§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 end-of-life, diabetes, renal disease, fractures, congestive heart failure, non-pressure-related skin ulcers, pain, or fecal impaction.

Definitions: §483.25
“Highest practicable physical, mental, and psychosocial well-being” is defined as the highest possible level of functioning and well-being, limited by the individual’s recognized pathology and normal aging process. Highest practicable is determined through the comprehensive resident assessment and by recognizing and competently and thoroughly addressing the physical, mental or psychosocial needs of the individual.

Interpretive Guidelines §483.25

In any instance in which there has been a lack of improvement or a decline, the survey team must determine if the occurrence was unavoidable or avoidable. A determination of unavoidable decline or failure to reach highest practicable well-being may be made only if all of the following are present:

• An accurate and complete assessment (see §483.20);

• A care plan that is implemented consistently and based on information from the assessment; and

• Evaluation of the results of the interventions and revising the interventions as necessary.

Determine if the facility is providing the necessary care and services based on the findings of the comprehensive assessment and plan of care. If services and care are being provided, determine if the facility is evaluating the resident's outcome and changing the interventions if needed. This should be done in accordance with the resident’s customary daily routine.
Procedures §483.25

Assess a facility’s compliance with these requirements by determining if the services noted in the plan of care are: based on a comprehensive and accurate functional assessment of the resident’s strengths, weaknesses, risk factors for deterioration and potential for improvement; continually and aggressively implemented; and updated by the facility staff. In looking at assessments, use both the MDS and CAA information, any other pertinent assessments, and resulting care plans.

If the resident has been in the facility for less than 14 days (before completion of all the RAI is required), determine if the facility is conducting ongoing assessment and care planning, and, if appropriate care and services are being provided.

General Investigative Protocol for F309, Quality of Care

Use:
Use this General Investigative Protocol to investigate Quality of Care concerns that are not otherwise covered in the remaining tags at §483.25, Quality of Care or for which specific investigative protocols have not been established. For investigating concerns regarding management of pain, use the pain management investigative protocol below. Surveyors should consider any quality of care issue that is not covered in a specific Quality of Care tag to be covered under this tag, F309.

Procedure:
Briefly review the assessment, care plan and orders to identify whether the facility has recognized and addressed the concerns or resident care needs being investigated. Also use this review to identify facility interventions and to guide observations to be made. Corroborate observations by interview and record review.

Observations:
Observe whether staff consistently implement the care plan over time and across various shifts. During observations of the interventions, note and/or follow up on deviations from the care plan, deviations from current standards of practice, and potential negative outcomes.

Resident/Representative Interview
Interview the resident or representative to the degree possible to determine the resident's or representative's:

- Awareness of the current condition(s) or history of the condition(s) or diagnosis/diagnoses;
- Involvement in the development of the care plan, goals, and if interventions reflect choices and preferences; and
- How effective the interventions have been and if not effective, whether alternate approaches have been tried by the facility.
Nursing Staff Interview
Interview nursing staff on various shifts to determine:

- Their knowledge of the specific interventions for the resident, including facility-specific guidelines/protocols;

- Whether nursing assistants know how, what, when, and to whom to report changes in condition; and

- How the charge nurse monitors for the implementation of the care plan, and changes in condition.

Assessment
Review information such as orders, medication administration records, multi-disciplinary progress notes, the RAI/MDS, and any specific assessments that may have been completed. Determine if the information accurately and comprehensively reflects the resident’s condition. In considering the appropriateness of a facility’s response to the presence or progression of a condition/diagnosis, take into account the time needed to determine the effectiveness of treatment, and the facility’s efforts, where possible, to remove, modify, or stabilize the risk factors and underlying causal factors.

NOTE: Although Federal requirements dictate the completion of RAI assessments according to certain time frames, standards of good clinical practice dictate that the assessment process is more fluid and should be ongoing. (Federal Register Vol. 62, No. 246, 12/23/97, page 67193)

Care Planning
Determine whether the facility developed a care plan that was consistent with the resident’s specific conditions, risks, needs, behaviors, preferences and with current standards of practice and included measurable objectives and timetables with specific interventions. If the care plan refers to a specific facility treatment protocol that contains details of the treatment regimen, the care plan should refer to that protocol and should clarify any major deviations from or revisions to the protocol for this resident. The treatment protocol must be available to the caregivers and staff should be familiar with the protocol requirements.

NOTE: A specific care plan intervention is not needed if other components of the care plan address related risks adequately. For example, the risk of nutritional compromise for a resident with diabetes mellitus might be addressed in that part of the care plan that deals with nutritional management.

Care Plan Revision
Determine whether staff have monitored the resident's condition and effectiveness of the care plan interventions and revised the care plan with input by the resident and/or the representative, to the extent possible, (or justified the continuation of the existing plan) based upon the following:
• Achieving the desired outcome;

• Resident failure or inability to comply with or participate in a program to attain or maintain the highest practicable level of well-being; and/or

• Change in resident condition, ability to make decisions, cognition, medications, behavioral symptoms or visual problems.

**Interview with Health Care Practitioners and Professionals**

If the care provided has not been consistent with the care plan or the interventions defined or care provided appear not to be consistent with recognized standards of practice, interview one or more health care practitioners and professionals as necessary (e.g., physician, charge nurse, director of nursing, therapist) who, by virtue of training and knowledge of the resident, should be able to provide information about the causes, treatment and evaluation of the resident’s condition or problem. If there is a medical question, contact the physician if he/she is the most appropriate person to interview. If the attending physician is unavailable, interview the medical director, as appropriate. Depending on the issue, ask about:

• How it was determined that chosen interventions were appropriate;

• Risks identified for which there were no interventions;

• Changes in condition that may justify additional or different interventions; or

• How staff validated the effectiveness of current interventions.

**DETERMINATION OF COMPLIANCE WITH F309 (Task 6, Appendix P) THAT IS NOT RELATED TO PAIN OR PAIN MANAGEMENT**

**Synopsis of Regulation (Tag F309)**

The resident must receive and the facility must provide the necessary care and services to attain or maintain his/her highest practicable level of physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care.

**Criteria for Compliance:**

**Compliance with F309, Quality of Care** - The facility is in compliance with this requirement if staff:

• Recognized and assessed factors placing the resident at risk for specific conditions, causes, and/or problems;
• Defined and implemented interventions in accordance with resident needs, goals, and recognized standards of practice;

• Monitored and evaluated the resident’s response to preventive efforts and treatment; and

• Revised the approaches as appropriate.

