish

Dietary staff must wear hair restraints (e.g., hairnet, hat, and/or beard restraint) to prevent their hair from contacting exposed food. Dietary staff maintaining nails that are clean and neat, and wearing intact disposable gloves in good condition, and that are changed appropriately will also help reduce the spread of microorganisms. Since jewelry can harbor microorganisms, it is recommended that dietary staff keep jewelry to a minimum and cover hand jewelry with gloves when handling food⁹.

Food Receiving and Storage

When food is brought into the nursing home, inspection for safe transport and quality upon receipt and proper storage helps ensure its safety. Keeping track of when to discard perishable foods and covering, labeling, and dating all foods stored in the refrigerator or freezer is indicated.

When food is brought into the facility from an off-site kitchen (any kitchen that is not operated by the facility) and the food preparation entity is approved or considered satisfactory by and is inspected by other federal, State, or local authorities, verify the last approved inspection of the supplier and continue to inspect the facility for safe food handling and storage and food quality.

- **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, rodent and insect infestation helps prevent deterioration or contamination of the food. Dry foods and goods should be handled and stored to maintain 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.

Keeping food off the floor and clear of ceiling sprinklers, sewer/waste disposal pipes, and vents can also help 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 animal 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.

NOTE: Chemical products, including, but not limited to cleaning supplies, should be stored away from food items.

Safe Food Preparation

Many steps in safe food preparation must be controlled or 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 prevent foodborne illness.

Commercially pre-washed, pre-cut, and pre-packaged lettuce and other fruits and vegetables are considered edible without further preparation.

- **Cross-Contamination** - Cross-contamination can occur when harmful substances or disease-causing microorganisms are transferred to food by hands, food contact surfaces, sponges, cloth towels, or utensils that are not cleaned after touching raw food and then touch ready-to-eat goods. 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 (see Manual Washing and Sanitizing section). Periodically testing the sanitizing solution helps assure that it maintains the correct concentration¹⁰.

Wash and sanitize cutting boards made of acceptable materials (e.g., hardwood, acrylic) between uses, consistent with applicable code¹¹, and
 - Clean and sanitize work surfaces and food-contact equipment (e.g., food processors, blenders, preparation tables, knife blades, can openers, and slicers) between uses.
- **Thawing** - Thawing frozen foods is often the first step in food preparation. Thawing food at room temperature is not acceptable because the food is 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** - Cooking is a critical control point in preventing foodborne illness. Cooking to heat all parts of 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 for 15 seconds determines when microorganisms can no longer survive and food is safe for consumption.

- Foods should reach the following internal temperatures:
 - Poultry and stuffed foods - 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 meats - 145 degrees F for 15 seconds;
 - Unpasteurized eggs when cooked to order in response to resident request and to be eaten promptly after cooking *must be cooked until all parts of the egg are completely firm*;
 - When cooking raw animal foods in the microwave, foods should be rotated and stirred during the cooking process so that all parts of the food 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 animal 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 the 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.
- **Pooled 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. Salmonella infections associated with unpasteurized eggs can be prevented by using pasteurized shell eggs or *be substituted for raw 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 toast¹².

The U.S. Department of Agriculture, Food Safety and Inspection Service, Salmonella Enteritidis (SE) Risk Assessment states "A partial list of persons with increased susceptibility to infectious agents includes persons with chronic diseases, and nursing home residents. The elderly are particularly susceptible to infectious agents such as SE for a number of reasons. The disproportionate impact of severe complications and death from Salmonellosis in the elderly is illustrated by epidemiologic evidence." Waivers to allow undercooked unpasteurized eggs for resident preference are not acceptable. Pasteurized shell eggs are available and allow for safe consumption of undercooked eggs.

NOTE: Raw eggs with damaged shells are also unsafe because of the potential for contamination.

Food Service and Distribution

Various systems are available for serving and distributing food items to residents. These include but are not limited to tray lines, portable steam tables transported to a unit or dining area, open shelved food transport carts with covered trays, or enclosed carts that have hot and cold compartments. Some systems incorporate a heating element (pellet) under each plate of hot food. The purpose of these systems is to provide safe holding and transport of the food to the resident's location. Food safety requires consistent temperature control from the tray line to transport and distribution to prevent contamination (e.g., covering food items). The length of time needed to transport trays is more critical when the food is simply covered and transported in open or closed carts without a heated and cooled environment.

- **Tray line and Alternative Meal Preparation and Service Area** - The tray line may include, but is not limited to the steam table where hot prepared foods are held and served, and the chilled area where cold foods are held and served. A resident's meal tray may consist of a combination of foods that require different temperatures. Food preparation or service area problems/risks to avoid include, but are not limited to:
 - Holding foods in danger zone temperatures which are between 41 degrees F and 135 degrees F;
 - Using the steam table to heat food;
 - Serving meals on soiled dishware and with soiled utensils; and
 - Handling food with bare hands or improperly handling equipment and utensils.

The maximum length of time that foods can be held on a steam table is a total of 4 hours. Monitoring of the temperature by food service workers while food is on the steam table is essential. Foods may be reheated (only once) to 165 degrees F. Reheated foods are best discarded if not eaten within two hours after reheating¹³.

Food Distribution - Dining locations include any area where one or more residents eat their meals. These can be located adjacent to the kitchen or a distance from the kitchen, such as residents' rooms and dining rooms in nursing units on other floors or wings of the building. Potential food handling problems/risks associated with food distribution include:

- Staff distributing trays without first properly washing their hands; and
- Serving food to residents after collecting soiled plates and food waste, without proper hand washing.

Snacks - Snacks refer to those foods that are 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; or stored at the nursing station, in a unit refrigerator or unit cupboards. 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;

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.

***Nursing Home Gardens** – Nursing homes with gardens are compliant with the food procurement requirements as long as the facility has and follows policies and procedures for maintaining the gardens. The facility should immediately report any outbreaks of food borne illnesses, for any cause, to their local health department.*

NOTE: *If there are local or State requirements related to food grown on the facility grounds for resident consumption, facilities are to be in compliance with the specific State requirement.*

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 prevent 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 who use poor hygiene, fail to wash hands adequately, or handle ice with their bare hands are not following appropriate infection control practices when dispensing water and 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.

Refrigeration - A potential cause of foodborne illness is improper storage of PHF/TCS food. The refrigerator must be in good repair and keep foods at or below 41 degrees F. 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 that has been inside for at least 24 hours 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.

EQUIPMENT AND UTENSIL CLEANING AND SANITIZATION

A potential cause of foodborne outbreaks is improper cleaning (washing and sanitizing) of contaminated equipment. Protecting equipment from contamination via splash, dust, grease, etc. is indicated. Dishwashing machines, operated according to the manufacturer specifications,

wash, rinse, and sanitize dishes and utensils using either heat or chemical sanitization. Manual dishwashing is often used for pots and pans, or when the dishwashing machine is not operational.

Machine Washing and Sanitizing

Dishwashing machines use either heat or chemical sanitization methods. The following are specifications according to the U.S. Department of Health and Human Services, Public Health Services, Food and Drug Administration Food Code (or according to manufacturer's directions) for each method.

- High Temperature Dishwasher (heat sanitization):
 - o Wash 150-165 degrees F wash; and
 - o Final Rinse 180 degrees F final rinse (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):
 - o Wash 120 degrees F wash; and
 - o Final Rinse 50 ppm (parts per million) hypochlorite (chlorine) on dish surface in final rinse.

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. 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, and for the effective contact time according to manufacturer's guidelines.

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. If explicit instructions are not provided by the manufacturer, the recommended sanitization concentrations are as follows:
 - o Chlorine 50-100 ppm minimum 10 second contact time
 - o Iodine 12.5 ppm minimum 30 second contact time

- o QAC space (Quaternary) 150-200 ppm concentration and contact time per Manufacturer's instructions (Ammonium Compound)

A high concentration of sanitation solutions may be potentially hazardous (see manufacturer's instructions). 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 are washed and sanitized and non-removable parts are 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.

ENDNOTES

¹ The Partnership for Food Safety and Education. (2006). Food Safety Glossary. Retrieved September 25, 2006 from <http://www.fightbac.org/content/view/15/22/>

² The Partnership for Food Safety and Education. (2006). Food Safety Glossary. <http://www.cdc.gov/mmwr/preview/mmwrhtml/ss4901a1.htm>

³ Mead, P.S., Slutsker, L., Dietz, V., McCaig, L.F., Bresee, J.S., Shapiro, C., Griffin, P.M., & Tauxe, R.V. (1999). Food-related illness and death in the United States. *Emerging Infectious Diseases*, 5(5), 607-625

⁴ Hedberg, C.W., Smith, S.J., Kirkland, E., Radke, V., Jones, T.F., Selman, C.A., & EHS-NET Working Group. (2006). Systematic environmental evaluations to identify food safety differences between outbreak and non-outbreak restaurants. *Journal of Food Protection*, 69(9). Need Pages

⁵ Centers for Disease Control and Prevention Outbreak Surveillance Data. (2006). Annual Listing of Foodborne Disease Outbreaks, United States, 1990-2004. Retrieved September 25, 2006 from http://www.cdc.gov/foodborneoutbreaks/outbreak_data.htm

⁶ U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration. (2005). Code (p. 48).

⁷ International Association of Food Protection. (1999). *Procedures to Investigate Foodborne Illness* (5th edition). Des Moines, IA: Author. [Prepared by the Committee on Communicable Diseases Affecting Man.]

⁸ U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration. (2005). Food Code (p. 43).

⁹ U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration. (2005). Food Code (pp. 43-45).

¹⁰ U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration. (2005). Food Code (p. 66).

¹¹ U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration. (2005). Food Code (pp. 103-104; 123).

¹² U.S. Food and Drug Administration Food Code
<http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/ucm374275.htm>.
Section 3-801.11(B).

¹³ U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration. (2005). Food Code (p. 114).

INVESTIGATIVE PROTOCOL

SANITARY CONDITIONS

Objectives

- To determine if the facility obtained food safe for consumption from approved sources;
- To determine if the facility stores, prepares, distributes, and serves food in a sanitary manner to prevent foodborne illness;
- To determine 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
- To determine 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.

Use

Use this protocol to investigate compliance at F371 (§483.35(i) (1) and (2)).

Procedures

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. During the initial tour of the facility and throughout the survey, observe the kitchen(s) and food service area(s) and review planned menus to determine when to assess food preparation processes. Observe subsequent kitchen/food services during times when food is being stored, prepared, cooked, plated, transported, and distributed to determine if safe food handling practices are being followed. Corroborate observations through interview, record review, and other appropriate documentation.

NOTE: When a facility receives food from an off-site kitchen (any kitchen not operated by the facility), determine whether the food was obtained from an approved source.

1. Observation

Conduct the following observations:

- Food procurement procedures:
 - o Determine whether food meets safe and sanitary conditions related to when, where, and how the food was received for residents consumption.
 - o Check invoices from food vendors when necessary to verify the source of food acquisition and the date of delivery.
- Food preparation procedures:
 - o Observe staff food handling practices, such as proper hand washing, the appropriate use of utensils, glove, and hairnets;

- o Observe food labeling and dates (e.g., used by dates);
- o 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);
- o If the facility is cooking a PHF/TCS food, evaluate if the food reached the acceptable final cooking temperatures, by inserting the stem of a calibrated thermometer into the middle or thickest part of the food;
- o If a PHF/TCS food is prepared from ingredients at room temperature, determine if it was cooled to 41 degrees F within 4 hours. For example, when observing tuna or chicken salad preparation, determine when the salad was prepared, then measure the current temperature; and
- o Observe staff preparing modified consistency (e.g., pureed, mechanical soft) PHF/TCS foods to determine whether food safety was compromised.
- o *Observe the facility's egg products to determine if the facility is using pasteurized shell eggs, liquid pasteurized eggs or unpasteurized shell eggs. If the staff is preparing resident requests for soft cooked and undercooked eggs (i.e. sunny side up, soft scrambled, soft boiled), determine if pasteurized shell eggs, liquid pasteurized eggs or unpasteurized shell eggs were used.*

Service of food during meal times -

- Observe the staff measuring the temperature of all hot and cold menu items. Cold foods should be at or below 41 degrees F when served. Hot foods should be at 135 degrees F or above when served.

Service after meal times:

- Observe whether facility personnel are operating the dish washing machine according to the manufacturer's specifications. Evaluate sanitization with a calibrated thermometer (for a high temperature machine), chlorine test tape (for a low temperature machine), or other manufacturer recommended method;
- Check whether the facility has the appropriate equipment and supplies to evaluate the safe operation of the dish machine and the washing of pots and pans (e.g., maximum registering thermometer, appropriate chemical test strips, and paper thermometers);
- Evaluate sanitization during manual pot and pan washing (3-step process). Test the final rinse water temperature if using hot water for sanitization or the concentration of chemical sanitizer being used. Determine if the appropriate test strip for that chemical is being utilized;

- 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.

Storage of food:

- Observe for evidence of pests, rodents and droppings and other sources of contamination in food storage areas;
- Observe food labeling and dates (e.g., used by dates);
- Observe that foods are stored off of the floor, and clear of ceiling sprinklers, sewer/waste disposal pipes and cleaning chemicals;
- Observe whether the facility has canned goods that have a compromised seal (e.g., punctures); and
- Observe whether staff access bulk foods without touching the food.

2. Interview

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. Request clarification from the dietary supervisor/manager or qualified dietitian concerning the following:

- 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;
- How does the facility identify problems with time and temperature control of PHF/TCS foods and what are the processes to address those problems;
- 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.
- *Is the facility aware of current CDC and FDA nursing home egg handling and preparation polices and does the facility have written egg storage and preparation policies that honor resident preferences safely.*

3. 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. Determine if the food service employees have received training related to such compliance;
- Food temperature records from the tray line, refrigerator/freezer temperature records, and dishwasher records;
- Maintenance records, such as work orders and manufacturer's specifications, related to equipment used to store, prepare, and serve food; and
- Facility infection control records regarding surveillance for foodborne illness and actions related to suspected or confirmed outbreaks of gastrointestinal illnesses.
- *The policies and procedures for maintaining nursing home gardens should be reviewed, if there is an outbreak of food borne illness and the facility's primary food service has been ruled out as the cause of the outbreak.*

4. 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 (e.g., refrigerator or dishwasher malfunction);
- 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.
- *Identify if negative outcomes are the result of system failure by interviewing dietary managers and staff to ascertain egg storage and preparation.*

DETERMINATION OF COMPLIANCE (TASK 6, APPENDIX P)

Synopsis of Regulation (F371)

The sanitary conditions requirement has two aspects. The first aspect requires that the facility procures food from sources approved or considered satisfactory by Federal, State, or local authorities. The second aspect requires that the facility stores, prepares, distributes, and serves food under sanitary conditions to prevent foodborne illness.

Criteria for Compliance

The facility is in compliance with 42 CFR 483.35(i) (1)(2), Sanitary Conditions, if staff:

- Procures, stores, handles, prepares, distributes, and serve food to minimize the risk of foodborne illness;
- Maintains PHF/TCS foods at safe temperatures, cools food rapidly, and prevents contamination during storage;
- Cooks food to the appropriate temperature and holds PHF/TCS food at or below 41 degrees F or at or above 135 degrees F;
- Utilizes proper hand washing and personal hygiene practices to prevent food contamination; and
- Maintains equipment and food contact surfaces to prevent food contamination.

If not, cite at Tag F371.

Noncompliance for F371

After completing the Investigative Protocol, analyze the data in order to determine whether noncompliance with the regulation exists. Noncompliance for Tag F371 may include, but is not limited to, failure to do one or more of the following:

- Procure, store, handle, prepare, distribute, and serve food in accordance with the standards summarized in this guidance;
- 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;
- Store raw foods (e.g., meats, fish) in a manner to reduce the risk of contamination of cooked or ready-to-eat foods;
- Cook food to the appropriate temperature to kill pathogenic microorganisms that may cause foodborne illness;
- Cool food in a manner that prevents the growth of pathogenic microorganisms;
- 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.
- *Failure to report a food borne illness outbreak to the local health department.*

Potential Tags for Additional Investigation

During the investigation of 42 CFR §483.35(i)(1)(2), the surveyor may have identified concerns related to these requirements. The surveyor should investigate these requirements before

determining whether noncompliance may be present. The following are related outcome, process, and structure requirements that may be considered:

- 42 CFR 483.25(g)(2), F322, Nasogastric Tubes
 - 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.
- 42 CFR 483.25(i), F325, Nutrition
 - Determine if multiple residents have experienced nausea, vomiting, diarrhea, or other gastrointestinal symptoms related to foodborne illness, which may impact their nutritional status.
- 42 CFR 483.30(a)(b), F353 Sufficient Staffing
 - Determine if the facility has sufficient staffing to meet the needs of the resident.
- 42 CFR 483.35(a)(1)(2), F361, 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.
- 42 CFR 483.35(b), F362, Standard Sufficient Staff
 - Determine if the facility employs sufficient support personnel competent to carry out the functions of the dietary service.
- 42 CFR 483.35(h) Paid Feeding Assistant
 - Determine if the Feeding Assistant has successfully completed a State-approved training course that meets Federal requirements and that the Feeding Assistant is utilizing proper techniques to prevent foodborne illness.
- 42 CFR 483.65(a), F441, Infection Control
 - Determine if the facility's infection control program included investigation, control, and prevention of foodborne illness.
- 42 CFR 483.65(b)(3), F444, Handwashing Techniques
 - Determine if the facility has practices in place to prevent the spread of infection, including proper hand washing techniques.
- 42 CFR 483.70(c)(2), F456, Maintain All Essential Equipment
 - Determine if the equipment in the kitchen, such as refrigerators, food carts, tray line equipment, freezers, dishwashers, ovens, stoves, and ranges etc. is maintained in safe operating condition and according to manufacturers' specifications.

- 42 CFR 483.70(h), F465, Other Environmental Conditions
 - o Determine if the kitchen physical environment, such as, floors, walls, ceilings, and vent hoods are safe, clean, and sanitary.
- 42 CFR 483.70(h)(4), F469, 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 roaches, ants, flies, mice, etc. in food storage, preparation and service areas.
- 42 CFR 483.70(o) (2) (i) (ii), F520, 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.

IV. DEFICIENCY CATEGORIZATION (PART IV, APPENDIX P)

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 resultant effect or potential for harm to the resident.

The key elements for severity determination for Tag F371 are as follows:

1. Presence of harm/negative outcome(s) or potential for negative outcomes because of the presence of unsanitary conditions. Actual or potential harm/negative outcome for Tag F371 may include, but is not limited to:

- Foodborne illness; or
- Ingestion or potential ingestion of food that was not procured from approved sources, and stored, prepared, distributed or served under sanitary conditions.

2. Degree of harm (actual or potential) related to the noncompliance. Identify how the facility's noncompliance caused, resulted in, allowed or contributed to the actual or potential for harm.

- If harm has occurred, determine if the harm is at the level of serious injury, impairment, death, compromise, or discomfort; or
- If harm has not yet occurred, determine the potential for serious injury, impairment, death, or compromise or discomfort to occur to the resident.

3. The immediacy of correction required. Determine whether the noncompliance requires immediate correction in order to prevent serious injury, harm, impairment, or death to one or more residents.

The survey team must evaluate the harm or potential for harm based upon the following levels of severity for Tag F371. First, the team must rule out whether Severity Level 4, Immediate Jeopardy to a resident's health or safety exists by evaluating the deficient practice in relation to immediacy, culpability, and severity. (Follow the guidance in Appendix Q.)

Severity Level 4 Considerations: Immediate Jeopardy to Resident Health or Safety

Immediate Jeopardy is a situation in which the facility's noncompliance with one or more requirements of participation:

- Has allowed/caused/resulted in or is likely to allow/cause/result in serious injury, harm, impairment, or death to a resident; and
- Requires immediate correction, as the facility either created the situation or allowed the situation to continue by failing to implement preventive or corrective measures.

NOTE: The death or transfer of a resident who was harmed or injured as a result of facility noncompliance does not remove a finding of immediate jeopardy. The facility is required to implement specific actions to remove the jeopardy and correct the noncompliance, which allowed or caused the immediate jeopardy.

Examples of negative outcomes that occurred or have the potential to occur at Severity Level 4 as a result of the facility's deficient practices may include:

- 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 not discarded and 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. Observations and interviews indicate that other food service staff with gastrointestinal illnesses are also permitted to prepare food.

Severity Level 3 Considerations: Actual Harm that is Not Immediate Jeopardy

Severity Level 3 indicates noncompliance that results in actual harm that is not immediate jeopardy. The negative outcome can include but may not be limited to clinical compromise, decline, or the resident's inability to maintain and/or reach his/her highest practicable level of well-being. Therefore, a Level 3 deficiency is indicated when unsafe food handling and inadequate sanitary conditions result in actual harm to residents.

Examples of avoidable actual or potential resident outcomes that demonstrate severity at Level 3 may include, but are not limited to:

- Outbreak of nausea and vomiting occurs in the facility related to the inadequate sanitizing of dishes and utensils; and

- Episode of food poisoning occurs because facility had an event in which tuna, chicken, and potato salads served in bulk were not kept adequately chilled and were still left out for eating after 5 hours.

Severity Level 2 Considerations: No Actual Harm with Potential for More Than Minimal Harm that is Not Immediate Jeopardy

Severity Level 2 indicates noncompliance that results in a resident outcome of no more than minimal discomfort and/or has the potential to compromise the resident's ability to maintain or reach his or her highest practicable level of well being. The potential exists for greater harm to occur if interventions are not provided.

As a result of the facility's noncompliance, the potential for food contamination and/or growth of pathogenic microorganisms exists. Examples of avoidable actual or potential resident outcomes that demonstrate severity at Level 2 may 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 usage. The facility failed to educate and train staff on how to clean and sanitize all kitchen equipment;
- 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; and
- 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.

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

The failure of the facility to procure, prepare, store, distribute and handle food under sanitary conditions places this highly susceptible population at risk for more than minimal harm. Therefore, Severity Level 1 does not apply for this regulatory requirement.

F388

(Rev. 127, Issued: 11-26-14, Effective: 11-26-14, Implementation: 11-26-14)

§483.40(c)(3) Except as provided in paragraphs (c)(4) and (f) of this section, all required physician visits must be made by the physician personally.

§483.40(c)(4) At the option of the physician, required visits in SNFs, after the initial visit, may alternate between personal visits by the physician and visits by a physician assistant, nurse practitioner or clinical nurse specialist in accordance with paragraph (e) of this section.

Definitions §483.40(c)

“**Must be seen**” means that the physician must make actual face-to-face contact with the resident. 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.

For the purposes of this guidance, “non-physician practitioner (NPP)” means a nurse practitioner (NP), clinical nurse specialist (CNS) or physician assistant (PA) as defined above.

Interpretive Guidelines §483.40(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, 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 [§483.40\(c\)](#). *Although the physician may not delegate the responsibility for conducting the initial visit in a SNF, NPP’s may perform other medically necessary visits prior to and after the physician’s initial visit, as allowed by State law.*

After the initial physician visit in SNFs, where States allow their use, a qualified NP, CNS or PA may make every other required visit. (See [§483.40\(e\)](#) 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).

In a NF, the physician visit requirement may be satisfied in accordance with State law by NP, CNS, or PA 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 F390-[§483.40\(f\)](#).)

Facility policy that allows an NP, CNS, or PA to make every other required visit, and that allows a 10 day slippage in the time of the visit, does not relieve the physician of the obligation to visit a resident when the resident’s medical condition makes that visit necessary.

Table 1: Authority for NPP to Perform Visits and Sign Orders when Permitted by the State

	<i>Initial Comprehensive Visit/Orders</i>	<i>Other Required Visits</i>	<i>Other Medically Necessary Visits &Orders</i>
<i>SNF's</i>			
<i>PA, NP & CNS employed by the facility</i>	<i>May not perform/ May not sign</i>	<i>May perform alternate visits</i>	<i>May perform and sign*</i>
<i>PA, NP & CNS not a facility employee</i>	<i>May not perform/ May not sign</i>	<i>May perform alternate visits</i>	<i>May perform and sign*</i>
<i>NF's</i>			
<i>PA, NP, & CNS employed by the facility</i>	<i>May not perform/ May not sign</i>	<i>May not perform</i>	<i>May perform and sign</i>
<i>PA, NP, & CNS not a facility employee</i>	<i>May perform/ May sign</i>	<i>May perform</i>	<i>May perform and sign</i>

**Except radiology and other diagnostic services as stated at §483.75(k)(2).*

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 applicable and if a NPP may perform the tasks. For example:

- For a resident receiving Part A Medicare benefits for the nursing home stay in a Medicare certified bed, the NPP must follow the requirements for physician services in a SNF. This includes, at the option of a physician, required physician visits alternated between personal visits by the physician and visits by a NPP after the physician makes the initial first visit; and*
- For a resident receiving Medicaid benefits, the NPP must follow the requirements for physician services in a NF. The NPP may perform required physician task for a Medicaid beneficiary in a Medicaid stay certified bed, at the option of the State. This NPP may not be an employee of the facility and must be working in collaboration with a physician*

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, there is no prohibition to this practice. The facility should inform the resident of this practice, in accordance with [§483.10\(b\)](#).

Probes: §483.40(c)

- How does the scheduling and frequency of physician visits relate to any identified quality of care problems?
- When a PA, clinical nurse specialist, or NP performs a delegate physician visit, and determines that the resident's condition warrants direct contact between the physician and the resident, does the physician follow-up promptly with a personal visit?

F390

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§483.40(e) Physician Delegation of Tasks in SNFs

(1) Except as specified in paragraph (e)(2) of this section, a physician may delegate tasks to a physician assistant, nurse practitioner, or clinical nurse specialist who--

- (i) Meets the applicable definition in [§491.2](#) of this chapter or, in the case of a clinical nurse specialist, is licensed as such by the State;**
- (ii) Is acting within the scope of practice as defined by State law; and**
- (iii) Is under the supervision of the physician.**

(2) A physician may not delegate a task when the regulations specify that the physician must perform it personally, or when the delegation is prohibited under State law or by the facility's own policies.

Definitions

“Nurse practitioner” is a registered professional nurse now licensed to practice in the State and who meets the State's requirements governing the qualification of nurse practitioners.

“Clinical nurse specialist” is a registered professional nurse currently in practice in the State and who meets the State's requirements governing the qualifications of clinical nurse specialists.

“Physician assistant” is a person who meets the applicable State requirements governing the qualifications for assistants to physician.

Interpretive Guidelines §483.40(e)

When **personal** performance of a particular task by a physician is specified in the regulations, performance of that task cannot be delegated to anyone else. The tasks of examining the resident, reviewing the resident's total program of care, writing progress notes, and signing orders may be delegated according to State law. The extent to which physician services are delegated to physician extenders in SNFs will continue to be determined by the provisions of [§483.40\(e\)](#), while the extent to which these services are performed by physician extenders in NFs will be determined by the individual States under [§483.40\(f\)](#). (*Refer to table in F388.*)

Probes: §483.40(e)

- Do the facility's attending physicians delegate to NPs, clinical nurse specialists, or PAs?
- Do NP/clinical nurse specialist/PA progress notes and orders follow the scope of practice allowed by State law?
- What evidence is there of physician supervision of NPs or PAs? For example, do physicians countersign NP/PA orders, if required by State law?

§483.40(f) Performance of Physician Tasks in NFs

At the option of State, any required physician task in a NF (including tasks which the regulations specify must be performed personally by the physician) may also be satisfied when performed by a nurse practitioner, clinical nurse specialist, or physician assistant who is not an employee of the facility but who is working in collaboration with a physician.

Interpretive Guidelines §483.40(f)

The performance of physician tasks in a NF includes NPP's (as defined in F388) performing required visits at the option of the State. The resident must be seen every 30 days for the first 90 days and every 60 days thereafter. NPPs that have a direct relationship with a physician and who are not employed by the facility may perform the initial visit, any other required physician visit and other medically necessary visit, and verify and sign orders for a resident of a NF as the State allows. NPPs may also perform other medically necessary visits prior to and after the initial visit. Where the NPP is permitted to perform a medically necessary visit, the NPP is likewise permitted to write applicable orders during that visit and may do so without a countersignature unless State law requires it.

The initial visit must take place no later than 30 days after admission.

According to F386, the physician or NPP (at the option of the State) must review the resident's total program of care, including medications and treatments, at each visit required under §483.40(c); write, sign, and date progress notes at each visit; and sign and date all orders with the exception of influenza and pneumococcal polysaccharide vaccines, which may be administered per physician-approved facility policy after an assessment for contraindications.

*The timing of physician visits is based on the admission date of the resident. In a NF, the first physician visit must be conducted within the first 30 days, and then at 30 day intervals up until 90 days after the admission date. After the first 90 days, visits must be 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 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 [§483.40\(c\)](#). (See also F388)*

Facility policy that allows an NPP to make required visits, and that allows a 10 day slippage in the time of the visit, does not relieve the physician of the obligation to visit a resident when the resident's medical condition makes that visit necessary.

NOTE: *If the facility is not in compliance with timeliness of physician visits, cite at F387 – [§483.40\(c\)](#) Frequency of Physician Visits.*

Orders written by an NPP who is employed by the NF and are written during visits that are not required visits, and are therefore “other medically necessary visits,” do not require physician co-signature except as mandated by State law.

If delegation of physician tasks is permitted in your State and the physician extender does not meet the qualifications listed here, cite F388.

Procedures [§483.40\(f\)](#)

If a nurse practitioner, clinical nurse specialist, or physician assistant is performing required physician tasks in a NF, is this allowed by the State? Is this person an employee of the facility? (Facility employees are prohibited from serving in this capacity.)

Probes: [§483.40\(f\)](#)

Is this person working in collaboration with the physician?

F425

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§483.60 Pharmacy Services

The facility must provide routine and emergency drugs and biologicals to its residents, or obtain them under an agreement described in [§483.75\(h\)](#) of this part. The facility may permit unlicensed personnel to administer drugs if State law permits, but only under the general supervision of a licensed nurse.

(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.

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

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

INTENT (F425) 42 CFR 483.60, 483.60(a) & (b)(1)

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 licensed pharmacist collaborates with facility leadership and staff to coordinate pharmaceutical services within the facility, and to guide development and evaluation of the implementation of pharmaceutical services procedures;
- The licensed pharmacist helps the facility identify, evaluate, and address/resolve pharmaceutical concerns and issues that affect resident care, medical care or quality of life such as the:
 - Provision of consultative services by a licensed pharmacist between the pharmacist's visits, as necessary; and
 - Coordination of the pharmaceutical services if multiple pharmaceutical service providers are utilized (e.g., pharmacy, infusion, hospice, prescription drug plans [PDP]); and
- The facility utilizes only persons authorized under state requirements to administer 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

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.
- **“Administering medication”** is the process of giving medication(s) to a resident.
- **“Biologicals”** are products isolated from a variety of natural sources—human, animal, or microorganism—or produced by biotechnology methods and other cutting-edge technologies. They may include a wide range of products such as vaccine, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins.
- **“Current standards of practice”** refers to approaches to care, procedures, techniques, treatments, etc., that are based on research and/or expert consensus and that are contained in current manuals, textbooks, or publications, or that are accepted, adopted or promulgated by recognized professional organizations or national accrediting bodies.
- **“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, releasing and/or destroying discontinued or expired medications.
- **“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 of accepting a medication from the facility’s pharmacy or an outside source (e.g., vending pharmacy delivery agent, Veterans Administration, family member).

OVERVIEW

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 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. Gurwitz and colleagues evaluated the incidence and preventability of adverse drug events in 18 nursing homes in Massachusetts noting that 51% of the adverse drug events were judged to be preventable including 171 (72%) of the 238 fatal, life threatening or serious events and 105 (34%) of the 308 significant events. If these findings are extrapolated to all US nursing homes, approximately 350,000 adverse drug events may occur annually among this patient population, including 20,000 fatal or life threatening events.

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 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:

- The American Society of Consultant Pharmacists (ASCP) <http://www.ascp.com>;
- The American Society of Health System Pharmacists (ASHP) <http://www.ashp.com>;

- The American Medical Directors Association (AMDA) <http://www.amda.com>;
- The National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP) <http://www.nccmerp.org>;
- US Department of Health and Human Services (DHHS), Food and Drug Administration (FDA) <http://www.fda.gov/cder>; and
- *American Society for Parenteral and Enteral Nutrition*, <https://www.nutritioncare.org/>.

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

PROVISION OF ROUTINE AND/OR EMERGENCY MEDICATIONS

The regulation at 42 CFR 483.60 (F425) 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 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 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.*

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 a surveyor becomes aware that a resident has in his or her possession imported prescription medications that are not FDA-approved, the surveyor should determine whether the facility is aware of the presence of the imported medications.

If the facility is unaware of the imported medications, the surveyor should determine whether the medications are delivered to the resident via the facility staff or are self-administered.

- *If the medications are administered by facility staff, the surveyor should cite the facility for this unsafe practice under §483.60(a) Pharmacy Services; or*
- *If the resident self-administers the medications without the facility's knowledge, the surveyor should notify the facility of the unsafe practice.*

In addition, if it is determined that the facility is providing/obtaining foreign medications for use by the residents that are not FDA approved, 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.

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, that are consistent with current standards of practice, and that meet state and federal requirements. This includes, but is not limited to, collaborating with the facility and medical director to:

- Develop, implement, evaluate, and revise (as necessary) the procedures for the provision of all aspects of pharmaceutical services;
- 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;
- Participate on the interdisciplinary team to address and resolve medication-related needs or problems;
- Establish procedures for:
 - conducting the monthly medication regimen review (MRR) for each resident in the facility,
 - addressing the expected time frames for conducting the review and reporting the findings,
 - addressing the irregularities,
 - documenting and reporting the results of the review (See F428 for provision of the review.); and
- Establish procedures that address medication regimen reviews for residents who are anticipated to stay less than 30 days or when the resident experiences an acute change of condition as identified by facility staff.

NOTE: Facility procedures should address how and when the need for a consultation will be communicated, how the medication review will be handled if the pharmacist is off-site, how the results or report of their findings will be communicated to the physician, expectations for the physician's response and follow up, and how and where this information will be documented.

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.

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 ordered);
- 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 and Staff Qualifications 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, insulins, pain medications, *proton pump inhibitors, metered dose inhalers, and medications via enteral feeding tubes*);

- *Not administering medications with known incompatibilities at the same time;*
- Avoid potential significant medication interactions such as medication-food or medication-medication interactions; and
- Recognize resident choices and activities, to the degree possible, consistent with the medical plan of care;
- 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;*
 - *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);¹ and*

1. <http://www.ismp.org/newsletters/acutecare/articles/20100506.asp> 5/06/10.

- 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” medications including the justification and response;
 - The route, if other than oral (intended route may be preprinted on 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);
- 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, medication orders to the pharmacy, and medication administration record (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;

Labeling and Storage of Medications, including Controlled Substances

Examples of procedures addressing accurate labeling of the medications (including appropriate accessory and cautionary instructions) include:

- Labeling medications prepared by facility staff, such as IV solutions prepared in the facility;
- Requirements for labeling medications not labeled by a pharmacy, such as bulk supplies/bottles of over-the counter (OTC) medications (as permitted);
- Modifying labels due to changes in the medication orders or directions, in accordance with state and federal requirements; and

- Labeling multi-dose vials to assure product integrity, considering the manufacturer's specifications (e.g., modified expiration dates upon opening the multi-dose vial).

Examples of procedures addressing the safe storage of medications include:

- Location, security (locking), and authorized access to the medication rooms, carts and other storage areas;
- Temperatures and other environmental considerations of medication storage area(s) such as the medication room(s) and refrigerators; and
- Location, access, and security for discontinued medications awaiting disposal.

Examples of procedures addressing controlled medications include:

- Location, access, and security for controlled medications, including the separately locked permanently affixed compartment for those Schedule II medications or preparations with Schedule II medications needing refrigeration;
- A system of records of receipt and disposition of all controlled medications that accounts for all controlled medications; and
- Periodic reconciliation of controlled medications including the frequency, method, administration by whom, and pertinent documentation.

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 procedures, and have access to current information regarding medications being used within the facility, 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;

- 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.

INVESTIGATIVE PROTOCOL

For investigating compliance with the requirements at 42 CFR 483.60 and 483.60(a) & (b), see State Operations Manual, Appendix P, II.B., The Traditional Standard Survey, Task 5, Sub-Task 5E Investigative Protocol: Medication Pass and Pharmacy Services.

DETERMINATION OF COMPLIANCE (Task 6, Appendix P)

Synopsis of Regulation (F425)

The Pharmaceutical Services, Procedures and Consultation requirement has four aspects. First, the facility must provide routine and/or emergency medications and biologicals or obtain them under an agreement described in 42 CFR 483.75(h). Second, the facility must have procedures for pharmaceutical services to meet the resident's needs. The procedures must assure accurate acquisition, receipt, dispensing, and administration of all medications and biologicals. Third, the facility must have a licensed pharmacist who provides consultation and oversees all aspects of the pharmaceutical services. Fourth, the facility must follow applicable laws and regulations about who may administer medications.

Criteria for Compliance

Compliance with 42 CFR 483.60, F425, Pharmaceutical Services

The facility is in compliance with this requirement, if they provide or arrange for:

- Each resident to receive medications and/or biologicals as ordered by the prescriber;
- The development and implementation of procedures for the pharmaceutical services;
- The services of a pharmacist who provides consultation regarding all aspects of pharmaceutical services; and
- Personnel to administer medications, consistent with applicable state law and regulations.

If not, cite F425.

Noncompliance for F425

After completing the Investigative Protocol, analyze the data and review the regulatory requirement in order to determine whether or not compliance with F425 exists. As the requirements for F425 include both process and structural components, a determination of noncompliance with F425 does not require a finding of harm to the resident. If the survey team identifies noncompliance at other tags which may be related to the roles and responsibilities of the pharmacist or the provision of pharmaceutical services, the team must also decide whether there is noncompliance with this requirement. Noncompliance for F425 may include (but is not limited to) the facility failure to:

- Utilize the services of a pharmacist;
- Ensure that only appropriate personnel administer medications;
- Provide medications and/or biologicals to meet the needs of the resident; and
- Develop or implement procedures for any of the following: acquiring, receiving, dispensing or accurately administering medications.

Potential Tags for Additional Investigation

If noncompliance with 42 CFR 483.60 and 483.60(a) & (b) has been identified, then concerns with additional requirements may also have been identified. The surveyor is cautioned to investigate these related additional requirements before determining whether noncompliance with the additional requirements may be present. Examples of some of the related requirements that should be considered when noncompliance has been identified include the following:

- 42 CFR 483.30(a), F353, Sufficient Staff
 - Determine if the facility had qualified staff in sufficient numbers 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 483.75(i)(2), F501, Medical Director
 - Determine whether the medical director, in collaboration with the facility and the pharmacist, and based on current standards of practice, helped the facility develop procedures for the safe and accurate provision of medications to meet the needs of the residents.
- 42 CFR 483.75 (o), F520, Quality Assessment and Assurance
 - Determine whether the quality assessment and assurance committee, if concerns regarding pharmaceutical services have been identified, has identified those concerns, responded to the concerns and, as appropriate, has developed,

implemented, and monitored appropriate plans of action to correct identified quality deficiencies.

- 42 CFR 483.75(l)(1), F514, Clinical 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.

IV. DEFICIENCY CATEGORIZATION (Part IV, Appendix P)

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

The key elements for severity determination for F425 are as follows:

1. Presence of potential or actual harm/negative outcome(s) due to a facility failure related to pharmaceutical services.