**Concerns with Independent but Associated Structure, Process, and/or Outcome Requirements.**

During the investigation, the surveyor may have identified concerns with related structure, process, and/or outcome requirements. If an additional concern has been identified, the surveyor must investigate the identified concern. Do not cite any related or associated requirements before first conducting an investigation to determine compliance or non-compliance with the related or associated requirement. Some examples include, but are not limited to, the following:

- **42 CFR 483.10(b)(11), F157, Notification of Changes**
  Determine whether staff notified the resident and consulted the physician regarding significant changes in the resident’s condition or a need to alter treatment significantly or notified the representative of a significant condition change.

- **42 CFR 483.(20)(b), F272, Comprehensive Assessments**
  Determine whether the facility assessed the resident’s condition, including existing status, and resident-specific risk factors (including potential causative factors) in relation to the identified concern under review.

- **42 CFR 483.20(k), F279, Comprehensive Care Plan**
  Determine whether the facility established a care plan with timetables and resident specific goals and interventions to address the care needs and treatment related to the clinical diagnosis and/or the identified concern.

- **42 CFR 483.20(k)(2)(iii), 483.10(d)(3), F280, Care Plan Revision**
  Determine whether the staff reviewed and revised the care plan as indicated based upon the resident’s response to the care plan interventions, and obtained input from the resident or representative to the extent possible.

- **42 CFR 483.20(k)(3)(i), F281, Services Provided Meets Professional Standards of Quality**
  Determine whether the facility, beginning from the time of admission, provided care and services related to the identified concern that meet professional standards of quality.

- **42 CFR 483.20(k)(3)(ii), F282, Care Provided by Qualified Persons in Accordance with Plan of Care**
  Determine whether care was provided by qualified staff and whether staff implemented the care plan correctly and adequately.
• **42 CFR 483.30(a), F353, Sufficient Staff**
  Determine whether the facility had qualified nursing staff in sufficient numbers to assure the resident was provided necessary care and services 24 hours a day, based upon the comprehensive assessment and care plan.

• **42 CFR 483.40(a)(1)&(2), F385, Physician Supervision**
  Determine whether the physician has assessed and developed a relevant treatment regimen and responded appropriately to the notice of changes in condition.

• **42 CFR 483.75(f), F498, Proficiency of Nurse Aides**
  Determine whether nurse aids demonstrate competency in the delivery of care and services related to the concern being investigated.

• **42 CFR 483.75(i)(2), F501, Medical Director**
  Determine whether the medical director:
  
  - Assisted the facility in the development and implementation of policies and procedures and that these are based on current standards of practice; and
  
  - Interacts with the physician supervising the care of the resident if requested by the facility to intervene on behalf of the residents.

• **42 CFR 483.75(l), F514, Clinical Records**
  Determine whether the clinical records:
  
  - Accurately and completely document the resident's status, the care and services provided in accordance with current professional standards and practices; and
  
  - Provide a basis for determining and managing the resident's progress including response to treatment, change in condition, and changes in treatment.

**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 harm or potential for harm to the resident. The key elements for severity determination for F309 Quality of Care requirements are as follows:

1. Presence of harm/negative outcome(s) or potential for negative outcomes because of lack of appropriate treatment and care, such as decline in function or failure to achieve the highest possible level of well-being.

2. Degree of harm (actual or potential) related to the non-compliance. 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 to the resident(s); and
If harm has not yet occurred, determine the potential for serious injury, impairment, death, compromise, or discomfort to occur to the resident(s).

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 for F309 based upon the four 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.

If specific guidance and examples have not been established elsewhere for the concern having been reviewed, follow the general guidance in Appendix P regarding Guidance on Severity and Scope Levels and Psychosocial Outcome Severity Guide.

**Interpretive Guidelines for Selected Specific Quality of Care Issues at §483.25.**

The following sections describe some specific issues or care needs that are not otherwise covered in the remaining tags of §483.25, Quality of Care. These are only some of the issues that may arise with a resident's quality of care. Surveyors should consider any quality of care issue that is not covered in a specific Quality of Care tag to be covered under this tag, F309.

**Review of a Resident with Non Pressure-Related Skin Ulcer/Wound.**

Residents may develop various types of skin ulceration. At the time of the assessment and diagnosis of a skin ulcer/wound, the clinician is expected to document the clinical basis (e.g., underlying condition contributing to the ulceration, ulcer edges and wound bed, location, shape, condition of surrounding tissues) which permit differentiating the ulcer type, especially if the ulcer has characteristics consistent with a pressure ulcer, but is determined not to be one. This section differentiates some of the different types of skin ulcers/wounds.

**NOTE:** Guidance regarding pressure ulcers is found at 42 CFR 483.25 (c), F314 Pressure Sore. Use F309 for issues of quality of care regarding non-pressure related ulcers.

An arterial ulcer is ulceration that occurs as the result of arterial occlusive disease when non-pressure related disruption or blockage of the arterial blood flow to an area causes tissue necrosis. Inadequate blood supply to the extremity may initially present as intermittent claudication. Arterial/Ischemic ulcers may be present in individuals with moderate to severe peripheral vascular disease, generalized arteriosclerosis, inflammatory or autoimmune disorders (such as arteritis), or significant vascular disease elsewhere (e.g., stroke or heart attack). The arterial ulcer is characteristically painful, usually occurs in the distal portion of the lower extremity and may be over the ankle or bony areas of the foot (e.g., top of the foot or toe, outside edge of the foot). The wound bed is frequently dry and pale with minimal or no exudate. The affected foot may exhibit: diminished or absent pedal pulse, coolness to touch, decreased pain when hanging down (dependent) or increased pain when elevated, blanching upon elevation, delayed capillary fill time, hair loss on top of the foot and toes, toenail thickening.
A venous ulcer (previously known as a stasis ulcer) is an open lesion of the skin and subcutaneous tissue of the lower leg, often occurring in the lower leg around the medial ankle. Venous ulcers are reported to be the most common vascular ulceration and may be difficult to heal, may occur off and on for several years, and may occur after relatively minor trauma. The ulcer may have a moist, granulating wound bed, may be superficial, and may have minimal to copious serous drainage unless the wound is infected. The resident may experience pain that may increase when the foot is in a dependent position, such as when a resident is seated with her or his feet on the floor.