Identify actual or potential harm/negative outcomes for F425 which may include, but are not limited to:

- The facility's failure to involve a pharmacist in developing, implementing, and evaluating pharmaceutical procedures including procedures for accurately acquiring, receiving, storing, controlling, dispensing, and administering routine and emergency medications and biologicals resulted in the lack of specific procedures or in procedures that were not consistent with current standards of practice, for example:
 - Absent or inadequate IV infusion procedures led to a resident developing congestive heart failure as a result of an IV infusing too quickly.
- The facility's failure to provide medications needed by a resident in a timely manner resulted in continued pain or worsening symptoms.
- The use of unauthorized personnel to administer medications created the potential for harm.

2. Degree of potential or actual harm/negative outcome(s) due to a facility failure related to pharmaceutical services.

Identify how the facility's practices caused, resulted in, allowed, or contributed to the actual or potential for harm:

- If harm has occurred, determine if the harm is at the level of serious injury, impairment, death, compromise, or discomfort.

- If harm has not yet occurred, determine how likely is the potential for serious injury, impairment, death, compromise, or discomfort to occur to the resident.

3. The immediacy of correction required.

Determine whether the noncompliance requires immediate correction in order to prevent serious injury, harm, impairment, or death to one or more residents.

The survey team must evaluate the harm or potential for harm based upon the following levels of severity for tag F425. First, the team must rule out whether Severity Level 4, Immediate Jeopardy to a resident's health or safety, exists by evaluating the deficient practice in relation to immediacy, culpability, and severity. (Follow the guidance in Appendix Q, Guidelines for Determining Immediate Jeopardy.)

NOTE: The death or transfer of a resident who was harmed or injured as a result of facility noncompliance does not remove a finding of immediate jeopardy. The facility is required to implement specific actions to remove the jeopardy and correct the noncompliance which allowed or caused the immediate jeopardy.

Severity Level 4 Considerations: Immediate Jeopardy to Resident Health or Safety

Immediate Jeopardy is a situation in which the facility's noncompliance with one or more requirements of participation:

- Has caused/resulted in, or is likely to cause, serious injury, harm, impairment, or death to a resident; and
- Requires immediate correction as the facility either created the situation or allowed the situation to continue by failing to implement preventative or corrective measures.

Examples may include, but are not limited to:

- Severity Level 4 (Immediate Jeopardy) deficiency at another tag (e.g., F309, F329, F332, F333, F428) and the noncompliance is related to a failure of the facility to provide or obtain the service of a pharmacist or to collaborate with the pharmacist to establish and implement procedures for using medications, resulting in the potential for significant adverse consequences.
- 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. For example, failure to assure availability of pain medication for a recently admitted resident resulting in the resident complaining of excruciating pain (e.g., a pain score of 9 on a 10-point scale).

- Assuring that devices used to administer medications (such as IV pumps) were working properly, leading to an adverse consequence at the immediate jeopardy level.
- Identifying medication errors, for example, medications were being dispensed without a valid prescriber's order, resulting in a resident incorrectly receiving three medications over two consecutive months.

NOTE: If immediate jeopardy has been ruled out based upon the evidence, then evaluate whether actual harm that is not immediate jeopardy exists at Severity Level 3.

Severity Level 3 Considerations: Actual Harm that is Not Immediate Jeopardy

Level 3 indicates noncompliance that results in actual harm, and may include, but is not limited to, clinical compromise, decline, or the resident's inability to maintain and/or reach his/her highest practicable well-being. Examples may include, but are not limited to:

- Severity Level 3 deficiency at another tag (e.g., F309, F329, F332, F333, F428) and the noncompliance is related to a failure of the facility to provide or obtain the services of a pharmacist or to collaborate with the pharmacist to develop and implement procedures for monitoring medication therapy, resulting in a failure to monitor treatment and the resident experiencing actual harm.
- The facility in collaboration with the pharmacist failed to assure that procedures were developed and implemented, such as:
 - An effective procedure/mechanism to assure 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, a transcription error led to an incorrect dose of a medication being administered and the resident experiencing spontaneous bruising and epistaxis requiring medical intervention.
 - 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 excessive dose of medication requiring subsequent hospitalization or receiving a sub-therapeutic dose of medication with consequential exacerbation of a condition (e.g., infection), continuation of treatment beyond the expected time frame, and subsequent functional decline.

NOTE: If Severity Level 3 (actual harm that is not immediate jeopardy) has been ruled out based upon the evidence, then evaluate as to whether Severity Level 2 (no actual harm with the potential for more than minimal harm) exists.

Severity Level 2 Considerations: No Actual Harm with Potential for More Than Minimal Harm that is Not Immediate Jeopardy

Level 2 indicates noncompliance that results in a resident outcome of no more than minimal discomfort and/or has the potential to compromise the resident's ability to maintain or reach his or her highest practicable level of well-being. The potential exists for greater harm to occur if interventions are not provided. Examples may include, but are not limited to:

- A Severity Level 2 deficiency at another tag (e.g., F309, F329, F332, F333, F428) and the noncompliance is related to a failure of the facility to implement established medication administration procedures. For example, as a result of failure of licensed staff to supervise medication administration by authorized unlicensed personnel, errors occurred in providing timely oral antibiotic therapy.
- 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:
 - As a result of not reordering medications often enough to maintain an adequate supply, a resident did not receive medication for heartburn for seven days and had difficulty sleeping 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 medication that was crushed, contrary to the manufacturer's specifications (e.g., an enteric coated aspirin). While the resident did not experience any harm, the potential for harm was present.

NOTE: If Severity Level 2 (no actual harm with potential for more than minimal harm that is not immediate jeopardy) has been ruled out based upon the evidence, then evaluate as to whether Severity Level 1 (no actual harm with the potential for minimal harm) exists.

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

In order to cite no actual harm with potential for minimal harm at this tag, the surveyor must verify that no resident harm or potential for more than minimal harm identified at other requirements was related to lack of pharmaceutical services, absence of or failure to implement pharmaceutical procedures, or absence of oversight by the pharmacist.

Examples of noncompliance for Severity Level 1 may include:

- The facility and the pharmacist failed to collaborate to:
 - Implement pharmaceutical procedures, but there were no negative resident outcomes or potential for more than minimal negative outcomes as a result of that deficient practice.

- There is no pharmacist; and
 - There were no negative resident outcomes or potential for more than minimal negative outcomes related to pharmaceutical services; and
 - Pharmaceutical procedures were in place; and
 - The facility was actively seeking a new pharmacist.

NOTE: If there is no pharmacist and there were negative outcomes, or procedures were not in place or if the facility was not looking for a replacement, cite at a Severity Level 2 or higher severity.

- There was a short term failure to provide medications that posed minimal risk to the resident, such as a routine order for a daily multivitamin.

ENDNOTES

¹ <http://www.ismp.org/newsletters/acute care/articles/20100506.asp> 5/06/10.

F428

(Rev. 127, Issued: 11-26-14, Effective: 11-26-14, Implementation: 11-26-14)

§483.60(c) Drug Regimen Review

(1) The drug regimen of each resident must be reviewed at least once a month by a licensed pharmacist.

(2) The pharmacist must report any irregularities to the attending physician, and the director of nursing, and these reports must be acted upon.

INTENT (F428) 42 CFR 483.60(c)(1)(2) Medication Regimen Review

The intent of this requirement is that the facility maintains the resident's highest practicable level of functioning and prevents or minimizes adverse consequences related to medication therapy to the extent possible, by providing:

- A licensed pharmacist's review of each resident's regimen of medications at least monthly; or
- A more frequent review of the regimen depending upon the resident's condition and the risks or adverse consequences related to current medication(s);
- The identification and reporting of irregularities to the attending physician and the director of nursing; and
- Action taken in response to the irregularities identified.

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, and 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

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

- **"Adverse consequence"** refers to an unpleasant symptom or event that is due to or associated with a medication, 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).

NOTE: Adverse drug reaction (ADR) is a form of adverse consequence. It may be either a secondary effect of a medication that is usually undesirable and different from the therapeutic and helpful effects of the medication or any response to a medication that is noxious and unintended and occurs in doses used for prophylaxis, diagnosis, or therapy. The term “side effect” is often used interchangeably with ADR; however, side effects are but one of five ADR categories. The others are hypersensitivity, idiosyncratic response, toxic reactions, and adverse medication interactions. A side effect is an expected, well-known reaction that occurs with a predictable frequency and may or may not rise to the level of being an adverse consequence.

- **“Clinically significant”** means effects, results, or consequences that materially affect or are likely to affect an individual’s mental, physical, or psychosocial well-being either positively by preventing, stabilizing, or improving a condition or reducing a risk, or negatively by exacerbating, causing, or contributing to a symptom, illness, or decline in status.
- **“Dose”** is the total amount/strength/concentration of a medication given at one time or over a period of time. The individual dose is the amount/strength/concentration received at each administration. The amount received over a 24-hour period may be referred to as the daily dose.
- **“Excessive dose”** (including duplicate therapy) means the total amount of any medication given at one time or over a period of time that is greater than the amount recommended by the manufacturer’s label, package insert, or current standards of practice for a resident’s age and condition; without evidence of a review for the continued necessity of the dose or of attempts at, or consideration of the possibility of, tapering a medication; and there is no documented clinical rationale for the benefit of, or necessity for the dose or for the use of multiple medications from the same class.
- **“Duration”** is the total length of time the medication is being received.
- **“Excessive Duration”** means the medication is administered beyond the manufacturer’s recommended time frames or facility-established stop order policies, beyond the length of time advised by current standards of practice, and/or without either evidence of additional therapeutic benefit for the resident or clear clinical factors that would warrant the continued use of the medication.
- **“Irregularity”** refers to any event that is inconsistent with usual, proper, accepted, or right approaches to providing pharmaceutical services (see definition in F425), or that impedes or interferes with achieving the intended outcomes of those services.

- **“Medication Interaction”** is the impact of another substance (such as another medication, herbal product, food or substances used in diagnostic studies) upon a medication. The interactions may alter absorption, distribution, metabolism, or elimination. These interactions may decrease the effectiveness of the medication or increase the potential for adverse consequences.
- **“Medication Regimen Review”** (MRR) is a thorough evaluation of the medication regimen of a resident, with the goal of promoting positive outcomes and minimizing adverse consequences associated with medication. The review includes preventing, identifying, reporting, and resolving medication-related problems, medication errors, or other irregularities, and collaborating with other members of the interdisciplinary team.
- **“Monitoring”** is the ongoing collection and analysis of information (such as observations and diagnostic test results) and comparison to baseline data in order to:
 - Ascertain the individual’s response to treatment and care, including progress or lack of progress toward a therapeutic goal;
 - Detect any complications or adverse consequences of the condition or of the treatments; and
 - Support decisions about modifying, discontinuing, or continuing any interventions.
- **“Pharmacy Assistant or Technician”** refers to ancillary personnel who work under the supervision and delegation of the pharmacist as consistent with state requirements.

OVERVIEW

Many nursing home residents require multiple medications to address their conditions, leading to complex medication regimens. Medications are used for their therapeutic benefits in diagnosing, managing, and treating acute and/or chronic conditions, for maintaining and/or improving a resident’s functional status, and for improving or sustaining the resident’s quality of life. The nursing home population may be quite diverse and may include geriatric residents as well as individuals of any age with special needs, such as those who are immunocompromised or who have end stage renal disease or spinal cord or closed head injuries. Regardless, this population has been identified as being at high risk for adverse consequences related to medications. Some adverse consequences may mimic symptoms of chronic conditions, the aging process, or a newly emerging condition.

Transitions in care such as a move from home or hospital to the nursing home, or vice versa, increase the risk of medication-related issues. Medications may be added, discontinued, omitted, or changed. It is important, therefore, to review the medications. Currently, safeguards to help identify medication issues include:

- The physician providing and reviewing the orders and total program of care on admission and the prescriber reviewing at each visit;
- The nurse reviewing medications when transmitting the orders to the pharmacy and/or prior to administering medications;
- The interdisciplinary team reviewing the medications as part of the comprehensive assessment for the Resident Assessment Instrument (RAI) and/or care plan;
- The pharmacist reviewing the prescriptions prior to dispensing; and
- The pharmacist performing the medication regimen review at least monthly.

During the MRR, the pharmacist applies his/her understanding of medications and related cautions, actions and interactions as well as current medication advisories and information. The pharmacist provides consultation to the facility and the attending physician(s) regarding the medication regimen and is an important member of the interdisciplinary team. Regulations prohibit the pharmacist from delegating the medication regimen reviews to ancillary staff.

Some resources are available to facilitate evaluating medication concerns related to the performance of the MRR, such as:

- American Society of Consultant Pharmacists (ASCP) <http://www.ascp.com>;
- American Medical Directors Association (AMDA) <http://www.amda.com>;
- National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP) <http://www.nccmerp.org>;
- American Geriatrics Society (AGS) <http://www.americangeriatrics.org>;
- U.S. Department of Health and Human Services, Food and Drug Administration (FDA) <http://www.fda.gov/medwatch/safety.htm>; and

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

This guidance is not intended to imply that all adverse consequences related to medications are preventable, but rather to specify that a system exists to assure that medication usage is evaluated on an ongoing basis, that risks and problems are identified and acted upon, and that medication-related problems are considered when the resident has a change in condition. This guidance will discuss the following aspects of the facility's MRR component of the pharmaceutical services systems:

- A pharmacist's review of the resident's medication regimen to identify and report irregularities; and
- Acting upon identified irregularities in order to minimize or prevent adverse consequences, to the extent possible.

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

MEDICATION REGIMEN REVIEW (MRR)

The MRR is an important component of the overall management and monitoring of a resident's medication regimen. The pharmacist must review each resident's medication regimen at least once a month in order to identify irregularities; and to identify clinically significant risks and/or adverse consequences resulting from or associated with medications. It may be necessary for the pharmacist to conduct the MRR more frequently, for example weekly, depending on the resident's condition and the risks for adverse consequences related to current medications.

The requirement for the MRR applies to each resident, including residents who:

- *Are receiving respite care;*
- *Are at the end of life or have elected the hospice benefit and are receiving respite care;*
- *Have an anticipated stay of less than 30 days; or*
- *Have experienced a change in condition.*

A complex resident generally benefits from a pharmacist's review during the transition from hospital to skilled nursing facility.¹ Medication review upon transition of care may prevent errors due to drug-drug interactions, omissions, duplication of therapy, or miscommunication during the transition from one team of care providers to another.

Generally, MRRs are conducted in the facility because important information about indications for use, potential medication irregularities or adverse consequences (such as symptoms of tardive dyskinesia, dizziness, anorexia, or falls) may be attainable only by talking to the staff, reviewing the medical record, and observing and speaking with the resident. However, electronic health and medication records and other available technology may permit the pharmacist to conduct some components of the review outside the facility.

Important aspects of the MRR include identification of irregularities, including medication-related errors and adverse consequences, location and notification of MRR findings, and response to identified irregularities. This guidance discusses these aspects and also provides some examples of clinically significant medication interactions.

Identification of Irregularities

An objective of the MRR is to try to minimize or prevent adverse consequences by identifying irregularities including, for example: syndromes potentially related to medication therapy, emerging or existing adverse medication consequences, as well as the potential for adverse drug reactions and medication errors. The resident's record may contain information regarding possible and/or actual medication irregularities. Possible sources to obtain this information include: the medication administration records (MAR); prescribers' orders; progress, nursing and consultants' notes; the Resident Assessment Instrument (RAI); laboratory and diagnostic test results, and other sources of information about behavior monitoring and/or changes in condition. The pharmacist may also obtain information from the Quality Measures/Quality Indicator reports, the attending physician, facility staff, and (as appropriate) from interviewing, assessing, and/or observing the resident.

The pharmacist's review considers factors such as:

- Whether the physician and staff have documented objective findings, diagnoses and/or symptom(s) to support indications for use;
- Whether the physician and staff have identified and acted upon, or should be notified about, the resident's allergies and/or potential side effects and significant medication interactions (such as medication-medication, medication-food, medication-disease, medication-herbal interactions);
- Whether the medication dose, frequency, route of administration, and duration are consistent with the resident's condition, manufacturer's recommendations, and applicable standards of practice;
- Whether the physician and staff have documented progress towards, or maintenance of, the goal(s) for the medication therapy;
- Whether the physician and staff have obtained and acted upon laboratory results, diagnostic studies, or other measurements (such as bowel function, intake and output) as applicable;
- Whether medication errors exist or circumstances exist that make them likely to occur; and
- Whether the physician and staff have noted and acted upon possible medication-related causes of recent or persistent changes in the resident's condition such as worsening of an existing problem or the emergence of new signs or symptoms. The following are examples of changes potentially related to medication use that could occur at any age, however, some of the changes are more common in the geriatric population and may be unrelated to medications:
 - Anorexia and/or unplanned weight loss, or weight gain;

- Behavioral changes, unusual behavior patterns (including increased distressed behavior);
- Bowel function changes including constipation, ileus, impaction;
- Confusion, cognitive decline, worsening of dementia (including delirium) of recent onset;
- Dehydration, fluid/electrolyte imbalance;
- Depression, mood disturbance;
- Dysphagia, swallowing difficulty;
- Excessive sedation, insomnia, or sleep disturbance;
- Falls, dizziness, or evidence of impaired coordination;
- Gastrointestinal bleeding;
- Headaches, muscle pain, generalized aching or pain;
- Rash, pruritus;
- Seizure activity;
- Spontaneous or unexplained bleeding, bruising;
- Unexplained decline in functional status (e.g., ADLs, vision); and
- Urinary retention or incontinence.

Upon conducting the MRR, the pharmacist may identify and report concerns in one or more of the following categories: (See F329 for additional discussion of irregularities relating to dose, duration, indications for use, monitoring, and adverse consequences.)

- The use of a medication without identifiable evidence of adequate indications for use;
- The use of a medication to treat a clinical condition without identifiable evidence that safer alternatives or more clinically appropriate medications have been considered;
- The use of an appropriate medication that is not helping attain the intended treatment goals because of timing of administration, dosing intervals, sufficiency of dose, techniques of administration, or other reasons;

- The use of a medication in an excessive dose (including duplicate therapy) or for excessive duration, thereby placing the resident at greater risk for adverse consequences or causing existing adverse consequences;
- The presence of an adverse consequence associated with the resident’s current medication regimen;
- The use of a medication without evidence of adequate monitoring; i.e., either inadequate monitoring of the response to a medication or an inadequate response to the findings;
- Presence of medication errors or the risk for such errors;
- Presence of a clinical condition that might warrant initiation of medication therapy; and

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

- A medication interaction associated with the current medication regimen.

The following table provides examples of some problematic medication interactions in the long-term care population. These examples represent common interactions but are not meant to be all inclusive.

NOTE: Concomitant use of these medication combinations is not necessarily inappropriate and these examples are not intended to imply that the medications cannot be used simultaneously. Often, several medications with documented interactions can be given together safely. However, concomitant use of such medications warrants careful consideration of potential alternatives, possible need to modify doses, and diligent monitoring.

Common Medication-Medication Interactions in Long Term Care

Medication 1	Medication 2	Impact
warfarin	NSAIDs such as ibuprofen, naproxen, COX-2 inhibitors	Potential for serious gastrointestinal bleeding
warfarin	sulfonamides such as trimethoprim/ sulfamethoxazole	Increased effects of warfarin, with potential for bleeding
warfarin	macrolides such as clarithromycin, erythromycin	Increased effects of warfarin, with potential for bleeding
warfarin	fluoroquinolones such as ciprofloxacin, levofloxacin, ofloxacin	Increased effects of warfarin, with potential for bleeding

Medication 1	Medication 2	Impact
warfarin	phenytoin	Increased effects of warfarin and/or phenytoin
ACE Inhibitors such as benazepril, captopril, enalapril, and lisinopril	potassium supplements	Elevated serum potassium levels
ACE Inhibitors such as benazepril, captopril, enalapril, and lisinopril	spironolactone	Elevated serum potassium levels
digoxin	amiodarone	digoxin toxicity
digoxin	verapamil	digoxin toxicity
theophylline	fluoroquinolones such as ciprofloxacin, levofloxacin, ofloxacin	theophylline toxicity

Location and Notification of Medication Regimen Review Findings

The pharmacist is expected to document either that no irregularity was identified or the nature of any identified irregularities. The pharmacist is responsible for reporting any identified irregularities to the attending physician and director of nursing. The timeliness of notification of irregularities depends on factors including the potential for or presence of serious adverse consequences; for example, immediate notification is indicated in cases of bleeding in a resident who is receiving anticoagulants or in cases of possible allergic reactions to antibiotic therapy. If no irregularities were identified during the review, the pharmacist includes a signed and dated statement to that effect. The facility and the pharmacist may collaborate to identify the most effective means for assuring appropriate notification. This notification may be done electronically.

The pharmacist does not need to document a continuing irregularity in the report each month if the pharmacist has deemed the irregularity to be clinically insignificant or evidence of a valid clinical reason for rejecting the pharmacist's recommendation was provided. In this situation, the pharmacist need only reconsider annually whether to report the irregularity again or make a new recommendation.

The pharmacist's findings are considered part of each resident's clinical record. If documentation of the findings is not in the active record, it is maintained within the facility and is readily available for review. The interdisciplinary team is encouraged to review the reports and to get the pharmacist's input on resident problems and issues. Establishing a consistent location for the pharmacist's findings and recommendations can facilitate communication with the attending physician, the director of nursing, the remainder of the interdisciplinary team, the medical director, the resident and his or her legal representative (in accord with 42 CFR 483.10(b)(2),(d)(2)), ombudsman (with permission of the resident in accord with 42 CFR 483.10(j)(3)), and surveyors.

Response to Irregularities Identified in the MRR

Throughout this guidance, a response from a physician regarding a medication problem implies appropriate communication, review, and resident management, but does not imply that the physician must necessarily order tests or treatments recommended or requested by the staff, unless the physician determines that those are medically valid and indicated.

For those issues that require physician intervention, the physician either accepts and acts upon the report and potential recommendations or rejects all or some of the report and provides a brief explanation of why the recommendation is rejected, such as in a dated progress note. It is not acceptable for a physician to document only that he/she disagrees with the report, without providing some basis for disagreeing.

If there is the potential for serious harm and the attending physician does not concur with or take action on the report, the facility and the pharmacist should contact the facility's medical director for guidance and possible intervention to resolve the issue. The facility should have a procedure to resolve the situation when the attending physician is also the medical director. For those recommendations that do not require a physician intervention, such as one to monitor vital signs or weights, the director of nursing or designated licensed nurse addresses and documents action(s) taken.

ENDNOTES

¹ *Boockvar KS, Carlson LaCorte H, Giambanco V, Fridman B, Siu A. Medication reconciliation for reducing drug discrepancy adverse effects. Am J Geriatr Pharmacother. 2006 Sep; 4(3): 236-43.*

INVESTIGATIVE PROTOCOL

Refer to the Investigative Protocol at F329 for evaluation of medication regimen review.

DETERMINATION OF COMPLIANCE (Task 6, Appendix P)

Synopsis of regulation (F428)

This requirement has four aspects relating to the safety of the resident's medication regimen, including:

- A review by the pharmacist of each resident's medication regimen at least once a month or more frequently depending upon the resident's condition and the risks or adverse consequences related to current medication(s);
- The identification of any irregularities;
- Reporting irregularities to the attending physician and the director of nursing; and
- Action in response to irregularities reported.

Criteria for compliance

Compliance with 42 CFR 483.60(c)(1) and (2), F428, Medication Regimen Review

The facility is in compliance with this requirement if:

- The pharmacist has performed a medication regimen review on each resident at least once a month or more frequently depending upon the resident's condition and/or risks or adverse consequence associated with the medication regimen;
- The pharmacist has identified any existing irregularities;
- The pharmacist has reported any identified irregularities to the director of nursing and attending physician; and
- The report of any irregularities has been acted upon.

If not, cite F428.

Noncompliance for F428

After completing the Investigative Protocol, analyze the data in order to determine whether or not compliance with F428 exists. A determination of noncompliance with F428 does not require a finding of harm to the resident. Noncompliance may include (but is not limited to) one or more of the following:

- The pharmacist failed to conduct an MRR at least monthly (or more frequently, as indicated *by the resident's condition*).
- The pharmacist failed to identify or report the absence of or inadequate indications for use of a medication, or a medication or medication combination with significant potential for adverse consequences or medication interactions.
- The pharmacist failed to identify or report medications in a resident's regimen that could (as of the review date) be causing or associated with new, worsening, or progressive signs and symptoms.
- The pharmacist failed to identify and report the absence of any explanation as to why or how the benefit of a medication(s) with potential for clinically significant adverse consequences outweighs the risk.
- The pharmacist failed to identify and report the lack of evidence or documentation regarding progress toward treatment goals.
- The facility failed to act upon a report of clinically significant risks or existing adverse consequences or other irregularities.

Potential Tags for Additional Investigation

If noncompliance with 483.60(c)(1) and (2) has been identified, then concerns with additional requirements may also have been identified. The surveyor is cautioned to investigate these related additional requirements before determining whether noncompliance with the additional requirements may be present. Examples of some of the related requirements that should be considered when noncompliance has been identified include the following:

- 42 CFR 483.10(b)(11), F157, 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 a need to alter treatment significantly (i.e., a need to discontinue an existing form of treatment due to adverse consequences, or to commence a different form of treatment).
- 42 CFR 483.25(l), F329, Unnecessary Medications
 - Review whether the resident is receiving any medications without an indication for use, in excessive dose or duration, with inadequate monitoring, or in the presence of any adverse consequences that indicate that the dose should be reduced or discontinued.
- 42 CFR 483.40(a), F385, Physician Supervision

- Review whether the attending physician supervised the resident's medical treatment, including assessing the resident's condition, identifying the need for and continuing use of medication to address the resident's needs, and identifying and addressing adverse consequences related to medications.
- 42 CFR 483.40(b), F386, Physician Visits
 - Review whether the attending physician or another designated practitioner reviewed the resident's total program of care including the beneficial and adverse effects of medications and treatment, and provided a relevant progress note at each visit.
- 42 CFR 483.60(a)(b)(1), F425, Pharmacy Services
 - Review whether the licensed pharmacist has provided consultation regarding all aspects of pharmaceutical services.
- 42 CFR 483.75(i), F501, Medical Director
 - Review whether the medical director, when requested by the facility, interacted with the attending physician regarding an inadequate response to identified or reported potential medication irregularities and adverse consequences.

IV. DEFICIENCY CATEGORIZATION (Part IV, Appendix P)

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 resultant harm or potential for harm to the resident. The survey team must identify whether noncompliance cited at other tags (e.g., F329, F332/333) was the direct result of or related to inadequate or absent MRR or response to notification regarding irregularities.

The key elements for severity determination for F428 are as follows:

1. Presence of potential or actual harm/negative outcome(s) due to a facility failure related to the MRR.

Identify actual or potential harm/negative outcomes which for F428 may include, but are not limited to:

- The resident experienced a clinically significant adverse consequence associated with a medication.
- Irregularities within the medication regimen or inaccuracy of medication-related documents created the potential for adverse consequences such as overdose, respiratory depression, rash, or anorexia.

2. Degree of potential or actual harm/negative outcome(s) due to a facility failure related to the MRR.

Identify to what degree the facility practices caused, resulted in, allowed, or contributed to the actual or potential harm:

- If harm has occurred, determine if the harm is at the level of serious injury, impairment, death, compromise, or discomfort; or
- If harm has not yet occurred, determine the potential for serious injury, impairment, death, compromise, or discomfort to occur to the resident.

3. The immediacy of correction required.

Determine whether the noncompliance requires immediate correction in order to prevent serious injury, harm, impairment, or death to one or more residents.

The survey team must evaluate the harm or potential for harm based upon the following levels of severity for tag F428. First, the team must rule out whether Severity Level 4, Immediate Jeopardy, to a resident's health or safety, exists by evaluating the deficient practice in relation to immediacy, culpability, and severity. (Follow the guidance in Appendix Q, Guidelines for Determining Immediate Jeopardy.)

NOTE: The death or transfer of a resident who was harmed or injured as a result of facility noncompliance does not remove a finding of immediate jeopardy. The facility is required to implement specific actions to remove the jeopardy and correct the noncompliance which allowed or caused the immediate jeopardy.

Severity Level 4 Considerations: Immediate Jeopardy to Resident Health or Safety

Immediate Jeopardy is a situation in which the facility's noncompliance with one or more requirements of participation:

- Has allowed, caused, or resulted in, or is likely to allow, cause, or result in serious injury, harm, impairment, or death to a resident; and
- Requires immediate correction, as the facility either created the situation or allowed the situation to continue by failing to implement preventative or corrective measures.

Examples may include, but are not limited to:

- Despite identifying irregularities with the potential for serious harm or death, the pharmacist did not report the irregularities to the attending physician or no action was taken on the irregularities reported.

- Findings of noncompliance at Severity Level 4 at Tag(s) F309, F329, F332, or F333 that show evidence of process failures for conducting the MRR.
- Repeated or cumulative failures in multiple areas of the medication regimen review process (e.g., failure to identify, report, or act upon) that resulted in the resident(s) experiencing actual or potential harm.

NOTE: If immediate jeopardy has been ruled out based upon the evidence, then evaluate whether actual harm that is not immediate jeopardy exists at Severity Level 3.

Severity Level 3 Considerations: Actual Harm that is Not Immediate Jeopardy

Level 3 indicates noncompliance that resulted in actual harm, and may include, but is not limited to, clinical compromise, decline, or the resident's inability to maintain and/or reach his/her highest practicable well-being. Examples may include, but are not limited to:

- The pharmacist's MRR failed to identify the indication for continued use for opioid analgesics that had been prescribed for a resident's acute pain which had resolved. As a result of prolonged duration of use, the resident became more lethargic, withdrawn, and anorectic.
- The pharmacist's MRR identified that the staff were crushing medications that should not be crushed, based on inappropriate standing orders to crush all medications. As a result of facility failure to act upon the notification, the resident experienced clinically significant adverse consequences such as hypoglycemia or hypotension that required medical intervention.
- The pharmacist's MRR identified that medications were not being given as ordered (such as antiparkinsons or pain medications not given prior to physical therapy), which may have contributed to impaired function. The facility failed to take any action to adhere to the orders.
- **The physician and/or director of nursing failed to act in response to the pharmacist's MRR which identified the indefinite continuation of an antidepressant in a resident who had no history of depression, who had been placed on the antidepressant without an evaluation to confirm presence of depression, and whose function and mood were not monitored while getting the medication for months. The resident experienced clinically significant adverse consequences such as falls, constipation, or change in weight.**
- The pharmacist's MRR failed to identify and report the medication regimen as a possible cause of recurrent falling in a resident who was given increasing doses of anticonvulsants to treat behavioral symptoms related to dementia, resulting in serious injury.

- The pharmacist's MRR failed to identify and report clinically significant medication interactions in a resident who was started on warfarin, and who had also been receiving one or more of the following: digoxin, phenytoin, antibiotics, amiodarone, or an oral antifungal, resulting in a marked elevation in the INR with significant gastrointestinal bleeding or hematuria.
- Findings of noncompliance at Severity Level 3 at tag(s) F309, F329, F332, F333 that show evidence of process failures for conducting the MRR.

NOTE: If Severity Level 3 (actual harm that is not immediate jeopardy) has been ruled out based upon the evidence, then evaluate as to whether Severity Level 2 (no actual harm with the potential for more than minimal harm) exists.

Severity Level 2 Considerations: No Actual Harm with Potential for More Than Minimal Harm that is Not Immediate Jeopardy

Level 2 indicates noncompliance that resulted in a resident outcome of no more than minimal discomfort and/or has the potential to compromise the resident's ability to maintain or reach his or her highest practicable level of well-being. The potential exists for greater harm to occur if interventions are not provided. Examples include, but are not limited to:

- **The facility failed to respond to the pharmacist's notification that the resident was not receiving all the medications ordered; however, there was no change in the resident condition.**
- The pharmacist's MRR failed to identify and report a resident who is receiving multiple antihypertensive medications, but is not being monitored for postural hypotension, and who complains of lightheadedness especially while upright.
- The pharmacist's MRR failed to identify and report risks of hyperkalemia in a resident who has impaired renal function and is receiving an ACE inhibitor and potassium supplements.
- The pharmacist's MRR failed to evaluate and report on the potential adverse consequences of a medication known to cause anorexia for a resident with a recently decreased appetite, who had not yet experienced a significant unplanned weight loss.
- Findings of noncompliance at Severity Level 2 at tag(s) F309, F329, or F332, F333 that show evidence of process failures for conducting the MRR.

NOTE: If Severity Level 2 (no actual harm with potential for more than minimal harm that is not immediate jeopardy) has been ruled out based upon the evidence, then evaluate as to whether Severity Level 1 (no actual harm with the potential for minimal harm) exists.

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

Level 1 indicates noncompliance that resulted in no harm to the resident, and the potential for no more than minimal harm. Examples may include, but are not limited to:

- The pharmacist conducted the medication review, identified an irregularity that has not resulted in a negative outcome and is of minimal consequence (such as a multi-vitamin not being given as ordered) and reported to the director of nursing and attending physician, but neither of them acted upon the report.

F431

(Rev. 127, Issued: 11-26-14, Effective: 11-26-14, Implementation: 11-26-14)

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

- (2) Establishes a system of records of receipt and disposition of all controlled drugs in sufficient detail to enable an accurate reconciliation; and
- (3) Determines that drug records are in order and that an account of all controlled drugs is maintained and periodically reconciled.

§483.60(d) Labeling of Drugs and Biologicals

Drugs and biologicals used in the facility must be labeled in accordance with currently accepted professional principles, and include the appropriate accessory and cautionary instructions, and the expiration date when applicable.

(e) Storage of Drugs and Biologicals

- (1) In accordance with State and Federal laws, the facility must store all drugs and biologicals in locked compartments under proper temperature controls, and permit only authorized personnel to have access to the keys.
- (2) The facility must provide separately locked, permanently affixed compartments for storage of controlled drugs listed in Schedule II of the Comprehensive Drug Abuse Prevention and Control Act of 1976 and other drugs subject to abuse, except when the facility uses single unit package drug distribution systems in which the quantity stored is minimal and a missing dose can be readily detected.

INTENT (F431) 42 CFR 483.60(b)(2)(3)(d) Labeling of Drugs and Biologicals & (e) Storage of Drugs and Biologicals

The intent of this requirement is that the facility, in coordination with the licensed pharmacist, provides for:

- Safe and secure storage (including proper temperature controls, limited access, and mechanisms to minimize loss or diversion) and safe handling (including disposition) of all medication;
- Accurate labeling to facilitate consideration of precautions and safe administration of medications;
- A system of medication records that enables periodic accurate reconciliation and accounting of all controlled medications; and
- Identification of loss or diversion of controlled medications so as to minimize the time between actual loss or diversion and the detection and determination of the extent of loss or diversion.

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

DEFINITIONS (refer to F425 and F428 for additional definitions)

- “Adverse consequence” refers to an unpleasant symptom or event that is due to or associated with a medication, 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).
- “Clinically significant” refers to effects, results, or consequences that materially affect or are likely to affect an individual’s physical, mental, or psychosocial well-being either positively by preventing, stabilizing, or improving a condition or reducing a risk, or negatively by exacerbating, causing, or contributing to a symptom, illness, or decline in status.

OVERVIEW

Due to the number and types of medications that may be used and the vulnerable populations being served, the regulations require a long term care facility to have formal mechanisms to safely handle and control medications, and to maintain accurate and timely medication records. These regulations also require the facility to use a pharmacist to help establish and evaluate these mechanisms or systems. This guidance addresses those portions of the facility’s pharmaceutical services related to medication access and storage, appropriate security and safeguarding of controlled medications, and labeling of medications to assure that they are stored safely and are provided to the residents accurately and in accordance with the prescriber’s instructions.

MEDICATION ACCESS AND STORAGE

A facility is required to secure all medications in a locked storage area and to limit access to authorized personnel (for example, pharmacy technicians or assistants who have been delegated access to medications by the facility's pharmacist as a function of their jobs) consistent with state or federal requirements and professional standards of practice.

Storage areas may include, but are not limited to, drawers, cabinets, medication rooms, refrigerators, and carts. Depending on how the facility locks and stores medications, access to a medication room may not necessarily provide access to the medications (for example, medications stored in a locked cart, locked cabinets, a locked refrigerator, or locked drawers within the medication room). When medications are not stored in separately locked compartments within a storage area, only appropriately authorized staff may have access to the storage area.

Access to medications can be controlled by keys, security codes or cards, or other technology such as fingerprints. Schedule II medications must be maintained in separately locked, permanently affixed compartments. The access system (e.g. key, security codes) used to lock Schedule II medications and other medications subject to abuse, cannot be the same access system used to obtain the non-scheduled medications. The facility must have a system to limit who has security access and when access is used. Exception: Controlled medications and those subject to abuse may be stored with non-controlled medications as part of a single unit package medication distribution system, if the supply of the medication(s) is minimal and a shortage is readily detectable.

During a medication pass, medications must be under the direct observation of the person administering the medications or locked in the medication storage area/cart. In addition, the facility should have procedures for the control and safe storage of medications for those residents who can self-administer medications.

Safe medication storage includes the provision of appropriate environmental controls. Because many medications can be altered by exposure to improper temperature, light, or humidity, it is important that the facility implement procedures that address and monitor the safe storage and handling of medications in accordance with manufacturers' specifications, State requirements and standards of practice (e.g., United States Pharmacopeia (USP) standards).

CONTROLLED MEDICATIONS

Regulations require that the facility have a system to account for the receipt, usage, disposition, and reconciliation of all controlled medications. This system includes, but is not limited to:

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

NOTE: The facility may store some controlled medications in an emergency medication supply in accordance with state requirements. The facility's policies and procedures must address the reconciliation and monitoring of this supply.

- Records of usage and disposition of all controlled medications with sufficient detail to allow reconciliation (e.g., the medication administration record [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 and inventory for all controlled medications (monthly or more frequently as defined by facility procedures or when loss is identified). The reconciliation identifies loss or diversion of controlled medications so as to minimize the time between the actual loss or diversion and the time of detection and follow-up to determine the extent of loss. Because diversion can occur at any time, the reconciliation should be done often enough to identify problems. Some 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.
 - If the systems have not been effective in preventing or identifying diversion or loss, it is important that the pharmacist and the facility review and revise related controls and procedures, as necessary, such as increasing the frequency of monitoring or the amount of detail used to document controlled substances.

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

If during a survey, a concern is identified regarding a controlled medication and the resulting investigation identifies diversion of a resident's medication, the surveyor must review for F224 - Misappropriation of Resident's Property. If it is determined that a resident's medications were diverted for staff use, 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; and possibly the State licensure Board for Nursing Home Administrators.

LABELING OF MEDICATIONS AND BIOLOGICALS

This section requires facility compliance with currently accepted labeling requirements, even though the pharmacies are responsible for the actual labeling. Labeling of medications and biologicals dispensed by the pharmacy must be consistent with applicable federal and State requirements and currently accepted pharmaceutical principles and practices. Although medication delivery systems may vary, the medication label at a minimum includes the medication name (generic and/or brand) and strength, the expiration date when applicable, and

typically includes the resident's name, route of administration, appropriate instructions and precautions (such as shake well, with meals, do not crush, special storage instructions).

For medications designed for multiple administrations (e.g., inhalers, eye drops), the label is affixed in a manner to promote administration to the resident for whom it was prescribed.