Recent literature implicates venous hypertension as a causative factor. Venous hypertension may be caused by one (or a combination of) factor(s) including: loss of (or compromised) valve function in the vein, partial or complete obstruction of the vein (e.g., deep vein thrombosis, obesity, malignancy), and/or failure of the calf muscle to pump the blood (e.g., paralysis, decreased activity). Venous insufficiency may result in edema and induration, dilated superficial veins, dry scaly crusts, dark pigmented skin in the lower third of the leg, or dermatitis. The pigmentation may appear as darkening skin, tan or purple areas in light skinned residents and dark purple, black or dark brown in dark skinned residents. Cellulitis may be present if the tissue is infected.

A diabetic neuropathic ulcer requires that the resident be diagnosed with diabetes mellitus and have peripheral neuropathy. The diabetic ulcer characteristically occurs on the foot, e.g., at mid-foot, at the ball of the foot over the metatarsal heads, or on the top of toes with Charcot deformity.

**Review of a Resident Receiving Hospice Services.**

When a facility resident has also elected the Medicare hospice benefit, the hospice and the nursing home must communicate, establish, and agree upon a coordinated plan of care for both providers which reflects the hospice philosophy, and is based on an assessment of the individual’s needs and unique living situation in the facility. The plan of care must include directives for managing pain and other uncomfortable symptoms and be revised and updated as necessary to reflect the individual’s current status. This coordinated plan of care must identify the care and services which the SNF/NF and hospice will provide in order to be responsive to the unique needs of the patient/resident and his/her expressed desire for hospice care.

The SNF/NF and the hospice are responsible for performing each of their respective functions that have been agreed upon and included in the plan of care. The hospice retains overall professional management responsibility for directing the implementation of the plan of care related to the terminal illness and related conditions.

For a resident receiving hospice benefit care, evaluate if:

- The facility completed a MDS Significant Change in Status Assessment (SCSA) when the resident elected the hospice benefit;
• The facility completed a MDS Significant Change in Status Assessment (SCSA) when the resident revoked the hospice benefit;

• The plan of care reflects the participation of the hospice, the facility, and the resident or representative to the extent possible;

• The plan of care includes directives for managing pain and other uncomfortable symptoms and is revised and updated as necessary to reflect the resident's current status;

• Medications and medical supplies are provided by the hospice as needed for the palliation and management of the terminal illness and related conditions;

• The hospice and the facility communicate with each other when any changes are indicated to the plan of care;

• The hospice and the facility are aware of the other’s responsibilities in implementing the plan of care;

• The facility’s services are consistent with the plan of care developed in coordination with the hospice, (the hospice patient residing in a SNF/NF should not experience any lack of SNF/NF services or personal care because of his/her status as a hospice patient); and

• The SNF/NF offers the same services to its residents who have elected the hospice benefit as it furnishes to its residents who have not elected the hospice benefit. The resident has the right to refuse services in conjunction with the provisions of 42 CFR 483.10(b)(4), Tag F155.

NOTE: If a resident is receiving services from a Medicare certified hospice and the hospice was advised of concerns by the facility and failed to address and/or resolve issues related to coordination of care or implementation of appropriate services, refer the concerns as a complaint to the State Agency responsible for oversight of this hospice, identifying the specific resident(s) involved and the concerns identified.

**Review of a Resident Receiving Dialysis Services.**
When dialysis is provided in the facility by an outside entity, or the resident leaves the facility to obtain dialysis, the nursing home should have an agreement or arrangement with the entity. This agreement/arrangement should include all aspects of how the resident’s care is to be managed, including:

• Medical and non-medical emergencies;
• Development and implementation of the resident’s care plan;

• Interchange of information useful/necessary for the care of the resident; and

• Responsibility for waste handling, sterilization, and disinfection of equipment.

If there is a sampled resident who is receiving dialysis care, evaluate the following, in addition to the standard Resident Review protocol:

• Review to assure that medications are administered before and after dialysis as ordered by the physician. This should account for the optimal timing to maximize effectiveness and avoid adverse effects of the medications;

• Whether staff know how to manage emergencies and complications, including equipment failure and alarm systems (if any), bleeding/hemorrhaging, and infection/bacteremia/septic shock;

• Whether facility staff are aware of the care of shunts/fistulas, infection control, waste handling, nature and management of end stage renal disease (including nutritional needs, emotional and social well-being, and aspects to monitor); and

• Whether the treatment for this (these) resident(s), affects the quality of life, rights or quality of care for other residents, e.g., restricting access to their own space, risk of infections.

NOTE: If a resident is receiving services from a dialysis provider, and the survey team has concerns about the quality of care and services provided to the resident by that provider, refer the concerns as a complaint to the State Agency responsible for oversight of the dialysis provider, identifying the specific resident(s) involved and the concerns identified.

Review of a Resident Who has Pain Symptoms, is being Treated for Pain, or Who has the Potential for Pain Symptoms Related to Conditions or Treatments.

Recognition and Management of Pain - In order to help a resident attain or maintain his or her highest practicable level of well-being and to prevent or manage pain, the facility, to the extent possible:

• Recognizes when the resident is experiencing pain and identifies circumstances when pain can be anticipated;

• Evaluates the existing pain and the cause(s), and

• Manages or prevents pain, consistent with the comprehensive assessment and plan of care, current clinical standards of practice, and the resident’s goals and preferences.
Definitions Related to Recognition and Management of Pain

• “Addiction” is a primary, chronic, neurobiological disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by an overwhelming craving for medication or behaviors that include one or more of the following: impaired control over drug use, compulsive use, continued use despite harm, and craving.1

• "Adjuvant Analgesics" describes any medication with a primary indication other than pain management but with analgesic properties in some painful conditions.2

• “Adverse Consequence” is an unpleasant symptom or event that is due to or associated with a medication, such as impairment or decline in a resident’s mental or physical condition or functional or psychosocial status. It may include various types of adverse drug reactions and interactions (e.g., medication-medication, medication-food, and medication-disease).

NOTE: Adverse drug reaction (ADR) is a form of adverse consequences. It may be either a secondary effect of a medication that is usually undesirable and different from the therapeutic effect of the medication or any response to a medication that is noxious and unintended and occurs in doses for prophylaxis, diagnosis, or treatment. The term “side effect” is often used interchangeably with ADR; however, side effects are but one of five ADR categories, the others being hypersensitivity, idiosyncratic response, toxic reactions, and adverse medication interactions. A side effect is an expected, well-known reaction that occurs with a predictable frequency and may or may not constitute an adverse consequence.

• “Complementary and Alternative Medicine” (CAM) is a group of diverse medical and health care systems, practices, and products that are not presently considered to be a part of conventional medicine.3

• “Non-pharmacological interventions” refers to approaches to care that do not involve medications, generally directed towards stabilizing or improving a resident’s mental, physical or psychosocial well-being.

• “Pain” is an unpleasant sensory and emotional experience that can be acute, recurrent or persistent.4 Following are descriptions of several different types of pain:

  – “Acute Pain” is generally pain of abrupt onset and limited duration, often associated with an adverse chemical, thermal or mechanical stimulus such as surgery, trauma and acute illness;

  – “Breakthrough Pain” refers to an episodic increase in (flare-up) pain in someone whose pain is generally being managed by his/her current medication regimen;

  – “Incident Pain” refers to pain that is typically predictable and is related to a precipitating event such as movement (e.g., walking, transferring, or dressing) or certain actions (e.g., disimpaction or wound care); and
“Persistent Pain” or “Chronic Pain” refers to a pain state that continues for a prolonged period of time or recurs more than intermittently for months or years.

- **“Physical Dependence”** is a physiologic state of neuroadaptation that is characterized by a withdrawal syndrome if a medication or drug is stopped or decreased abruptly, or if an antagonist is administered.

- **“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.

- **“Tolerance”** is a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce the same effect or a reduced effect is observed with a constant dose.

**Overview of Pain Recognition and Management**

Effective pain recognition and management requires an ongoing facility-wide commitment to resident comfort, to identifying and addressing barriers to managing pain, and to addressing any misconceptions that residents, families, and staff may have about managing pain. Nursing home residents are at high risk for having pain that may affect function, impair mobility, impair mood, or disturb sleep, and diminish quality of life. The onset of acute pain may indicate a new injury or a potentially life-threatening condition or illness. It is important, therefore, that a resident’s reports of pain, or nonverbal signs suggesting pain, be evaluated.

The resident’s needs and goals as well as the etiology, type, and severity of pain are relevant to developing a plan for pain management. It should be noted that while analgesics can reduce pain and enhance the quality of life, they do not necessarily address the underlying cause of pain. It is important to consider treating the underlying cause, where possible. Addressing underlying causes may permit pain management with fewer analgesics, lower doses, or medications with a lower risk of serious adverse consequences.

Certain factors may affect the recognition, assessment, and management of pain. For example, residents, staff, or practitioners may misunderstand the indications for, and benefits and risks of, opioids and other analgesics; or they may mistakenly believe that older individuals have a higher tolerance for pain than younger individuals, or that pain is an inevitable part of aging, a sign of weakness, or a way just to get attention. Other challenges to successfully evaluating and managing pain may include communication difficulties due to illness or language and cultural barriers, stoicism about pain, and cognitive impairment.

It is a challenge to assess and manage pain in individuals who have cognitive impairment or communications difficulties. Some individuals with advanced cognitive impairment can accurately report pain and/or respond to questions regarding pain.
One study noted that 83 percent of nursing home residents could respond to questions about pain intensity. 14

Those who cannot report pain may present with nonspecific signs such as grimacing, increases in confusion or restlessness or other distressed behavior. Effective pain management may decrease distressed behaviors that are related to pain. 15 However, these nonspecific signs and symptoms may reflect other clinically significant conditions (e.g., delirium, depression, or medication-related adverse consequences) instead of, or in addition to, pain. To distinguish these various causes of similar signs and symptoms, and in order to manage pain effectively, it is important to evaluate (e.g., touch, look at, move) the resident in detail, to confirm that the signs and symptoms are due to pain.

**Resources Related to Pain Management**

Examples of clinical resources available for guidance regarding the assessment and management of pain include:

- American Geriatrics Society Clinical Practice Guideline at: http://www.americangeriatrics.org/education/cp_index.shtml;
- American Academy of Hospice and Palliative Medicine at www.aahpm.org;
- American Pain Society at www.ampainsoc.org;
- Brown University’s Pain and Physical Symptoms Toolkit at http://www.chcr.brown.edu/pcoc/physical.htm;
- Hospice and Palliative Nurses Association at http://www.hpna.org;
- John A Hartford Institute for Geriatric Nursing "Try This" series at http://www.hartfordign.org/Resources/Try_This_Series;
- National Initiative on Pain Control at www.painedu.org;
- Partners Against Pain at http://www.partnersagainstpain.com;
- Quality Improvement Organizations at www.medqic.org; and
Care Process for Pain Management
Processes for the prevention and management of pain include:

- Assessing the potential for pain, recognizing the onset or presence of pain, and assessing the pain;

- Addressing/treating the underlying causes of the pain, to the extent possible;

- Developing and implementing interventions/approaches to pain management, depending on factors such as whether the pain is episodic, continuous, or both;

- Identifying and using specific strategies for different levels or sources of pain or pain-related symptoms, including:
  - Identifying interventions to address the pain based on the resident-specific assessment, a pertinent clinical rationale, and the resident’s goals;

- Trying to prevent or minimize anticipated pain;16

- Considering non-pharmacological and CAM interventions;
  - Using pain medications judiciously to balance the resident’s desired level of pain relief with the avoidance of unacceptable adverse consequences;

- Monitoring appropriately for effectiveness and/or adverse consequences (e.g., constipation, sedation) including defining how and when to monitor the resident’s symptoms and degree of pain relief; and

- Modifying the approaches, as necessary.

Pain Recognition
Because pain can significantly affect a person’s well-being, it is important that the facility recognize and address pain promptly. The facility’s evaluation of the resident at admission and during ongoing assessments helps identify the resident who is experiencing pain or for whom pain may be anticipated during specific procedures, care, or treatment. In addition, it is important that a resident be monitored for the presence of pain and be evaluated when there is a change in condition and whenever new pain or an exacerbation of pain is suspected. As with
many symptoms, pain in a resident with moderate to severe cognitive impairment may be more difficult to recognize and assess.17,18,19

Expressions of pain may be verbal or nonverbal. A resident may avoid the use of the term “pain.” Other words used to report or describe pain may differ by culture, language and/or region of the country. Examples of descriptions may include heaviness or pressure, stabbing, throbbing, hurting, aching, gnawing, cramping, burning, numbness, tingling, shooting or radiating, spasms, soreness, tenderness, discomfort, pins and needles, feeling “rough,” tearing or ripping. Verbal descriptions of pain can help a practitioner identify the source, nature, and other characteristics of the pain. Nonverbal indicators which may represent pain need to be viewed in the entire clinical context with consideration given to pain as well as other clinically pertinent explanations. Examples of possible indicators of pain include, but are not limited to the following:

- Negative verbalizations and vocalizations (e.g., groaning, crying/whimpering, or screaming);
- Facial expressions (e.g., grimacing, frowning, fright, or clenching of the jaw);
- Changes in gait (e.g., limping), skin color, vital signs (e.g., increased heart rate, respirations and/or blood pressure), perspiration;
- Behavior such as resisting care, distressed pacing, irritability, depressed mood, or decreased participation in usual physical and/or social activities;
- Loss of function or inability to perform Activities of Daily Living (ADLs), rubbing a specific location of the body, or guarding a limb or other body parts;
- Difficulty eating or loss of appetite; and
- Difficulty sleeping (insomnia).