When medications are prepared or compounded for intravenous infusion, the label contains the name and volume of the solution, resident's name, infusion rate, name and quantity of each additive, date of preparation, initials of compounder, date and time of administration, initials of person administering medication if different than compounder, ancillary precautions as applicable, and date after which the mixture must not be used.

For over-the-counter (OTC) medications in bulk containers (e.g., in states that permit bulk OTC medications to be stocked in the facility), the label contains the original manufacturer's or pharmacy-applied label indicating the medication name, strength, quantity, accessory instructions, lot number, and expiration date when applicable. If supplies of bulk OTC medications are used for a specific resident, the container identifies that resident by name and must contain the original manufacturer's or pharmacy-applied label.

The facility ensures that medication labeling in response to order changes is accurate and consistent with applicable state requirements.

INVESTIGATIVE PROTOCOL

For investigating compliance with the requirement at 483.60(d) & (e), see State Operations Manual, Appendix P, II.B. The Traditional Standard Survey, Task 5, Sub- Task 5E Investigative Protocol: Medication Pass and Pharmacy Services.

DETERMINATION OF COMPLIANCE (Task 6, Appendix P)

Synopsis of regulation (F431)

This requirement has several aspects. The pharmaceutical services must:

- Provide for the safe and secure storage of medications, i.e., medications must be stored at proper temperatures and locked at all times (except when under direct staff observation);
- Limit access to medications only to authorized staff;
- Label medications in accordance with Federal and State labeling requirements and accepted standards of practice; and
- Have safeguards and systems in place to control, account for, and periodically reconcile controlled medications *in order to prevent loss, diversion, or accidental exposure.*

Criteria for Compliance

Compliance with 42 CFR 483.60(b)(2)(3)(d)(e), F431, Labeling, Storage, and Controlled Medications

The facility is in compliance if:

- The facility safeguards medications by locking the medications, limiting access, and disposing of medications appropriately;
- Medications are stored under proper temperature controls and in accordance with manufacturers' specifications;
- Medication labeling identifies, at a minimum, the medication's name, strength, expiration date when applicable, and lot number, and provides instructions as necessary for safe administration;
- Schedule II medications are stored in separately locked, permanently affixed compartments, except when the facility uses single unit medication distribution systems in which the quantity stored is minimal and a missing dose can be readily detected; and
- Controlled medications are reconciled accurately.

If not, cite F431.

Noncompliance for F431

After completing the investigation, determine whether compliance with the regulation exists. Noncompliance for F431 may include (but is not limited to) facility failure to:

- Store medications to preserve their integrity, for example allowing medications that should be stored between 40 and 86 degrees Fahrenheit to either reach temperatures below 32 degrees or above 100 degrees;
- Provide accurate labeling with appropriate accessory and cautionary instructions, thereby creating a potential for the wrong medication to be administered or for the correct medications to be given by the wrong route; and
- Accurately reconcile controlled medications.

IV. DEFICIENCY CATEGORIZATION (Part IV, Appendix P)

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 resultant harm or potential for harm to the resident.

The key elements for severity determination for F431 are as follows:

1. Presence of actual or potential harm/negative outcome(s) due to a facility failure related to storage, labeling, or reconciliation of controlled medications.

Identify actual or potential harm/negative outcomes for F431 which may include, but are not limited to:

- Accidental ingestion of medication(s) by a resident(s) as a result of failure to lock medications;

One or more residents received (or had the potential to receive) the wrong medication or dose or the correct medication by the wrong route as a result of inaccurate or incomplete labeling;

- Potential for a resident(s) to receive potentially ineffective medication(s) as a result of storing medications or vaccines at wrong temperatures, resulting in their potential inactivation; *or*

- *Potential for a resident or other individual to abuse or overdose as a result of improper disposal of used controlled medications, e.g. used Fentanyl transdermal patches or remaining controlled medication in a syringe.*

2. Degree of actual or potential harm/negative outcome(s) due to a facility failure related to storage, labeling, or reconciliation of controlled medications.

Identify how the facility practices caused, resulted in, allowed, or contributed to the actual or potential for harm:

- If harm has occurred, determine if the harm is at the level of serious injury, impairment, death, compromise, or discomfort; *or*
- If harm has not yet occurred, determine the potential for serious injury, impairment, death, compromise, or discomfort to occur to the resident.

3. The immediacy of correction required.

Determine whether the noncompliance requires immediate correction in order to prevent serious injury, harm, impairment, or death to one or more residents.

The survey team must evaluate the harm or potential for harm based upon the following levels of severity for tag F431. First, the team must rule out whether Severity Level 4, Immediate Jeopardy, to a resident's health or safety, exists by evaluating the deficient practice in relation to immediacy, culpability, and severity. (Follow the guidance in Appendix Q, Guidelines for Determining Immediate Jeopardy.)

NOTE: The death or transfer of a resident who was harmed or injured as a result of facility noncompliance does not remove a finding of immediate jeopardy. The facility is required to implement specific actions to remove the jeopardy and correct the noncompliance which allowed or caused the immediate jeopardy.

Severity Level 4 Considerations: Immediate Jeopardy to Resident Health or Safety

Immediate Jeopardy is a situation in which the facility's noncompliance with one or more requirements of participation:

- Has caused/resulted in, or is likely to cause, serious injury, harm, impairment, or death to a resident; and
- Requires immediate correction as the facility either created the situation or allowed the situation to continue by failing to implement preventative or corrective measures.

Examples may include, but are not limited to:

- The facility failed to restrict access to medications resulting in serious injury or harm or death from ingestion of the medications (e.g., warfarin, digoxin, antibiotics, opioids, anticonvulsants, antipsychotics) or posed a significant risk to the health of the residents resulting in the potential for clinically significant adverse consequences such as kidney or liver failure, anaphylaxis, cardiac arrest, or death; or
- As a result of an incorrect label on the package, staff administered the wrong medication or wrong dose(s) of a medication (e.g., anticonvulsant, antihyperglycemic, benzodiazepine) with a potential for clinically significant adverse consequences, which resulted in or had the potential for serious harm or death (e.g., toxic levels of the medication, unresponsiveness, uncontrolled seizures).

NOTE: If immediate jeopardy has been ruled out based upon the evidence, then evaluate whether actual harm that is not immediate jeopardy exists at Severity Level 3.

Severity Level 3 Considerations: Actual Harm that is Not Immediate Jeopardy

Level 3 indicates noncompliance that resulted in actual harm, and can include but may not be limited to compromise, decline, or interference with the resident's ability to maintain and/or reach his/her highest practicable well-being. Examples may include, but are not limited to:

- Medication labeling was incomplete and lacked instructions that the medication was not to be given with specific foods (e.g., milk or milk-based products) resulting in altered effectiveness of the medication and worsening of the residents' symptoms, requiring medical intervention; or

- The facility failed to implement a system to reconcile controlled medications. As a result, medications were unavailable for residents for whom the medications were prescribed. Residents experienced moderate pain that compromised their ability to perform ADLs.

NOTE: If Severity Level 3 (actual harm that is not immediate jeopardy) has been ruled out based upon the evidence, then evaluate as to whether Severity Level 2 (no actual harm with the potential for more than minimal harm) exists.

Severity Level 2 Considerations: No Actual Harm with Potential for More Than Minimal Harm that is Not Immediate Jeopardy

Level 2 indicates noncompliance that resulted in a resident outcome of no more than minimal discomfort and/or the potential to compromise the resident's ability to maintain or reach his or her highest practicable level of well-being. The potential exists for greater harm to occur if interventions are not provided. Examples may include, but are not limited to:

- The facility's medication cart was not kept locked or under direct observation of authorized staff and a wandering resident with dementia ingested a medication that he/she had taken off the cart but did not suffer any adverse consequences; or
- As a result of inaccurate labeling, the resident received the wrong medication or dose or the correct medication by the wrong route and experienced discomfort but did not require any interventions.

NOTE: If Severity Level 2 (no actual harm with potential for more than minimal harm that is not immediate jeopardy) has been ruled out based upon the evidence, then evaluate as to whether Severity Level 1 (no actual harm with the potential for minimal harm) exists.

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

Level 1 indicates noncompliance that resulted in no harm to the resident, and the potential for no more than minimal harm. Examples may include, but are not limited to:

- The facility failed to reconcile controlled medications but there was no negative resident outcome and no potential for more than minimal harm.

F441

(Rev. 127, Issued: 11-26-14, Effective: 11-26-14, Implementation: 11-26-14)

§483.65 Infection Control

The facility must establish and maintain an Infection Control Program designed to provide a safe, sanitary and comfortable environment and to help prevent the development and transmission of disease and infection.

§483.65(a) Infection Control Program

The facility must establish an Infection Control Program under which it –

- (1) Investigates, controls, and prevents infections in the facility;**
- (2) Decides what procedures, such as isolation, should be applied to an individual resident; and**
- (3) Maintains a record of incidents and corrective actions related to infections.**

§483.65(b) Preventing Spread of Infection

- (1) When the Infection Control Program determines that a resident needs isolation to prevent the spread of infection, the facility must isolate the resident.**
- (2) 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.**
- (3) The facility must require staff to wash their hands after each direct resident contact for which hand washing is indicated by accepted professional practice.**

§483.65(c) Linens

Personnel must handle, store, process and transport linens so as to prevent the spread of infection.

INTENT: (F441) 42CFR 483.65 Infection Control

The intent of this regulation is to assure that the facility develops, implements, and maintains an Infection Prevention and Control Program in order to prevent, recognize, and control, to the extent possible, the onset and spread of infection within the facility. The program will:

- Perform surveillance and investigation to prevent, to the extent possible, the onset and the spread of infection;
- Prevent and control outbreaks and cross-contamination using transmission-based precautions in addition to standard precautions;
- Use records of infection incidents to improve its infection control processes and outcomes by taking corrective actions, as indicated;
- Implement hand hygiene (hand washing) practices consistent with accepted standards of practice, to reduce the spread of infections and prevent cross-contamination; and
- Properly store, handle, process, and transport linens to minimize contamination.

DEFINITIONS

Definitions are provided to clarify terminology or terms related to infection control practices in nursing homes.

- **“Airborne precautions”** refers 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 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-containing preparation base designed for application to the hands to reduce the number of viable microorganisms.
- **“Antifungal”** refers to a medication used to treat a fungal infection such as athlete’s foot, ringworm or candidiasis.
- **“Anti-infective”** refers to a group of medications used to treat infections.
- **“Antiseptic hand wash”** is “washing hands with water and soap or other detergents containing an antiseptic agent.”²
- **“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). During outbreaks, healthcare personnel may be assigned to a cohort of residents to further limit opportunities for transmission (cohorting staff).
- **“Colonization”** refers to the presence of microorganisms on or within body sites without detectable host immune response, cellular damage, or clinical expression.
- **“Communicable disease”** (also known as [a.k.a.] “Contagious disease”) refers to an infection transmissible (as from person-to-person) by direct contact with an affected individual or the individual's body fluids or by indirect means (as by a vector).
- **“Community associated infections”** (formerly “Community Acquired Infections”) refers to infections that are present or incubating at the time of admission, or generally develop within 72 hours of admission.
- **“Contact precautions”** are measures that are “intended to prevent transmission of infectious agents, including epidemiologically important microorganisms, which are spread by direct or indirect contact with the resident or the resident’s environment.”³

- **“Droplet precautions”** refers to actions designed to reduce/prevent the transmission of pathogens spread through close respiratory or mucous membrane contact with respiratory secretions.⁴
- **“Hand hygiene”** is a general term that applies to washing hands with water and either plain soap or soap/detergent containing an antiseptic agent; or thoroughly applying an alcohol-based hand rub (ABHR).
- **“Hand washing”** refers to washing hands with plain (i.e., nonantimicrobial) soap and water.
- **“Health care associated infection [HAI]”** (a.k.a. “nosocomial” and “facility-acquired” infection) refers to an infection that generally occurs after 72 hours from the time of admission to a health care facility.
- *“Hygienically Clean” means being free of pathogens in sufficient numbers to cause human illness.”⁵*
- **“Infection”** refers 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 prevention and control program”** refers to a program (including surveillance, investigation, prevention, control, and reporting) that provides a safe, sanitary and comfortable environment to help prevent the development and transmission of infection.
- **“Infection preventionist (IP)”** (a.k.a. infection control professional) refers to a person whose primary training is in either nursing, medical technology, microbiology, or epidemiology and who has acquired additional training in infection control.
- **“Isolation”** refers to the practices employed to reduce the spread of an infectious agent and/or minimize the transmission of infection.
- **“Isolation precautions”** see “Transmission-Based Precautions”
- **“Medical waste”** refers to any solid waste that is generated in the diagnosis, treatment, or immunization of human beings or animals, in research pertaining to, or in the production or testing of biologicals (e.g., blood-soaked bandages, sharps).
- **“Methicillin resistant staphylococcus aureus (MRSA)”** refers to Staphylococcus aureus bacteria that are resistant to treatment with semi-synthetic penicillins (e.g., Oxacillin/Nafcillin/Methicillin).
- **“Multi-Drug resistant organisms (MDROs)”** refers 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.⁶

- **“Outbreak”** is the occurrence of more cases of a particular infection than is normally expected, the occurrence of an unusual organism, or the occurrence of unusual antibiotic resistance patterns.⁷
- **“Personal protective equipment” (PPE)** refers to protective items or garments worn to protect the body or clothing from hazards that can cause injury.
- **“Standard precautions”** (formerly “Universal Precautions”) refers to infection prevention practices that apply to all residents, regardless of suspected or confirmed diagnosis or presumed infection status. Standard Precautions is a combination and expansion of Universal Precautions and Body Substance Isolation (a practice of isolating all body substances such as blood, urine, and feces).⁸
- **“Surveillance”** refers to the ongoing, systematic collection, analysis, interpretation, and dissemination of data to identify infections and infection risks, to try to reduce morbidity and mortality and to improve resident health status.
- **“Transmission-based precautions”** (a.k.a. “Isolation Precautions”) refers to the 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.
- **“Vancomycin resistant enterococcus (VRE)”** refers to enterococcus that has developed resistance to vancomycin.

OVERVIEW

Infections are a significant source of morbidity and mortality for nursing home residents and account for up to half of all nursing home resident transfers to hospitals. Infections result in an estimated 150,000 to 200,000 hospital admissions per year at an estimated cost of \$673 million to \$2 billion annually. When a nursing home resident is hospitalized with a primary diagnosis of infection, the death rate can reach as high as 40 percent.

It is estimated that an average of 1.6 to 3.8 infections per resident occur annually in nursing homes. Urinary tract, respiratory (e.g., pneumonia and bronchitis), and skin and soft tissue infections (e.g., pressure ulcers) represent the most common endemic infections in residents of nursing homes.⁹ Other common infections include conjunctivitis, gastroenteritis, and influenza.¹⁰

Confirming and managing an infectious outbreak can be costly and time consuming. An effective facility-wide infection prevention and control program can help to contain costs and reduce adverse consequences. An effective program relies upon the involvement, support, and

knowledge of the facility's administration, the entire interdisciplinary team, residents, and visitors.

Critical aspects of the infection prevention and control program include recognizing and managing infections at the time of a resident's admission to the facility and throughout their stay, as well as following recognized infection control practices while providing care (e.g., hand hygiene, handling and processing of linens, use of standard precautions, and appropriate use of transmission-based precautions and cohorting or separating residents). It is important that residents' conditions be reassessed because older adults may have coexisting diseases that complicate the diagnosis of an infection (e.g., joint degeneration vs. infectious arthritis, COPD versus pneumonia), and they may also have atypical or non-specific signs and symptoms related to infections, such as altered mental status, function or behavior, and impaired fever response.

Because of the potential negative impact that a resident may experience as a result of the implementation of special precautions, the facility is challenged to promote the individual resident's rights and well-being while trying to prevent and control the spread of infections.

NOTE: It is important that all infection prevention and control practices reflect current Centers for Disease Control (CDC) guidelines.

INFECTION PREVENTION AND CONTROL PROGRAM

An effective infection prevention and control program is necessary to control the spread of infections and/or outbreaks.

Program Development and Oversight

Program development and oversight emphasize the prevention and management of infections. Program oversight involves establishing goals and priorities for the program, planning, and implementing strategies to achieve the goals, monitoring the implementation of the program (including the interdisciplinary team's infection control practices), and responding to errors, problems, or other identified issues. Additional activities involved in program development and oversight may include but are not limited to:

- Identifying the staff's roles and responsibilities for the routine implementation of the program as well as in case of an outbreak of a communicable disease, an episode of infection, or the threat of a bio-hazard attack;
- Developing and implementing appropriate infection control policies and procedures, and training staff on them;
- Monitoring and documenting infections, including tracking and analyzing outbreaks of infection as well as implementing and documenting actions to resolve related problems;
- Defining and managing appropriate resident health initiatives, such as:
 - The immunization program (influenza, pneumonia, etc); and

- Tuberculosis screening on admission and following the discovery of a new case, and managing active cases consistent with State requirements;
- Providing a nursing home liaison to work with local and State health agencies; and
- Managing food safety, including employee health and hygiene, pest control, investigating potential food-borne illnesses, and waste disposal.

The facility identifies personnel responsible for overall program oversight, which may involve collaboration of the administrator, the medical director or his/her designee, the director of nursing, and other appropriate facility staff as needed. This group may define how and when the program is to be routinely monitored and situations that may trigger a focused review of the program. The group communicates the findings from collecting and analyzing data to the facility's staff and management, and directs changes in practice based on identified trends, government infection control advisories, and other factors.

Components of an Infection Prevention and Control Program

An effective infection prevention and control program incorporates, but is not limited to, the following components:

- Policies, procedures, and practices which promote consistent adherence to evidence-based infection control practices;
- Program oversight including planning, organizing, implementing, operating, monitoring, and maintaining all of the elements of the program and ensuring that the facility's interdisciplinary team is involved in infection prevention and control;
- Infection preventionist, a person designated to serve as coordinator of the infection prevention and control program;
- Surveillance, including process and outcome surveillance, monitoring, data analysis, documentation and communicable diseases reporting (as required by State and Federal law and regulation);
- Education, including training in infection prevention and control practices, to ensure compliance with facility requirements as well as State and Federal regulation; and
- Antibiotic review including reviewing data to monitor the appropriate use of antibiotics in the resident population.

Examples of activities related to the Infection Prevention and Control Program may include but are not limited to:

- Undertaking process and/or outcome surveillance activities to identify infections that are causing, or have the potential to cause an outbreak;

- Conducting data analysis to help detect unusual or unexpected outcomes and to determine the effectiveness of infection prevention and control practices;
- Documenting observations related to the causes of infection and/or infection trends; and
- Implementing measures to prevent the transmission of infectious agents and to reduce risks for device and procedure-related infections.

Policies and Procedures

Policies and procedures are the foundation of the facility's infection prevention and control program. Policies and procedures are reviewed periodically and revised as needed to conform to current standards of practice or to address specific facility concerns.

Written policies establish the program's expectations and parameters. For example, policies may specify the use of standard precautions facility-wide and use of transmission-based precautions when indicated, define the frequency and nature of surveillance activities, require that staff use accepted hand hygiene after each direct resident contact for which hand hygiene is indicated, or prohibit direct resident contact by an employee who has an infected skin lesion or communicable disease.

Procedures guide the implementation of the policies and performance of specific tasks. Procedures may include, for example, how to identify and communicate information about residents with potentially transmissible infectious agents, how to obtain vital signs for a resident on contact precautions and what to do with the equipment after its use, and essential steps and considerations (including choosing agents) for performing hand hygiene.

Infection Preventionist (IP)

A facility may designate an IP to serve as the coordinator of an Infection Prevention and Control Program. Responsibilities may include collecting, analyzing, and providing infection data and trends to nursing staff and health care practitioners; consulting on infection risk assessment, prevention, and control strategies; providing education and training; and implementing evidence-based infection control practices, including those mandated by regulatory and licensing agencies, and guidelines from the Centers for Disease Control and Prevention.

Surveillance

Essential elements of a surveillance system include use of standardized definitions and listings of the symptoms of infections, use of surveillance tools such as infection surveys and data collection templates, walking rounds throughout the facility,¹¹ identification of segments of the resident populations at risk for infection, identification of the processes or outcomes selected for surveillance, statistical analysis of data that can uncover an outbreak, and feedback of results to the primary caregivers so that they can assess the residents for signs of infection.

Two types of surveillance (process and outcome) can be implemented in facilities.

Process Surveillance

Process surveillance reviews practices directly related to resident care in order to identify whether the practices comply with established prevention and control procedures and policies based on recognized guidelines. Examples of this type of surveillance include monitoring of compliance with transmission based precautions, proper hand hygiene,¹² and the use and disposal of gloves. Process surveillance determines, for example, whether the facility:

- Minimizes exposure to a potential source of infection;
- Uses appropriate hand hygiene prior to and after all procedures;¹³
- Ensures that appropriate sterile techniques are followed; for example, that staff:
 - Use sterile gloves, fluids, and materials, when indicated,¹⁴ depending on the site and the procedure;¹⁵
 - Avoid contaminating sterile procedures;¹⁶ and
 - Ensure that contaminated/non-sterile items are not placed in a sterile field.
- Uses Personal Protective Equipment (PPE) when indicated;¹⁷
- Ensures that reusable equipment is appropriately cleaned, disinfected, or reprocessed; and
- Uses single-use medication vials and other single use items appropriately (proper disposal after every single use).¹⁸

Outcome Surveillance

In contrast to process surveillance, outcome surveillance is designed to identify and report evidence of an infection. The outcome surveillance process consists of collecting/documenting data on individual cases and comparing the collected data to standard written definitions (criteria) of infections. The IP or other designated staff reviews data (including residents with fever or purulent drainage, and cultures or other diagnostic test results consistent with potential infections) to detect clusters and trends. Other sources of relevant data may include antibiotic orders, laboratory antibiograms (antibiotic susceptibility profiles), medication regimen review reports, and medical record documentation such as physician progress notes and transfer summaries accompanying newly admitted residents.¹⁹ The facility's program should choose to either track the prevalence of infections (existing/current cases both old and new) at a specific point, or focus on regularly identifying new cases during defined time periods. When conducting outcome surveillance, the facility may choose to use one or more of the automated systems and authoritative resources that are available, and include definitions.

Documentation

Facilities may use various approaches to gathering, documenting, and listing surveillance data. The facility's infection control reports describe the types of infections and are used to identify

trends and patterns. Descriptive documentation provides the facility with summaries of the observations of staff practices and/or the investigation of the causes of an infection and/or identification of underlying cause(s) of infection trends.

It is important that the infection prevention and control program define how often and by what means surveillance data will be collected, regardless of whether the facility creates its own forms, purchases preprinted forms, or uses automated systems.

Monitoring

Monitoring of the implementation of the program, its effectiveness, the condition of any resident with an infection, and the resolution of the infection and/or an outbreak is considered an integral part of nursing home infection surveillance. The facility monitors practices (e.g., dressing changes and transmission-based precaution procedures) to ensure consistent implementation of established infection prevention and control policies and procedures based on current standards of practice. All residents are monitored for current infections and infection risks.

Data Analysis

Determining the origin of infections helps the facility identify the number of residents who developed infections within the nursing home. Comparing current infection control surveillance data (including the incidence or prevalence of infections and staff practices) to past data enables detection of unusual or unexpected outcomes, trends, effective practices, and performance issues. The facility can then evaluate whether it needs to change processes or practices to enhance infection prevention and minimize the potential for transmission of infections.

It is important that surveillance reports be shared with appropriate individuals including, but not limited to, the director of nursing and medical director. In addition, it is important that the staff and practitioners receive reports that are relevant to their practices to help them recognize the impact of their care on infection rates and outcome.

Communicable Disease Reporting

It is important for each facility to have processes that enable them to consistently comply with State and local health department requirements for reporting communicable diseases.

Education

Both initial and ongoing infection control education help staff comply with infection control practices. Updated education and training are appropriate when policies and procedures are revised or when there is a special circumstance, such as an outbreak, that requires modification or replacement of current practices.²⁰ In addition to education regarding general infection control principles, some infection control training is discipline and task specific (e.g., insertion of urinary catheters, suctioning, intravenous care or blood glucose monitoring). Follow-up competency evaluations identify staff compliance.

Essential topics of infection control training include, but are not limited to routes of disease transmission, hand hygiene, sanitation procedures, MDROs, transmission-based precaution techniques, and the federally required OSHA education.

Antibiotic Review

Because of increases in MDROs, review of the use of antibiotics (including comparing prescribed antibiotics with available susceptibility reports) is a vital aspect of the infection prevention and control program. It is the physician's (or other appropriate authorized practitioner's) responsibility to prescribe appropriate antibiotics and to establish the indication for use of specific medications. As part of the medication regimen review, the consultant pharmacist can assist with the oversight by identifying antibiotics prescribed for resistant organisms or for situations with questionable indications, and reporting such findings to the director of nursing and the attending physician. See the Guidance at §483.65, Tag F329 regarding use of a medication without adequate indication for use and at §483.65, Tag F428 regarding medication regimen review.

PREVENTING THE SPREAD OF INFECTION

Factors Associated with the Spread of Infection in Nursing Homes

Many factors contribute to a substantial severity and frequency of infections and infectious diseases in nursing homes. These infections can arise from individual or institutional factors, or both. Modes of transmission of infection include, but are not limited to:

- Contact;
- Droplet; and
- Airborne.

Individual Factors

Examples of individual factors contributing to infections and the severity of the infection outcomes in facility residents include, but are not limited to the following:

- Medications affecting resistance to infection such as corticosteroids and chemotherapy;
- Limited physiologic reserve (e.g., decreased function of the heart, lungs, and kidneys);
- Compromised host defenses (e.g., decreased or absent cough reflex predisposing to aspiration pneumonia, thinning skin associated with pressure ulcers, decreased tear production predisposing to conjunctivitis, vascular insufficiency, and impaired immune function);
- Coexisting chronic diseases (e.g., diabetes, arthritis, cancer, COPD, anemia);

- Complications from invasive diagnostic procedures such as skin or bloodstream infections;
- Impaired responses to infection (e.g., cell mediated responses); and
- Increased frequency of therapeutic toxicity (e.g., declining kidney and liver function).

Institutional Factors

In addition to individual factors, institutional factors may also facilitate transmission of infections among residents, including but not limited to:

- Pathogen exposure in shared communal living space (e.g., handrails and equipment);
- Common air circulation;
- Direct/indirect contact with health care personnel/visitors/other residents;
- Direct/indirect contact with equipment used to provide care; and
- Transfer of residents to and from hospitals or other settings.

Residents can be exposed to potentially pathogenic organisms in several ways, including but not limited to the following:

- Improper hand hygiene;
- Improper glove use (e.g., utilizing a single pair of gloves for multiple tasks or multiple residents); and
- Improper food handling.

Direct Transmission (Person to Person)

Direct transmission occurs when microorganisms are transferred from an infected/colonized person to another person. Contaminated hands of healthcare personnel are often implicated in direct contact transmission. Agents that can be transmitted by direct contact include, but are not limited to MRSA, VRE, and Influenza.

Indirect Transmission

Indirect transmission involves the transfer of an infectious agent through a contaminated intermediate object. The following are examples of opportunities for indirect contact.

- Resident-care devices (e.g., electronic thermometers or glucose monitoring devices) may transmit pathogens if devices contaminated with blood or body fluids are shared without cleaning and disinfecting between uses for different residents; and

- 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 Clostridium difficile). Indirect contact may occur through toilets and bedpans. Examples of illnesses spread via a fecal-oral route include salmonella, shigella, and pathogenic strains of E. coli, norovirus, and symptomatic Clostridium difficile.

Reducing and/or preventing infections through indirect contact requires the decontamination (i.e., cleaning, sanitizing, 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. The choice of decontamination method depends on the risk of infection to the resident coming into contact with equipment or medical devices.

The CDC has adopted the Spaulding classification system that identifies three risk levels associated with medical and surgical instruments: critical, semi-critical and noncritical.²¹ This includes:

- Critical items (e.g., needles, intravenous catheters, indwelling urinary catheters) are defined as those items which normally enter sterile tissue, or the vascular system, or through which blood flows. The equipment must be sterile when used, based on one of several accepted sterilization procedures;²¹
- Semi-critical items (e.g., thermometers, podiatry equipment, electric razors) are defined as those objects that touch mucous membranes or skin that is not intact. Such items require meticulous cleaning followed by high-level disinfection treatment using an FDA-approved chemo sterilizer agent, or they may be sterilized; and
- Non-critical items (e.g., stethoscopes, blood pressure cuffs, over-bed tables) are defined as those that come into contact with intact skin or do not contact the resident. They require low level disinfection by cleaning periodically and after visible soiling, with an EPA disinfectant detergent or germicide that is approved for health care settings.
- *Single-use disposable equipment is an alternative to sterilizing reusable medical instruments. Single-use devices must be discarded after use and are never used for more than one resident. Nursing homes may purchase reprocessed single-use devices when these devices are reprocessed by an entity or a third party reprocessor that is registered with the FDA. The 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.*

Single Dose/Single Use Medications

The United States Pharmacopeia (USP) has established standards for compounding which, to the extent such practices are also subject to regulation by the Food and Drug Administration (FDA), may also be recognized and enforced under §§501 and 502 of the Federal Food, Drug

and Cosmetics Act (FDCA). These USP compounding standards include USP General Chapter 797, Pharmaceutical Compounding - Sterile Preparations (“USP <797>”).

Medications labeled as single-dose vials or single use vials, collectively referred to as SDVs in this guidance, must not be used for multiple patients due to the risk of spreading infectious diseases.

Medications labeled as single-use or single dose by manufacturers typically lack antimicrobial preservatives, and once a SDV is entered, the contents can support the growth of microorganisms.

The risk of infection transmission associated with using SDVs for multiple patients is well documented, with evidence accumulated from the investigation of multiple outbreaks.

However, when **previously unopened** SDVs are repackaged consistent with aseptic conditions under the requirements of United States Pharmacopeia <797>, and subsequently stored consistent with USP <797> and the manufacturer’s package insert, it is permissible for healthcare personnel to administer repackaged doses derived from SDVs to multiple patients, provided that each repackaged dose is used for a single patient in accordance with applicable storage and handling requirements.

Among other things, these standards currently require that:

- The facility doing the repackaging must use qualified, trained personnel to do so, under International Organization for Standardization (ISO) Class 5 air quality conditions within an ISO Class 7 buffer area. All entries into a SDV for purposes of repackaging under these conditions must be completed within 6 hours of the initial needle puncture.
- All repackaged doses prepared under these conditions must be assigned and labeled with a beyond use date (BUD), based on an appropriate determination of contamination risk level in accordance with USP <797>, by the licensed healthcare professional supervising the repackaging process

Administering drugs from one SDV to multiple residents without adhering to USP <797> standards is not acceptable.

Insulin Pens

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. 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 patient/resident, even when the needle is changed.²² The Food and Drug Administration (FDA) makes the following recommendations to prevent transmission of blood-borne 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 or other identifiers to verify that the correct pen is used on the correct resident.

- *Facilities should review their policies and procedures and educate their staff regarding safe use of insulin pens.*

***NOTE:** Sharing insulin pens between residents is similar to reusing needles or syringes for more than one resident, and such a finding may warrant a further investigation of the overall infection control practices within the facility. If it is discovered that insulin pens are shared between residents, the facility's plan of correction should include notification of the local health department or state epidemiologist for determination of the need for post-exposure follow up of patients and residents.*

Facilities who fail to observe appropriate infection control and prevention standards of practice during medication administration may also require evaluation under F332 and F333, Medication Errors.

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., via air, water, inanimate objects). Healthcare personnel and resident care equipment often move from resident to resident and therefore may serve as a vehicle for transferring infectious organisms. Another potential challenge is that the transmission of infectious organisms within the facility may be facilitated by inadequate hand hygiene facilities, rinsing bed pans in inappropriate places (e.g., resident's sink), or inappropriate placement of colonized or infected residents (e.g., sharing a bathroom with a non-infected resident).

Airborne transmission can occur by inhaling pathogenic droplet nuclei (e.g., M Tuberculosis). Contaminated environmental surfaces are also potential reservoirs for infections. Infections caused by bacteria and viruses are especially common. Clostridium difficile can live on inanimate surfaces for up to 5 months²³ while the hepatitis B virus can last up to a week²⁴ 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.²⁵

The appropriate disposal of waste helps minimize the potential transmission of infections. It is important for the facility to monitor safe handling of blood and body fluids and the disposal of contaminated waste.

General Approaches to Prevention and Control

A facility's infection control practices are important to preventing the transmission of infections. Infection control precautions used by the facility include two primary tiers: "Standard Precautions" and "Transmission-Based Precautions."

Standard Precautions

Standard precautions are based upon the principle that all blood, body fluids, secretions, excretions (except sweat), non-intact skin, and mucous membranes may contain transmissible infectious agents. Standard precautions are intended to be applied to the care of all persons in all

healthcare settings, regardless of the suspected or confirmed presence of an infectious agent. Implementation of standard precautions constitutes the primary strategy for preventing healthcare-associated transmission of infectious agents among residents and healthcare personnel. Appropriate infection control measures should be used in each resident interaction.

Standard precautions include but are not limited to hand hygiene, safe injection practices, the proper use of PPE (e.g., gloves, gowns, and masks), resident placement, and care of the environment, textiles, and laundry. Also, 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).²⁶ In addition to proper hand hygiene, it is important for staff to use appropriate protective equipment as a barrier to exposure to any body fluids (whether known to be infected or not). For example, in situations identified as appropriate, gloves and other equipment such as gowns and masks are to be used as necessary to control the spread of infections. Standard precautions are also intended to protect residents by ensuring that healthcare personnel do not carry infectious agents to residents on their hands or via equipment used during resident care.

Disposal of waste is also handled as though all body fluids are infectious. Potentially contaminated articles are stored and disposed of in appropriate containers (e.g., sharps containers, biohazard bags, etc.), and the environment is cleaned using germicidal agents to reduce the risk of transmission of infection.

Hand Hygiene

Hand hygiene continues to be the primary means of preventing the transmission of infection. The following is a list of some situations that require hand hygiene:

- When coming on duty;
- When hands are visibly soiled (hand washing with soap and water); Before and after direct resident contact (for which hand hygiene is indicated by acceptable professional practice);
- Before and after performing any invasive procedure (e.g., fingerstick blood sampling);
- Before and after entering isolation precaution settings;
- Before and after eating or handling food (hand washing with soap and water);
- Before and after assisting a resident with meals;
- Before and after assisting a resident with personal care (e.g., oral care, bathing);

- Before and after handling peripheral vascular catheters and other invasive devices;
- Before and after inserting indwelling catheters;
- Before and after changing a dressing;
- Upon and after coming in contact with a resident's intact skin, (e.g., when taking a pulse or blood pressure, and lifting a resident);
- After personal use of the toilet (hand washing with soap and water);
- Before and after assisting a resident with toileting;
- After contact with a resident with infectious diarrhea including, but not limited to infections caused by norovirus, salmonella, shigella, and C. difficile (hand washing with soap and water);
- After blowing or wiping nose;
- After contact with a resident's mucous membranes and body fluids or excretions;
- After handling soiled or used linens, dressings, bedpans, catheters and urinals;
- After handling soiled equipment or utensils;
- After performing your personal hygiene (hand washing with soap and water);
- After removing gloves or aprons; and
- After completing duty.

Consistent use by staff of proper hygienic practices and techniques is critical to preventing the spread of infections. It is necessary for staff to have access to proper hand washing facilities with available soap (regular or anti-microbial), warm water, and disposable towels and/or heat/air drying methods. Alcohol based hand rubs (ABHR) cannot be used in place of proper hand washing techniques in a food service setting.²⁷

Recommended techniques for washing hands with soap and water include wetting hands first with clean, running warm water, applying the amount of product recommended by the manufacturer to hands, and rubbing hands together vigorously for at least 15 seconds covering all surfaces of the hands and fingers; then rinsing hands with water and drying thoroughly with a disposable towel; and turning off the faucet on the hand sink with the disposable paper towel.

Except for situations where hand washing is specifically required, antimicrobial agents such as ABHR are also appropriate for cleaning hands and can be used for direct resident care. Recommended techniques for performing hand hygiene with an ABHR include applying product

to the palm of one hand and rubbing hands together, covering all surfaces of hands and fingers, until the hands are dry. In addition, gloves or the use of baby wipes are not a substitute for hand hygiene.

Other Staff-Related Preventive Measures

Facility staff who have direct contact with residents or who handle food must be free of communicable diseases and open skin lesions, if direct contact will transmit the disease. It is important that the facility maintain documentation of how they handle staff with communicable infections or open skin lesions.

It is important that all staff involved in direct resident contact maintain fingernails that are clean, neat, and trimmed. Wearing intact disposable gloves in good condition and that are changed after each use helps reduce the spread of microorganisms. It is important for dietary staff to wear hair restraints (e.g., hairnet, hat, and/or beard restraint) while in the kitchen areas to prevent their hair from contacting exposed food. Since jewelry can harbor microorganisms, it is recommended by the FDA that dietary staff keep jewelry to a minimum and remove or cover hand jewelry when handling food.²⁸

Transmission-based Precautions

Transmission-based precautions are used for residents who are known to be, or suspected of being infected or colonized with infectious agents, including pathogens that require additional control measures to prevent transmission. In nursing homes, it is appropriate to individualize decisions regarding resident placement (shared or private), balancing infection risks with the need for more than one occupant in a room, the presence of risk factors that increase the likelihood of transmission, and the potential for adverse psychological impact on the infected or colonized resident.²⁹

It is essential both to communicate transmission-based precautions to all health care personnel, and for personnel to comply with requirements. Pertinent signage (i.e., isolation precautions) and verbal reporting between staff can enhance compliance with transmission-based precautions to help minimize the transmission of infections within the facility.

It is important to use the standard approaches, as defined by the CDC for transmission-based precautions: airborne, contact, and droplet precautions.³⁰ The category of transmission-based precaution determines the type of PPE to be used. Communication (e.g., verbal reports, signage) regarding the particular type of precaution to be utilized is important. When transmission-based precautions are in place, PPE should be readily available. Proper hand washing remains a key preventive measure, regardless of the type of transmission-based precaution employed.

Transmission-based precautions are maintained for as long as necessary to prevent the transmission of infection. It is appropriate to use the least restrictive approach possible that adequately protects the resident and others. Maintaining isolation longer than necessary may adversely affect psychosocial well-being. The facility should document in the medical record the rationale for the selected transmission-based precautions.

Airborne Precautions

Airborne precautions prevent the transmission of organisms that remain infectious when suspended in the air (e.g., varicella zoster (shingles) and *M. tuberculosis*). Resident health activities related to infection control include tuberculosis (TB) screening and management of active cases, consistent with State requirements. Management of some airborne infections such as active TB requires a single-resident airborne infection isolation room (AIIR) that is equipped with special air handling and ventilation capacity. Although not all residents with airborne infections will require an AIIR, residents with infections requiring an AIIR may need to 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 it is important for the facility to have a plan 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.

Personnel caring for residents on airborne precautions should wear a mask or respirator that is donned prior to room entry, depending on the disease-specific recommendations.³¹ Depending on the condition, staff can use N95 or higher level respirators or wear masks if respirators are not available.

Contact Precautions

Contact transmission risk requires the use of contact precautions to prevent infections that are spread by person-to-person contact. Contact precautions require the use of appropriate PPE, including a gown and gloves upon entering the contact precaution room. Prior to leaving the contact precaution room the PPE is removed and hand hygiene is performed.