In addition to the pain item sections of the MDS, many sections such as sleep cycle, change in mood, decline in function, instability of condition, weight loss, and skin conditions can be potential indicators of pain. Any of these findings may indicate the need for additional and more thorough evaluation.

Many residents have more than one active medical condition and may experience pain from several different causes simultaneously. Many medical conditions may be painful such as pressure ulcers, diabetes with neuropathic pain, immobility, amputation, post-CVA, venous and arterial ulcers, multiple sclerosis, oral health conditions, and infections. In addition, common procedures, such as moving a resident or performing physical or occupational therapies or changing a wound dressing may be painful. Understanding the underlying causes of pain is an important step in determining optimal approaches to prevent, minimize, or manage pain.
Observations at rest and during movement, particularly during activities that may increase pain (such as dressing changes, exercises, turning and positioning, bathing, rising from a chair, walking) can help to identify whether the resident is having pain. Observations during eating or during the provision of oral hygiene may also indicate dental, mouth and/or facial pain.

Recognizing the presence of pain and identifying those situations where pain may be anticipated involves the participation of health care professionals and direct care and ancillary staff who have contact with the resident. Information may be obtained by talking with the resident, directly examining the resident, and observing the resident’s behavior. Staffing consistency and the nursing staff’s level of familiarity with the residents was reported in one study to have a significant effect on the staff member’s ability to identify and differentiate pain-related behavior from other behavior of cognitively impaired residents.

Nursing assistants may be the first to notice a resident’s symptoms; therefore, it is important that they are able to recognize a change in the resident and the resident’s functioning and to report the changes to a nurse for follow-up. Family members or friends may also recognize and report when the resident experiences pain and may provide information about the resident’s pain symptoms, pain history and previously attempted interventions. Other staff, e.g., dietary, activities, therapy, housekeeping, who have direct contact with the resident may also report changes in resident behavior or resident complaints of pain.

**Assessment**

Observing the resident during care, activities, and treatments helps not only to detect whether pain is present, but also to potentially identify its location and the limitations it places on the resident. The facility must complete the Resident Assessment Instrument (RAI) (See 42 CFR 483.20 F272). According to the CMS Long-Term Care Facility Resident Assessment Instrument User's Manual, Version 3.0, Chapter 1, "Good clinical practice is an expectation of CMS. As such, it is important to note that completion of the MDS does not remove a nursing home’s responsibility to document a more detailed assessment of particular issues relevant for a resident….documentation that contributes to identification and communication of residents' problems, needs and strengths, that monitors their condition on an on-going basis, and that records treatment and response to treatment is a matter of good clinical practice and is an expectation of trained and licensed health care professionals.” An assessment or an evaluation of pain based on clinical standards of practice may necessitate gathering the following information, as applicable to the resident:

- History of pain and its treatment (including non-pharmacological and pharmacological treatment);

- Characteristics of pain, such as:
  - Intensity of pain (e.g., as measured on a standardized pain scale);
  - Descriptors of pain (e.g., burning, stabbing, tingling, aching);
  - Pattern of pain (e.g., constant or intermittent);
- Location and radiation of pain;
- Frequency, timing and duration of pain;

- Impact of pain on quality of life (e.g., sleeping, functioning, appetite, and mood);

- Factors such as activities, care, or treatment that precipitate or exacerbate pain;

- Strategies and factors that reduce pain;

- Additional symptoms associated with pain (e.g., nausea, anxiety);

- Physical examination (may include the pain site, the nervous system, mobility and function, and physical, psychological and cognitive status);

- Current medical conditions and medications; or

- The resident’s goals for pain management and his or her satisfaction with the current level of pain control.

**Management of Pain**

Based on the evaluation, the facility, in collaboration with the attending physician/prescriber, other health care professionals, and the resident and/or his/her representative, develops, implements, monitors and revises as necessary interventions to prevent or manage each individual resident’s pain, beginning at admission. These interventions may be integrated into components of the comprehensive care plan, addressing conditions or situations that may be associated with pain, or may be included as a specific pain management need or goal.

The interdisciplinary team and the resident collaborate to arrive at pertinent, realistic and measurable goals for treatment, such as reducing pain sufficiently to allow the resident to ambulate comfortably to the dining room for each meal or to participate in 30 minutes of physical therapy. Depending on the situation and the resident’s wishes, the target may be to reduce the pain level, but not necessarily to become pain-free. To the extent possible, the interdisciplinary team educates the resident and/or representative about the need to report pain when it occurs and about the various approaches to pain management and the need to monitor the effectiveness of the interventions used.

The basis for effective interventions includes several considerations, such as the resident’s needs and goals; the source(s), type and severity of pain (recognizing that the resident may experience pain from one or more sources either simultaneously or at different times) and awareness of the available treatment options. Often, sequential trials of various treatment options are needed to develop the most effective approach.
It is important for pain management approaches to follow pertinent clinical standards of practice and to identify who is to be involved in managing the pain and implementing the care or supplying the services (e.g., facility staff, such as RN, LPN, CNA; attending physician or other practitioner; certified hospice; or other contractors such as therapists). Pertinent current standards of practice may provide recommended approaches to pain management even when the cause cannot be or has not been determined.

If a resident or the resident’s representative elects the Medicare hospice benefit for end-of-life care, the facility remains the resident’s primary care giver and the SNF/NF requirements for participation in Medicare or Medicaid still apply for that resident. According to the Medicare Hospice Conditions of Participation at 42 CFR 418.112(b) Standard: Professional Management, "The hospice must assume responsibility for professional management of the resident's hospice services provided, in accordance with the hospice plan of care and the hospice conditions of participation, and make any arrangements necessary for hospice-related inpatient care in a participating Medicare/Medicaid facility according to §418.100 and §418.112(b)." The care of the resident, including pain management, must be appropriately coordinated among all providers. In order to provide effective pain management, it is important that staff be educated and guided regarding the proper evaluation and management of pain as reflected in or consistent with the protocols, policies, and procedures employed by the facility.

Non-pharmacological interventions
Non-pharmacologic interventions may help manage pain effectively when used either independently or in conjunction with pharmacologic agents. Examples of non-pharmacologic approaches may include, but are not limited to:

• Altering the environment for comfort (such as adjusting room temperature, tightening and smoothing linens, using pressure redistributing mattress and positioning, comfortable seating, and assistive devices);

• Physical modalities, such as ice packs or cold compresses (to reduce swelling and lessen sensation), mild heat (to decrease joint stiffness and increase blood flow to an area), neutral body alignment and repositioning, baths, transcutaneous electrical nerve stimulation (TENS), massage, acupuncture/acupressure, chiropractic, or rehabilitation therapy;

• Exercises to address stiffness and prevent contractures; and

• Cognitive/Behavioral interventions (e.g., relaxation techniques, reminiscing, diversions, activities, music therapy, coping techniques and education about pain).

The list of Complementary and Alternative Medicine (CAM) options is evolving, as those therapies that are proven safe and effective are used more widely.

NOTE: Information on CAM may be found on the following sites:

• National Center for Complementary and Alternative Medicine at www.nccam.nih.gov; and

• Food and Drug Administration (FDA) at www.fda.gov.
Because CAM can include herbal supplements, some of which potentially can interact with prescribed medications, it is important that any such agents are recorded in the resident’s chart for evaluation by the physician and consultant pharmacist.

**Pharmacological interventions**

The interdisciplinary team (nurses, practitioner, pharmacists, etc.) is responsible for developing a pain management regimen that is specific to each resident who has pain or who has the potential for pain, such as during a treatment. The regimen considers factors such as the causes, location, and severity of the pain, the potential benefits, risks and adverse consequences of medications; and the resident’s desired level of relief and tolerance for adverse consequences. The resident may accept partial pain relief in order to experience fewer significant adverse consequences (e.g., desire to stay alert instead of experiencing drowsiness/confusion). The interdisciplinary team works with the resident to identify the most effective and acceptable route for the administration of analgesics, such as orally, topically, by injection, by infusion pump, and/or transdermally.

It is important to follow a systematic approach for selecting medications and doses to treat pain. Developing an effective pain management regimen may require repeated attempts to identify the right interventions. General guidelines for choosing appropriate categories of medications in various situations are widely available. 23,24

Factors influencing the selection and doses of medications include the resident’s medical condition, current medication regimen, nature, severity, and cause of the pain and the course of the illness. Analgesics may help manage pain; however, they often do not address the underlying cause of pain. Examples of different approaches may include, but are not limited to: administering lower doses of medication initially and titrating the dose slowly upward, administering medications “around the clock” rather than “on demand” (PRN); or combining longer acting medications with PRN medications for breakthrough pain. Recurrent use of or repeated requests for PRN medications may indicate the need to reevaluate the situation, including the current medication regimen. Some clinical conditions or situations may require using several analgesics and/or adjuvant medications (e.g., antidepressants or anticonvulsants) together. Documentation helps to clarify the rationale for a treatment regimen and to acknowledge associated risks.

Opioids or other potent analgesics have been used for residents who are actively dying, those with complex pain syndromes, and those with more severe acute or chronic pain that has not responded to non-opioid analgesics or other measures. Opioids should be selected and dosed in accordance with current standards of practice and manufacturers’ guidelines in order to optimize their effectiveness and minimize their adverse consequences. Adverse consequences may be especially problematic when the resident is receiving other medications with significant effects on the cardiovascular and central nervous systems. Therefore, careful titration of dosages based on monitoring/evaluating the effectiveness of the medication and the occurrence of adverse consequences is necessary. The clinical record should reflect the ongoing communication between the prescriber and the staff is necessary for the optimal and judicious use of pain medications.
Other interventions have been used for some residents with more advanced, complex, or poorly controlled pain. Examples include, but are not limited to: radiation therapy, neurostimulation, spinal delivery of analgesics (implanted catheters and pump systems), and neurolytic procedures (chemical or surgical) \(^2\) that are administered under the close supervision of expert practitioners.

**Monitoring, Reassessment, and Care Plan Revision**

Monitoring the resident over time helps identify the extent to which pain is controlled, relative to the individual’s goals and the availability of effective treatment. The ongoing evaluation of the status (presence, increase or reduction) of a resident’s pain is vital, including the status of underlying causes, the response to interventions to prevent or manage pain, and the possible presence of adverse consequences of treatment. Adverse consequences related to analgesics can often be anticipated and to some extent prevented or reduced. For example, opioids routinely cause constipation, which may be minimized by an appropriate bowel regimen.

Identifying target signs and symptoms (including verbal reports and non-verbal indicators from the resident) and using standardized assessment tools can help the interdisciplinary team evaluate the resident’s pain and responses to interventions and determine whether the care plan should be revised, for example:

- If pain has not been adequately controlled, it may be necessary to reconsider the current approaches and revise or supplement them as indicated; or

- If pain has resolved or there is no longer an indication or need for pain medication, the facility works with the practitioner to discontinue or taper (as needed to prevent withdrawal symptoms) analgesics.

**Endnotes for Pain Management**

Investigative Protocol for Pain Management

Quality of Care Related to the Recognition and Management of Pain

Objective
The objective of this protocol is to determine whether the facility has provided and the resident has received care and services to address and manage the resident’s pain in order to support his or her highest practicable level of physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care.

Use
Use this protocol for a resident who has pain symptoms or who has the potential for pain symptoms related to conditions or treatments. This includes a resident:
• Who states he/she has pain or discomfort;
• Who displays possible indicators of pain that cannot be readily attributed to another cause;
• Who has a disease or condition or who receives treatments that cause or can reasonably be anticipated to cause pain;
• Whose assessment indicates that he/she experiences pain;
• Who receives or has orders for treatment for pain; and/or
• Who has elected a hospice benefit for pain management.

Procedures
Briefly review the care plan and orders to identify any current pain management interventions and to focus observations. Corroborate observations by interview and record review.
NOTE: Determine who is involved in the pain management process (for example, the staff and practitioner, and/or another entity such as a licensed/certified hospice).