Depending on the situation, options for residents on contact precautions may include the following: a private room, cohorting, or sharing a room with a roommate with limited risk factors (e.g., without indwelling devices, without pressure ulcers and not immunocompromised).

Droplet Precautions

In contrast to contact transmission, respiratory droplets transmit infections directly from the respiratory tract of an infected individual to susceptible mucosal surfaces of the recipient. Since this generally occurs at close proximity, facial protection is necessary. Respiratory droplets are generated when an infected person coughs, sneezes, or talks; or during procedures such as suctioning, endotracheal intubation, cough induction by chest physiotherapy, and cardiopulmonary resuscitation. Studies have shown that respiratory viruses can enter the body via the nasal mucosa, conjunctivae and less frequently the mouth.³² Examples of droplet-borne organisms that may cause infections include, but are not limited to influenza and mycoplasma.

The maximum distance for droplet transmission is currently unresolved, but the area of defined risk based on epidemiological findings is approximately 3-10 feet.³³ In contrast to airborne pathogens, droplet-borne pathogens are generally not transmitted through the air over long distances. Masks are to be used within approximately 6 to 10 feet of a resident or upon entry into a resident's room with respiratory droplet precautions. Residents with droplet precautions

are placed in either a private room, cohorted, or share a room with a roommate with limited risk factors.

Implementation of Transmission-Based Precautions

It is important that facility staff clearly identify the type of precautions and the appropriate PPE to be used in the care of the resident. The PPE should be readily available near the entrance to the resident's room. Signage can be posted on the resident's door instructing visitors to see the nurse before entering.

It is not always possible to identify prospectively residents needing transmission-based precautions. 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.³⁴ The use of appropriate transmission-based precautions when a resident develops symptoms or signs of a transmissible infection or arrives at a nursing home with symptoms of an infection (pending laboratory confirmation) reduces transmission opportunities. However, once it is confirmed that the resident is no longer a risk for transmitting the infection, removing transmission-based precautions avoids unnecessary social isolation.

Safe Water Precautions

Safe drinking water is also critical to controlling the spread of infections. The facility is responsible for maintaining a safe and sanitary water supply, by meeting nationally recognized standards set by the FDA for drinking water (<500 CFU/mL per heterotrophic plate count).

HANDLING LINENS TO PREVENT AND CONTROL INFECTION TRANSMISSION

It is important that all potentially contaminated linen be handled with appropriate measures to prevent cross-transmission. If the facility handles all used linen as potentially contaminated (i.e., using standard precautions), no additional separating or special labeling of the linen is recommended. No special precautions (i.e., double bagging) or categorizing is recommended for linen originating in isolation rooms. 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. Alternatively, leak-resistant bags are recommended for linens contaminated with blood or body substances. If standard precautions for contaminated linens are not used, then some identification with labels, color coding or other alternatives means of communication is important.

For the routine handling of contaminated laundry, minimum agitation is recommended, to avoid the contamination of air, surfaces, and persons. The risk of environmental contamination may be reduced by having personnel bag or contain contaminated linen at the point of use, and not sorting or pre-rinsing in resident care areas.

It is important that laundry areas have hand washing facilities and products, as well as appropriate PPE (i.e., gloves and gowns) available for workers to wear while sorting linens. Laundry equipment should be used and maintained according to the manufacturer's instructions to prevent microbial contamination of the system. It is recommended that damp linen is not left in machines overnight. *The CDC recommends leaving washing machines open to air when not in use to allow the machine to dry completely and to prevent growth of microorganisms in wet, potentially warm environments.*

Detergent and water physically remove many microorganisms from the linen through dilution during the wash cycle. *Advances in 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. Facilities may use any detergent designated for laundry in laundry processing. Further, laundry detergents used within facilities are not required to have stated anti-microbial claims. Facilities should closely follow manufacturer's instructions for laundry detergents used. The CMS, in collaboration with the CDC, has determined that ozone cleaning systems are acceptable methods of processing laundry. Ozone cleaning systems also should be used per manufacturer's instructions.*

An effective way to destroy microorganisms in laundry items is through hot water washing at temperatures above 160°F (71°C) for 25 minutes.³⁵ Alternatively, low temperature washing at 71 to 77 degrees F (22-25 degrees C) plus a 125-part-per-million (ppm) chlorine bleach rinse has been found to be effective and comparable to high temperature wash cycles.³⁶ *Laundry washing within facilities typically occurs in a low water temperature environment. Many laundry items are composed of materials that cannot withstand a chlorine bleach rinse and remain intact. 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. However, a chlorine bleach rinse may still be used for laundry items composed of materials such as cottons. Hot water washing at temperatures greater than 160 degrees F for 25 minutes and low temperature washing at 71 to 77 degrees F (22-25 degrees C) with a 125-part-per-million (ppm) chlorine bleach rinse continue to be effective ways to wash laundry. If a facility chooses to process laundry using a hot water temperature environment, the temperature maintained for 25 minutes should be at or above 160 degrees Fahrenheit (71°C).*

Facilities are not required to maintain a record of water temperatures during laundry processing cycles. Facilities are required to follow manufacturer's instructions for all materials involved in laundry processing (e.g., washing machines; dryers; any laundry detergents, rinse aids, or other additives employed during the laundry process). Facilities should also follow manufacturer's instructions for clothing, linens, and other laundry items to determine the appropriate methods to use to produce a hygienically clean product. Facilities should also consider a resident's individual needs (e.g., allergies) when selecting methods for processing laundry.

If laundry chutes are used, it is recommended that they are properly 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).

If linen is sent off to a professional laundry, the facility should obtain an initial agreement between the laundry service and facility that stipulates the laundry will be hygienically clean and handled to prevent recontamination from dust and dirt during loading and transport. *For example, an ozone laundry cleaning system is a method which may require a professional laundry service. The facility will need to obtain such an agreement in this instance. Whether laundry processing is completed within the facility or outside the facility, facilities should have written policies & procedures which should include training for staff who will handle linens and laundry.*

Standard 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. Therefore it is recommended that mattress covers with tears or holes be replaced. It is recommended that moisture resistant mattress covers be cleansed and disinfected between residents with an EPA approved germicidal detergent to help prevent the spread of infections, and fabric mattress covers should be laundered between residents. Pillow covers and washable pillows should be laundered in a hot water laundry cycle between residents or when they become contaminated with body substances. Discarding mattresses if fluids have penetrated into the mattress fabric and washing pillows and pillow covers in a hot-water laundry cycle will also reduce the risk of indirect contact with infectious agents.³⁷

RECOGNIZING AND CONTAINING OUTBREAKS

It is important that facilities know how to recognize and contain infectious outbreaks. An outbreak is typically one or more of the following:³⁸

One case of an infection that is highly communicable;

Trends that are 10 percent higher than the historical rate of infection for the facility that may reflect an outbreak or seasonal variation and therefore warrant further investigation; or

- Occurrence of three or more cases of the same infection over a specified length of time on the same unit or other defined areas.

Once an outbreak has been identified, it is important that the facility take the appropriate steps to contain it. State health departments offer guidance and regulations regarding responding to and reporting outbreaks. This information is often received in advance of an outbreak and included in the infection prevention and control program. Plans for containing outbreaks usually include efforts to prevent further transmission of the infection while considering the needs of all residents and staff.³⁸

PREVENTING SPREAD OF ILLNESS RELATED TO MDROs

The MDROs found in facilities include, but are not limited to MRSA, VRE, and clostridium difficile (C. difficile). Transmission-based precautions are employed for residents who are

actively infected with multi-drug resistant organisms. Aggressive infection control measures and strict compliance by healthcare personnel can help minimize the spread of MDROs to other susceptible individuals.³⁹

Staphylococcus is a common cause of infections in hospitals and nursing homes, and increasingly in the community. Common sites of MRSA colonization include the rectum, perineum, skin and nares.⁴⁰ Colonization may precede or endure beyond an acute infection. MRSA is transmitted person-to-person (most common), and on inanimate objects.

The MRSA infection is commonly treated with vancomycin, which in turn can lead to increased enterococcus antibiotic resistance. Therefore, preventing infection with MRSA and the limited use of antibiotics for individuals who are only colonized can also help prevent the development of VRE. Enterococcus is an organism that normally occurs in the colorectal tract. VRE infections have been associated with prior antibiotic use.

C. difficile is a bacterial species of the genus clostridium, which are [gram-positive](#), [anaerobic](#), [spore](#)-forming rods (bacilli). The organism normally lives benignly in the colon in spore form. When antibiotic use eradicates normal [intestinal flora](#), the organism may become active and produce a toxin that causes symptoms such as diarrhea, abdominal pain, and fever. More severe cases can lead to additional complications such as intestinal damage and severe fluid loss. Treatment options include stopping antibiotics and starting specific anticlostridial antibiotics, e.g., [metronidazole](#) or oral vancomycin. If a resident has diarrhea due to C. difficile, large numbers of C. difficile organisms will be released from the intestine into the environment and may be transferred to other individuals, causing additional infections.

Contact precautions are instituted for residents with symptomatic C. difficile infection. Thorough hand washing with soap and water after caring for the resident reduces the risk of cross-transmission. Another control measure is to give the resident his or her own toilet facilities that will not be shared by other residents.

The C. difficile can survive in the environment (e.g., on floors, bed rails or around toilet seats) in its spore form for up to 6 months. Rigorously cleaning the environment removes C. difficile spores, and can help prevent transmission of the organism.⁴¹ Cleaning equipment used for residents with C. difficile with a 1:10 dilution of sodium hypochlorite (nine parts water to one part bleach) will also reduce the spread of the organism. Once mixed, the solution is effective for 24 hours.

PREVENTING INFECTIONS RELATED TO THE USE OF SPECIFIC DEVICES

Intravascular catheters are used widely to provide vascular access, and are increasingly seen in nursing homes. While providing such access, they may increase the risk for local and systemic infections and additional complications such as septic thrombophlebitis.

Central venous catheters (CVCs) have also been associated with infectious complications. Other intravascular catheters such as dialysis catheters and implanted ports may be accessed multiple times per day, such as for hemodynamic measurements, or to obtain samples for laboratory

analysis, thus increasing the risk of contamination and subsequent clinical infection. Limiting access to central venous catheters for only the primary purpose may help reduce the risk of infection.

Consistent use of appropriate infection control measures when caring for residents with vascular access catheters reduces the risk for catheter-related infections.⁴² Surveillance consistently includes all residents with vascular access, including those with venous access and implanted ports such as peripherally inserted central catheter lines, and midline access catheters. Activities to reduce infection risk includes surveillance such as observation of insertion sites, routine dressing changes, use of appropriate PPE and hand hygiene during the care and treatment of residents with venous catheters, and review of the resident for clinical evidence of infection⁴². It is important that practices reflect the most current CDC guidelines.

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INVESTIGATIVE PROTOCOL FOR INFECTION CONTROL

Objectives

- To determine if the facility has an infection prevention and control program that prevents, investigates, and controls infections in the facility, and determines appropriate procedures to be applied to a resident with an infection;
- To determine if the facility has a program that collects information regarding infections acquired in the facility, analyzes the information and develops a plan of action to prevent further infections;
- To determine if staff practices are consistent with current infection control principles and prevent cross-contamination (e.g., laundry and hand hygiene practices); and
- To determine whether staff with communicable disease or open lesions are prohibited, as appropriate, from direct contact with the resident.

Use

Use this protocol to investigate compliance at F441 for every initial certification and recertification survey. In addition, use this protocol on revisit or abbreviated surveys (complaint investigations) when indicated.

Procedures

The surveyor(s), throughout the survey, should conduct the following observations, interviews and record reviews. In addition, the surveyor(s) should also review the facility's infection control policies, procedures, as well as documentation of staff training, and as necessary, interview facility staff with responsibility for oversight of the infection prevention and control program.

Observations

Observe various disciplines (nursing, dietary, and housekeeping) to determine if they follow appropriate infection control practices and transmission based precaution procedures. Observe, for example, whether:

- Linens are handled, processed, transported, and stored to prevent contamination and the transmission of infection;
- Employees exhibit overt signs of illness or communicable disease that have the potential to transmit disease (e.g., cold symptoms, infected, open lesions on hands) and if present, whether they are prohibited from contact with the resident or the resident's food;
- Staff and visitors adhere to precautions and related processes, including the use of PPE;
- Precautions/accommodations are in place and followed (as recommended, e.g., gowns, singles rooms or adequate space between residents, exclusion from group activities, etc.) for residents with potentially transmissible infections;

- *Insulin Pens containing multiple doses of insulin are used for the resident prescribed only, even when the needle is changed, and clearly labeled with the resident's name or other identifiers to verify correct use.*
- Staff utilize appropriate precautions when residents on special precautions are permitted out of their rooms,(e.g., mask on resident with TB in the halls, wound drainage contained); and
- Staff involved in the care and management of residents with special needs, e.g., urinary catheters (also note characteristics of urine, which may indicate potential infection), wound care, respiratory treatments, and residents on ventilators, receiving IVs, or with tracheotomies follow current accepted infection control standards of practice.

Also, observe residents for signs and symptoms of potential infection, such as:

- Elevated respiratory rate or labored breathing, coughing, congestion;
- Vomiting or loss of appetite, diarrhea;
- Skin rash, reddened or draining eyes, wound drainage; and
- Frequency/urgency of urination, malodorous urine.

Observe for cleaning and disinfecting to determine whether:

- Equipment in transmission based precaution rooms is either dedicated to that resident and appropriately cleaned or is thoroughly cleaned and disinfected between residents using appropriate agents and procedures;
- High touch surfaces in the environment are visibly soiled (i.e., contaminated) or have been cleaned and disinfected;
- Small non-disposable equipment such as glucose meters, scissors, and thermometers are cleaned and appropriately disinfected after each use for individual resident care;
- Single-use items (e.g., blood glucose lancet, other sharps) are properly disposed of after one use;
- Single resident use items (e.g., basins, bed pans) are maintained to be visibly clean for use, and are disposed of after use by a single resident;
- Resident dressings and supplies are properly stored to maintain their integrity, and soiled dressings and supplies are appropriately discarded; and
- Multiple use items (e.g., shower chairs, bedside scales, resident lifts, commodes, tubs) are properly cleaned/disinfected between each resident use.

Observe whether hand hygiene and use of gloves (when indicated) is in accordance with current standards. Hand hygiene should occur before and after putting on sterile gloves and after taking off all gloves during all resident care that requires the use of gloves. This includes:

- Medication administration (e.g., eye drops, sublinguals, and injections);
- Dressing changes that require the use of gloves (e.g., anticipated contact with body fluid, excretions, tissue and specimens);
- Insertion or removal of a catheter; and
- Any invasive procedure.

Note the availability of gloves and the equipment and products to perform hand hygiene.

Interview

During the resident review, interview the resident, family or responsible party to the extent possible to identify, as appropriate, whether they have received education and information about infection control practices, such as appropriate hand hygiene and any special precautions applicable to the resident.

Interview direct care staff to determine:

- Whether they are aware of and have reported any signs or symptoms exhibited by the resident that may be associated with an infection;
- Whether they are aware of and have been instructed on any special precautions that are applicable to any resident on transmission based precautions;
- Whether they are familiar with the indications for washing hands and/or using alcohol based products and understand the basis for the use of gloves and when they are to be removed;
- How staff know which residents are covered by transmission-based precautions; and
- Whether staff is aware of what specific actions are required for each type of transmission-based precautions.

Record Review

Review the resident's record to determine, for example:

- Whether the resident's record included an evaluation of the factors which may increase a resident's risk of infection (e.g., indwelling urinary catheters, intravenous catheters, and tracheostomy tubes), and if an infection is present, whether the resident's record reflects the identification of the infection, potential causes and contributing factors; and

- Whether the resident's plan of care identifies interventions (device management and isolation precaution measures) to prevent the transmission of infection.

Review the facility's record of incidents of infection and related corrective actions to help determine whether the facility is identifying, recording, and analyzing infections.

In order to investigate identified infection control concerns, review, as applicable, the facility's:

- Infection control policies to determine if they are consistent with current professional standards of practice and if the infection control policies are defined by department (e.g., dietary, nursing, laundry);

Documentation of whether and how the infection prevention and control program collects, analyzes, and uses data and implements a program to guide all disciplines to prevent the spread of infections and identify infections in a standardized and systematic way;

- Policies regarding handling and processing soiled linens as well as handling, transporting, and storing clean linens;
- Applied preventive components of the infection prevention and control program in the care of individual residents;
- Policies, procedures, and documentation regarding identifying and prohibiting contact with residents or food by employees with open lesions or communicable diseases and addressing occupational communicable disease exposure and post-exposure follow up;
- Employee records to determine if employees receive initial and ongoing employee infection control training regarding critical elements of the infection control plan; and
- Documentation related to their review of the appropriateness and effectiveness of antibiotics for residents that are identified as receiving antibiotics.

Interview the Designated Infection Control Representative

If concerns are identified, (e.g., practices are not consistent with accepted principles of infection control or residents are exhibiting symptoms of infections, but have not been assessed or surveillance data are not available or being utilized) interview the facility staff members who are responsible for implementing and overseeing the infection prevention and control program.

Investigate as appropriate, for example, whether:

- The facility identifies where infections are acquired (e.g., nursing home, hospital, or community);
- The infection prevention and control program includes any review, in addition to the medication regimen review, of whether antibiotic use in the nursing home is appropriate and effective;

- Staff training includes critical areas of infection control such as hand hygiene, areas for improvement from surveillance data, and appropriate use of protective equipment and isolation precautions; how staff are apprised of changes in policies and procedures;
- The facility collects, analyzes, and uses data related to infections, to identify and prevent the spread of infections and to adjust its infection prevention and control program,(e.g., policies and procedures) as appropriate;
- The program implements processes to identify and address infection control issues and to monitor staff hand hygiene and sterile technique, and the implementation and discontinuation of transmission-based or other isolation precautions and cohorting or separating, as applicable;
- The facility appropriately implements and discontinues transmission based precaution procedures, and communicates initiation and discontinuation of these transmission-based precaution policies across departments;
- The facility has in place effective means to identify individuals (residents, staff, visitors, volunteers, practitioners) with infections;
- The facility has policies and procedures addressing linen handling and how it monitors how linens are stored, transported, and processed to prevent the spread of infection;
- The infection prevention and control program identifies and addresses infection control issues, for example whether the facility's infection control practices are consistent with CDC recommendations; and
- The facility effectively identifies and prevents employees with a communicable disease or infected skin lesions from direct contact with residents or their food, if direct contact will transmit the disease.

DETERMINATION OF COMPLIANCE CRITERIA FOR COMPLIANCE

Synopsis of Regulation (F441)

Criteria for Compliance

The facility is in compliance with 42 CFR 483.65 Infection Control if:

- The infection prevention and control program demonstrates ongoing surveillance, recognition, investigation and control of infections to prevent the onset and the spread of infection, to the extent possible;
- The facility demonstrates practices to reduce the spread of infection and control outbreaks through transmission-based precautions (e.g., isolation precautions);

- The facility demonstrates practices and processes (e.g., intravenous catheter care, hand hygiene) consistent with infection prevention and prevention of cross-contamination;
- The facility demonstrates that it uses records of incidents to improve its infection control processes and outcomes by taking corrective action;
- The facility has processes and procedures to identify and 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;
- The facility consistently demonstrates appropriate hand hygiene (e.g., hand washing) practices, after each direct resident contact as indicated by professional practice; and
- The facility demonstrates handling, storage, processing and transporting of linens so as to prevent the spread of infection.
- *The facility demonstrates appropriate use of SDVs (including appropriate repackaging).*

If not, cite at Tag F441.

Noncompliance for F441

After completing the Investigative Protocol, analyze the data in order to determine whether noncompliance with the regulation exists. Noncompliance for Tag F441 may include, but is not limited to, failure to do one or more of the following:

- Develop an infection prevention and control program;
- Utilize infection precautions to minimize the transmission of infection;
- Identify and prohibit employees with a communicable disease from direct contact with a resident;
- *Use fingerstick devices (e.g. pen like devices) for only one resident in accordance with appropriate infection control practices and processes;*
- *Appropriately use of or repackaging of SVDs (e.g., adherence to USP <797>);*
- *Using a blood glucose meter (or other point-of-care device) for more than one resident, cleaning and disinfecting it after each use;*
- Demonstrate proper hand hygiene;
- Properly dispose of soiled linens;

- Demonstrate the use of surveillance; or
- Adjust facility processes as needed to address a known infection risk.

Potential Tags for Additional Investigation

During the investigation of F441, the surveyor may have identified concerns with additional outcome, process, and/or structure requirements. The surveyor is cautioned to investigate these related requirements before determining whether non-compliance may be present. Examples of some related requirements that may be considered when non-compliance at F441 has been identified include the following:

- 42 CFR §483.20(b), F272, Comprehensive Assessments

If the infection or risks were present at the time of the required comprehensive assessment, determine whether the facility comprehensively assessed the resident's physical, mental, and psychosocial needs to identify the risks and/or to determine underlying causes (to the extent possible) of the resident's condition and the impact upon the resident's function, mood, and cognition.

- 42 CFR §483.20(b), F274, Significant Change Assessments

If there was a significant change in the infection or risk to the resident's condition, determine whether the facility did a significant change comprehensive assessment within 14 days.

- 42 CFR §483.20(k)(1)(i), F279, Comprehensive Care Plan

Determine if the facility developed a care plan consistent with the resident's specific infection status, risks, needs, behaviors, and current standards of practice and included measurable objectives and timetables, and specific interventions/services to prevent the onset and/or transmission of infection.

- 42 CFR §483.20(k)(2)(iii), F280, Comprehensive Care Plan Revision

Determine whether staff reassessed the effectiveness of the interventions and review and revised the plan of care (with input from the resident or representative, to the extent possible), if necessary, to meet the needs of the resident.

- 42 CFR §483.25(l), F329, Unnecessary Drugs

Determine if the facility has reviewed with the prescriber the rationale for placing the resident on an antibiotic to which the organism seems to be resistant or when the resident remains on antibiotic therapy without adequate monitoring or appropriate indications, or for an excessive duration.

- 42 CFR §483.25(l)(2)(n), F334, Influenza and Pneumococcal Immunizations

Determine if the facility has systems in place to immunize residents against influenza and pneumococcal infections.

- 42 CFR §483.35(i)(2), F371, Sanitary Conditions

Determine if the facility has implemented processes to prevent infection transmission via food handling, storing and delivery systems.

- 42 CFR 483.75(f) (F498) Proficiency of Nurse Aides

Determine whether the nurse aides demonstrate the knowledge and skills regarding use of accepted infection control principles, e.g., hand hygiene, transmission barriers, signs and symptoms of infection to report to the nurse, etc.

V. DEFICIENCY CATEGORIZATION (PART IV, APPENDIX P)

Once the 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 resultant effect or potential for harm to the resident.

The key elements for severity determination for Tag F441 are as follows:

1. Presence of harm/negative outcome(s) or potential for negative outcomes due to a failure of care and services. Actual or potential harm/negative outcomes for F441 may include but are not limited to facility failure to:
 - Properly implement transmission based precautions when indicated resulting in an increase (or potential) of infections or communicable diseases;
 - Develop and implement corrective actions despite recording an increase in infections in the facility;
 - Recognize and act on an increase or trend in infections within the facility;
 - Prohibit employees with symptoms of active communicable infections from continuing to provide resident care or have direct contact with food;
 - Properly perform hand hygiene when entering and exiting the room of a resident on special precautions; and
 - Recognize and investigate a resident's complaints of rash and pruritis resulting in additional resident's requiring treatment for scabies.

2. Degree of harm (actual or potential) related to the noncompliance. Identify how the facility practices caused, resulted in, allowed, or contributed to the actual or potential for harm:
 - If harm has occurred, determine if the harm is at the level of serious injury, impairment, death, compromise, or discomfort; and
 - If harm has not yet occurred, determine how likely the potential is for serious injury, impairment, death, compromise or discomfort to occur to the resident.
3. The immediacy of correction required. Determine whether the noncompliance requires immediate correction in order to prevent serious injury, harm, impairment, or death to one or more residents.

The survey team must evaluate the harm or potential for harm based upon the following levels of severity for this tag. First, the team must rule out whether Severity Level 4, immediate jeopardy to a resident's health or safety exists by evaluating the deficient practice in relation to immediacy, culpability, and severity. (Follow the guidance in Appendix Q.)

Severity Level 4 Considerations: Immediate jeopardy to resident health or safety

Immediate jeopardy is a situation in which the facility's noncompliance:

- With one or more requirements of participation has caused/resulted in, or is likely to cause, serious injury, harm, impairment, or death to a resident; and
- Requires immediate correction as the facility either created the situation or allowed the situation to continue by failing to implement preventative or corrective measures.

NOTE: The death or transfer of a resident who was harmed as a result of facility practices, does not remove a finding of immediate jeopardy. The facility is required to implement specific actions to correct the deficient practices which allowed or caused the immediate jeopardy.

Examples of negative outcomes that occurred or have the potential to occur at Severity Level 4 as a result of the facility's deficient practices may include:

- *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 re-using 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 restrict a staff member with a documented open, draining and infected skin lesion that was colonized with MRSA from working without adequately covering the area, resulting in MSRA transmission and infection of one or more residents under that staff person's care.

- The facility failed to investigate, document surveillance of and try to contain an outbreak of gastrointestinal illness among residents; as a result, additional residents became ill with diarrheal illnesses.

NOTE: If immediate jeopardy has been ruled out based upon the evidence, then evaluate whether actual harm that is not immediate jeopardy exists at Severity Level 3 or the potential for more than minimal harm at Level 2 exists.

Severity Level 3 Considerations: Actual Harm that is not Immediate Jeopardy

Level 3 indicates noncompliance that results in actual harm that is not immediate jeopardy. The negative outcome can include, but may not be limited to clinical compromise, decline, or the resident's inability to maintain and/or reach his/her highest practicable well-being.

Examples of avoidable actual resident outcomes that demonstrate severity at Level 3 may include, but are not limited to:

- The facility routinely sent urine cultures of asymptomatic residents with indwelling catheters, putting residents with positive cultures on antibiotics, resulting in two residents acquiring antibiotic-related colitis and significant weight loss.
- The facility failed to institute internal surveillance for adherence to hand washing procedures or pertinent reminders to staff regarding appropriate respiratory precautions during an influenza outbreak, resulting in additional cases of influenza in residents on another, previously unaffected unit or section of the facility.

NOTE: If Severity Level 3 (actual harm that is not immediate jeopardy) has been ruled out based upon the evidence, then evaluate as to whether Severity Level 2 (no actual harm with the potential for more than minimal harm) exists.

Severity Level 2 Considerations: No Actual Harm with potential for more than minimal harm that is not Immediate Jeopardy

Level 2 indicates noncompliance that results in a resident outcome of no more than minimal discomfort and/or has the potential to compromise the resident's ability to maintain or reach his or her highest practicable level of well being. The potential exists for greater harm to occur if interventions are not provided.

For Level 2 severity, the resident was at risk for, or has experienced the presence of one or more outcome(s). Examples of avoidable outcomes include, but are not limited to:

- The facility failed to ensure that their staff demonstrates proper hand hygiene between residents to prevent the spread of infections. The staff administered medications to a resident via a gastric tube and while wearing the same gloves proceeded to administer oral medications to another resident. The staff did not remove the used gloves and wash or sanitize their hands between residents.

- The facility failed to implement a surveillance program including the investigation of infections or attempt to distinguish facility-acquired infections from community-acquired infections.
- The facility identified issues related to staff infection control practices, as part of its infection prevention and control program, but did not follow up to identify the cause, and institute measures to correct the problems.

Severity Level 1: No actual harm with potential for minimal harm

The failure of the facility to provide appropriate care and services for infection control practices places the resident at risk for more than minimal harm. Therefore, Severity Level 1 does not apply for this regulatory requirement.

F492

(Rev. 127, Issued: 11-26-14, Effective: 11-26-14, Implementation: 11-26-14)

§483.75(b) Compliance With Federal, State, and Local Laws and Professional Standards

The facility must operate and provide services in compliance with all applicable Federal, State, and local laws, regulations, and codes, and with accepted professional standards and principles that apply to professionals providing services in such a facility.

Intent: §483.75(b)

The intent of this regulation is to ensure that a facility is in compliance with Federal, State, and local laws, regulations, and codes relating to health, safety, and sanitation *and with accepted professional standards and principles that apply to professionals providing services in facilities.*

Definitions: §483.75(b)

“Accepted professional standards and principles” means the individual State professional licensure practice acts and scope of practice regulations and/or standards. This may include the various practice acts and scope of practice regulations in each State, and current, commonly accepted health standards established by national organizations, boards and councils as well as various licensed professionals (i.e., Physicians, Nurses, Therapists, etc.) as specifically defined under individual State law and regulations.

An authority having jurisdiction is a Federal, State, local, or other regional department or individual, such as a fire chief; fire marshal; chief of a fire prevention bureau, labor department, or health department; building official; electrical inspector; professional licensure boards; or others having statutory authority. A Federal, State or the local authority having jurisdiction is responsible for making decisions about whether there are violations of the applicable Federal, State or local laws, regulations, codes and/or standards for which they have statutory and oversight authority.

“Final adverse action” means an adverse action imposed by the authority having jurisdiction that is more than a corrective action plan or the imposition of a civil money penalty, such as a ban on admissions, suspension or loss of a facility or professional license, etc., and is NOT under appeal or litigation by the facility or the professional providing services in the facility. The authority having jurisdiction is the public agency or official(s) having the authority to make a determination of noncompliance, and is responsible for providing and signing official correspondence notifying the facility or professional of the final adverse action.

Interpretive Guidelines: §483.75(b)

The State is responsible for making decisions about whether there are violations of State laws and regulations. Licenses, permits and approvals of the facility must be available to you upon request. Current reports of inspections by State and/or local health authorities are on file, and notations are made of action taken by the facility to correct deficiencies.

*Failure of the facility to meet a Federal, State or local law, regulation, code, or accepted professional standards and principles that apply to professionals providing services in facilities **may only be cited** when the Federal, State or local authority having jurisdiction has both made a determination of non-compliance AND has taken a final adverse action.*

Do not cite Tag F492:

- When a determination is made by the authority having jurisdiction that a facility is not in compliance with Federal, State, or local requirements, regulations, codes and /or standards and final adverse action has not been taken by the authority having jurisdiction;*
- To simply cite non-compliance with State or local licensure requirements; or*
- As past non-compliance if at the time of the standard, complaint or follow-up survey, the facility or professional within the facility is in compliance with the Federal, State or local law, regulation, code and /or standard but was found not to be in compliance with those requirements during a time before the on-site survey. If there is a question, the SA may confirm the facility’s current compliance status with the authority having jurisdiction for State and local authorities or the Regional Office (RO) for other Federal agencies.*

§483.75(c) Relationship to Other HHS Regulations

In addition to compliance with the regulations set forth in this subpart, facilities are obliged to meet the applicable provisions of other HHS regulations, including but not limited to those pertaining to nondiscrimination on the basis of race, color, or national origin (45 CFR part 80); nondiscrimination on the basis of handicap (45 CFR part 84); nondiscrimination on the basis of age (45 CFR part 91); protection of human subjects of research (45 CFR part 46); and fraud and abuse (42 CFR part 455). Although these regulations are not in themselves considered requirements under this part, their violation

may result in the termination or suspension of, or the refusal to grant or continue payment with Federal funds.

Procedures *42 CFR §§483.75(b) and (c)*

If resident/family interviews reveal possible problems with admission contracts, review these contracts for violations of requirements at [§§483.10](#) and [483.12](#). As appropriate, refer problems to an ombudsman or other agencies, e.g., Office for Civil Rights.

If interviews with residents suggest that the facility may have required deposits from Medicare residents at admission, review the facility's admissions documents.

*Some State or local laws and regulations are more stringent than the Federal requirement on the same issue. If you believe you have identified a situation indicating that the facility or professional providing services in the facility may not be in compliance with a State or local law, regulation, code and/or standard, refer that information to the authority having jurisdiction for their follow-up action. If you have determined **and** received written confirmation from the authority having jurisdiction that a final adverse action has been taken, then the facility could be found to not meet the requirements at 42 CFR §§483.75(b) and (c) and a deficiency may be cited at Tag F492.*

If during the survey you identify and suspect that you have observed noncompliance with a law, regulation, code and/or standard which is under the purview of another Federal agency other than CMS, notify the RO. The RO may assist you to contact the appropriate Federal agency to refer your observation and/or concern.

Do not prolong or delay a survey waiting for confirmation from an authority having jurisdiction to determine compliance with this requirement.

F514

(Rev. 127, Issued: 11-26-14, Effective: 11-26-14, Implementation: 11-26-14)

§483.75(l) Clinical Records

(1) The facility must maintain clinical records on each resident in accordance with accepted professional standards and practices that are--

- (i) Complete;**
- (ii) Accurately documented;**
- (iii) Readily accessible; and**
- (iv) Systematically organized.**

Intent §483.75(l)(1)

To assure that the facility maintains accurate, complete and organized clinical information about each resident that is readily accessible for resident care.

Interpretive Guidelines §483.75(l)(1)

A complete clinical record contains an accurate and functional representation of the actual experience of the individual in the facility. It must contain enough information to show that the facility knows the status of the individual, has adequate plans of care, and provides sufficient evidence of the effects of the care provided. Documentation should provide a picture of the resident's progress, including response to treatment, change in condition, and changes in treatment.

The facility determines how frequently documentation of an individual's progress takes place apart from the annual comprehensive assessment, periodic reassessments when a significant change in status occurs, and quarterly monitoring assessments. Good practice indicates that for functional and behavioral objectives, the clinical record should document change toward achieving care plan goals. Thus, while there is no "right" frequency or format for "reporting" progress, there is a unique reporting schedule to chart each resident's progress in maintaining or improving functional abilities and mental and psychosocial status. Be more concerned with whether the staff has sufficient progress information to work with the resident and less with how often that information is gathered.

Electronic Health Records and Use of Electronic Signatures

In cases in which facilities have created the option for an individual's record to be maintained by computer, rather than hard copy, electronic signatures are acceptable *whether or not the record is entirely electronic, and when permitted to do so by state and local law and when this is authorized by the facility's policies. If a facility implements the use of electronic signatures, they must have policies in place and implemented that identify those who are authorized to sign electronically and describe the security safeguards to prevent unauthorized use of electronic signatures. Such security safeguards (policies) include, but are not limited to, the following:*

- *Built-in safeguards to minimize the possibility of fraud;*
- *That each staff responsible for an attestation has an individualized identifier;*
- The date and time is recorded from the computer's internal clock at the time of entry;
- An entry is not to be changed after it has been recorded, *and;*
- The computer program controls what sections/areas any individual can access or enter data, based on the individual's personal identifier (and, therefore his/her level of professional qualifications).

NOTE: *As there are no regulatory requirements delineating the use of a specific Electronic Health Records (EHR) system, a facility may utilize the EHR system that meets their specific needs. The facility must grant access to any medical record, including EHRs, when requested by the survey team. If access to an EHR is requested by the surveyor, the facility will (a) provide*

the surveyor with a tutorial on how to use its particular electronic system and (b) designate an individual who will, when requested by the surveyor, access the system, respond to any questions or assist the surveyor as needed in accessing electronic information in a timely fashion. Each surveyor will determine the EHR access method that best meets the need for that survey.

If the facility is unable to provide direct print capability to the survey team, the provider must make available a printout of any record or part of a record upon request in a timeframe that does not impede the survey process. Impeding the survey process by unnecessarily delaying or restricting access to the medical records may lead to determinations of noncompliance and enforcement actions. The facility should ensure that data are backed up and secure, and access does not impede the survey process or the provision of care and services to the resident.

Probes §483.75(1)(1)

In reviewing sampled residents' clinical records:

- Is there enough record documentation for staff to conduct care programs and to revise the program, as necessary, to respond to the changing status of the resident as a result of interventions?
- How is the clinical record used in managing the resident's progress in maintaining or improving functional abilities and mental and psychosocial status?

§483.75(1)(5) the clinical record must contain--

- (i) Sufficient information to identify the resident;**
- (ii) A record of the resident's assessments;**
- (iii) the plan of care and services provided;**
- (iv) The results of any preadmission screening conducted by the State; and**
- (v) progress notes.**

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(Rev. 127, Issued: 11-26-14, Effective: 11-26-14, Implementation: 11-26-14)

§483.20(f)(5)

(5) Resident-identifiable information.

- (i) A facility may not release information that is resident-identifiable to the public.**

(ii) The facility may release information that is resident-identifiable to an agent only in accordance with a contract under which the agent agrees not to use or disclose the information except to the extent the facility itself is permitted to do so.

Interpretive Guidelines §483.20(f)(5):

Automated RAI data are part of a resident's clinical record and as such are protected from improper disclosure by facilities under current law. Facilities are required by §§1819(c)(1)(A)(iv) and 1919(c)(1)(A)(iv) of the Act and 42 CFR Part 483.75(1)(3) and (1)(4), to keep confidential all information contained in the resident's record and to maintain safeguards against the unauthorized use of a resident's clinical record information, regardless of the storage method of the records.

§483.75(1) (3) The facility must safeguard clinical record information against loss, destruction, or unauthorized use;

Intent §483.75(1)(3)

To maintain the safety and confidentiality of the resident's record.

***Interpretive Guidelines* §483.75(1)(3)**

Determine through observations and interviews with staff, the policy and implementation of that policy, for maintaining confidentiality of residents' records.

Electronic Health Records (EHR)

All providers and suppliers that conduct standard transactions (electronic claims filing, etc.) are "covered entities" and, as such, they must comply with the HIPAA Privacy Rule and the HIPAA Security Rule. These rules are found at 45 CFR Parts 160 and 164. Surveyors are not responsible for assessing compliance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy and Security Rules. The Department of Health and Human Services Office of Civil Rights has the primary responsibility for enforcing the HIPAA Privacy Rule. The Office of eHealth Standards and Services within CMS is responsible for enforcing the HIPAA Security Rule. The surveyors' responsibility is to assess compliance with the provider or supplier-specific requirements for maintaining the content and confidentiality of the medical record.

A facility that utilizes EHRs is responsible for ensuring the necessary backing up of data and security of information in the resident's medical record. In situations where a facility EHR system is shared with other facilities because of the same ownership, the facility must not be cited strictly due to their participation in an EHR system that includes multiple facilities. CMS actively encourages the development of systems that permit appropriate sharing of clinical information across providers, if the development of such systems is fully consistent with the requirement for protecting the confidentiality of the medical record.

There is no expectation that the State Agency evaluate the overall features of the EHR system for compliance with HIPAA Security and Privacy Rules. Surveyors instead are to focus on how the EHR system is being used in the facility, and whether that use is consistent with the Medicare CoPs or CfCs. If a survey team has a concern that the facility's practice may constitute significant violations of the HIPAA Privacy Rule, the SA has the discretion to file a complaint with the Office of Civil Rights and/or the CMS Office of eHealth Standards and Services.

Probes: §483.75(1)(3)

- How does the facility ensure confidentiality of resident records?
- If there is a problem with confidentiality, is it systematic, that is, does the problem lie in the recordkeeping system, or with a staff person's use of records, e.g., leaving records in a place easily accessible to residents, visitors, or other unauthorized persons?
- *Are computer screens showing clinical record information left unattended and readily observable or accessible by other residents or visitors?*
- *Are there documents publicly posting passwords, which would be evidence of noncompliance with confidentiality?*

NOTE: *Use F-287, §483.20(f)(5) if breach of confidentiality is related to the RAI.*