1. Observation
Observe the resident during various activities, shifts, and interactions with staff. Use the observations to determine:

• If the resident exhibits signs or symptoms of pain, verbalizes the presence of pain, or requests interventions for pain, or whether the pain appears to affect the resident’s function or ability to participate in routine care or activities;

• If there is evidence of pain, whether staff have assessed the situation, identified, and implemented interventions to try to prevent or address the pain and have evaluated the status of the resident’s pain after interventions;
• If care and services are being provided that reasonably could be anticipated to cause pain, whether staff have identified and addressed these issues, to the extent possible;

• Staff response, if there is a report from the resident, family, or staff that the resident is experiencing pain;

• If there are pain management interventions for the resident, whether the staff implements them. Follow up on:
  – Deviations from the care plan;
  – Whether pain management interventions have a documented rationale and if it is consistent with current standards of practice; and
  – Potential adverse consequence(s) associated with treatment for pain (e.g., medications); and

• How staff responded, if the interventions implemented did not reduce the pain consistent with the goals for pain management.

2. Resident/Representative Interviews

Interview the resident, or representative to the degree possible in order to determine the resident's/representative's involvement in the development of the care plan, defining the approaches and goals, and if interventions reflect choices and preferences, and how they are involved in developing and revising pain management strategies; revisions to the care plan, if the interventions do not work. If the resident is presently or periodically experiencing pain, determine:

• Characteristics of the pain, including the intensity, type (e.g., burning, stabbing, tingling, aching), pattern of pain (e.g., constant or intermittent), location and radiation of pain and frequency, timing and duration of pain;

• Factors that may precipitate or alleviate the pain;

• How the resident typically has expressed pain and responded to various interventions in the past;

• Who the resident and/or representative has told about the pain/discomfort, and how the staff responded;

• What treatment options (e.g., pharmacological and/or non-pharmacological) were discussed;

• How effective the interventions have been; and

• If interventions have been refused, whether there was a discussion of the potential impact on the resident, and whether alternatives or other approaches were offered.

3. Nurse Aide(s) Interview. Interview staff who provide direct care on various shifts to determine:
• If they are aware of a resident’s pain complaints or of signs and symptoms that could indicate the presence of pain;

• To whom they report the resident’s complaints and signs, or symptoms; and

• If they are aware of, and implement, interventions for pain/discomfort management for the resident consistent with the resident’s plan of care, (for example, allowing a period of time for a pain medication to take effect before bathing and/or dressing).

4. Record review
Assessment. Review information such as orders, medication administration records, multidisciplinary progress notes, The RAI/MDS, and any specific assessments regarding pain that may have been completed. Determine if the information accurately and comprehensively reflects the resident’s condition, such as:

• Identifies the pain indicators and the characteristics, causes, and contributing factors related to pain;

• Identifies a history of pain and related interventions, including the effectiveness and any adverse consequences of such interventions;

• Identifies the impact of pain on the resident’s function and quality of life;

• Identifies the resident’s response to interventions including efficacy and adverse consequences, and any modification of interventions as indicated; and

• Identifies if the resident triggers the CAA for pain.
NOTE Although Federal requirements dictate the completion of RAI assessments according to certain time frames, standards of good clinical practice dictate that the assessment process is more fluid and should be ongoing. (Federal Register, Vol. 62, No. 246, 12/23/97, Page 67193)

Care Plan. Review the care plan. Determine if pain management interventions include as appropriate:

• Measurable pain management goals, reflecting resident needs and preferences;

• Pertinent non-pharmacological and/or pharmacological interventions;

• Time frames and approaches for monitoring the status of the resident’s pain, including the effectiveness of the interventions; and

• Identification of clinically significant medication-related adverse consequences such as falling, constipation, anorexia, or drowsiness, and a plan to try to minimize those adverse consequences. If the care plan refers to a specific facility pain management protocol, determine whether interventions are consistent with that protocol. If a resident’s care plan deviates from the protocol, determine through staff interview or record review the reason for the deviation.
If the resident has elected a hospice benefit, all providers must coordinate their care of the resident. This care includes aspects of pain management, such as choice of palliative interventions, responsibility for assessing pain and providing interventions, and responsibility for monitoring symptoms and adverse consequences of interventions and for modifying interventions as needed.

**NOTE** If a resident is receiving services from a Medicare certified hospice and the hospice was advised of concerns by the facility and failed to address and/or resolve issues related to coordination of care or implementation of appropriate services, file a complaint with the State Agency responsible for oversight of this hospice, identifying the specific resident(s) involved and the concerns identified.

**Care Plan Revisions**
Determine whether the pain has been reassessed and the care plan has been revised as necessary (with input from the resident or representative, to the extent possible). For example, if the current interventions are not effective, if the pain has resolved, or the resident has experienced a change of condition or status.

**5. Interviews with health care practitioners and professionals:**

**Nurse Interview.** Interview a nurse who is knowledgeable about the needs and care of the resident to determine:

- How and when staff try to identify whether a resident is experiencing pain and/or circumstances in which pain can be anticipated;

- How the resident is assessed for pain;

- How the interventions for pain management have been developed and the basis for selecting them;

- If the resident receives pain medication (including PRN and adjuvant medications), how, when, and by whom the results of medications are evaluated (including the dose, frequency of PRN use, schedule of routine medications, and effectiveness);

- How staff monitor for the emergence or presence of adverse consequences of interventions;

- What is done if pain persists or recurs despite treatment, and the basis for decisions to maintain or modify approaches;

- How staff communicate with the prescriber/practitioner about the resident’s pain status, current measures to manage pain, and the possible need to modify the current pain management interventions; and

- For a resident who is receiving care under a hospice benefit, how the hospice and the facility coordinate their approaches and communicate about the resident’s needs and monitor the outcomes (both effectiveness and adverse consequences).
Interviews with Other Health Care Professionals. If the interventions or care provided do not appear to be consistent with current standards of practice and/or the resident’s pain appears to persist or recur, interview one or more health care professionals as necessary (e.g., attending physician, medical director, consultant pharmacist, director of nursing or hospice nurse) who, by virtue of training and knowledge of the resident, should be able to provide information about the evaluation and management of the resident’s pain/symptoms. Depending on the issue, ask about:

• How chosen interventions were determined to be appropriate;

• How they guide and oversee the selection of pain management interventions;

• The rationale for not intervening, if pain was identified and no intervention was selected and implemented;

• Changes in pain characteristics that may warrant review or revision of interventions; or

• When and with whom the professional discussed the effectiveness, ineffectiveness and possible adverse consequences of pain management interventions.

If during the course of this review, 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.

DETERMINATION OF COMPLIANCE WITH F309 FOR PAIN MANAGEMENT
(Task 6, Appendix P)

Synopsis of Regulation (Tag F309)
The resident must receive and the facility must provide the necessary care and services to attain or maintain his/her highest practicable level of physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care.

Criteria for Compliance with F309 for a Resident with Pain or the Potential for Pain
For a resident with pain or the potential for pain (such as pain related to treatments), the facility is in compliance with F309 Quality of Care as it relates to the recognition and management of pain, if each resident has received and the facility has provided 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 i.e., the facility:

• Recognized and evaluated the resident who experienced pain to determine (to the extent possible) causes and characteristics of the pain, as well as factors influencing the pain;

• Developed and implemented interventions for pain management for a resident experiencing pain, consistent with the resident’s goals, risks, and current standards of practice; or has provided a clinically pertinent rationale why they did not do so;
• Recognized and provided measures to minimize or prevent pain for situations where pain could be anticipated;

• Monitored the effects of interventions and modified the approaches as indicated; and

• Communicated with the health care practitioner when a resident was having pain that was not adequately managed or was having a suspected or confirmed adverse consequence related to the treatment. If not, cite at F309.

**Noncompliance with F309 for a Resident with Pain or the Potential for Pain**

After completing the Investigative Protocol, analyze the data in order to determine whether or not noncompliance with the regulation exists. Noncompliance for F309, with regard to pain management, may include, for example, failure to:

• Recognize and evaluate the resident who is experiencing pain in enough detail to permit pertinent individualized pain management;

• Provide interventions for pain management in situations where pain can be anticipated;

• Develop interventions for a resident who is experiencing pain (either specific to an overall pain management goal or as part of another aspect of the care plan);

• Implement interventions to address pain to the greatest extent possible consistent with the resident’s goals and current standards of practice and have not provided a clinically pertinent rationale why this was not done;

• Monitor the effectiveness of intervention to manage pain; or

• Coordinate pain management as needed with an involved hospice to meet the resident’s needs.

**Concerns with Independent but Associated Structure, Process, and/or Outcome Requirements for a Resident with Pain or the Potential for Pain**

During the investigation of care and services provided regarding pain management, the surveyor may have identified concerns with related structure, process, and/or outcome requirements. If an additional concern has been identified, the surveyor must investigate the identified concern. Do not cite any related or associated requirements before first conducting an investigation to determine compliance or non-compliance with the related or associated requirement. Some examples include, but are not limited to, the following:

• 42 CFR 483.10(b)(4) F155, The Right to Refuse Treatment
If a resident has refused treatment or services, determine whether the facility has assessed the reason for this resident's refusal, clarified and educated the resident as to the consequences of refusal, offered alternative treatments, and continued to provide all other services.
• 42 CFR 483.10(b)(11), F157, Notification of Changes

Determine if staff notified:
- The physician when pain persisted or recurred despite treatment or when they suspected or identified adverse consequences related to treatments for pain; and
- The resident’s representative (if known) of significant changes in the resident’s condition in relation to pain management and/or the plan of care for pain.

• 42 CFR 483.15(b), F242, Self-determination and Participation.
Determine if the facility has provided the resident with relevant choices about aspects of pain management.

• 42 CFR 483.15(e)(1), F246, Accommodation of Needs
Determine whether the facility has adapted the resident’s physical environment (room, bathroom, furniture) to reasonably accommodate the resident’s individual needs, related to pain management.

• 42 CFR 483.20, F272, Comprehensive Assessments
Determine if the facility comprehensively assessed the resident’s physical, mental, and psychosocial needs to identify characteristics and determine underlying causes (to the extent possible) of the resident’s pain and the impact of the pain upon the resident’s function, mood, and cognition.

• 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 facility’s comprehensive care plan for the resident included measurable objectives, time frames, and specific interventions/services to meet the resident’s pain management needs, consistent with the resident’s specific conditions, risks, needs, goals, and preferences and current standards of practice.

• 42 CFR 483.20(k)(2)(iii), 483.10(d)(3), F280, Comprehensive Care Plan Revision
Determine if the care plan was periodically reviewed and revised by a team of qualified persons with input from the resident or representative to try to reduce pain or discomfort.

• 42 CFR 483.20(k)(3)(i), F281, Services provided meet professional standards of quality
Determine if care was provided in accordance with accepted professional standards of quality for pain management.

• 42 CFR 483.20(k)(3)(ii), F282, Care provided by qualified persons in accordance with the plan of care
Determine whether care is being provided by qualified staff, and/or whether the care plan is adequately and/or correctly implemented.

• 42 CFR 483.25(l), F329, Unnecessary Drugs
Determine whether medications ordered to treat pain are being monitored for effectiveness and for adverse consequences, including whether any symptoms could be related to the medications.

- 42 CFR 483.40(a), F385, Physician Supervision
  Determine if pain management is being supervised by a physician, including participation in the comprehensive assessment process, development of a treatment regimen consistent with current standards of practice, monitoring, and response to notification of change in the resident’s medical status related to pain.

- 42 CFR 483.60, F425, Pharmacy Services
  Determine if the medications required to manage a resident’s pain were available and administered as indicated and ordered at admission and throughout the stay.

- 42 CFR 483.75(i)(2), F501, Medical Director
  Determine whether the medical director helped the facility develop and implement policies and procedures related to preventing, identifying and managing pain, consistent with current standards of practice; and whether the medical director interacted with the physician supervising the care of the resident if requested by the facility to intervene on behalf of a resident with pain or one who may have been experiencing adverse consequences related to interventions to treat pain.

- 42 CRF 483.75(l) F514, Clinical Records
  Determine whether the clinical record:
  - Accurately and completely documents the resident's status, the care and services provided, (e.g., to prevent to the extent possible, or manage the resident's pain) in accordance with current professional standards and practices and the resident's goals; and
  - Provide a basis for determining and managing the resident's progress including response to treatment, change in condition, and changes in treatment.

DEFICIENCY CATEGORIZATION (Part IV, Appendix P) for a Resident with Pain or Potential for Pain

Once the survey team has completed its investigation, analyzed the data, reviewed the regulatory requirements, and determined that noncompliance exists, the team must determine the severity of each deficiency, based on the harm or potential for harm to the resident. The key elements for severity determination for F309 Quality of Care regarding pain assessment and management are as follows:

1. Presence of harm/negative outcome(s) or potential for negative outcomes because of lack of appropriate treatment and care. Actual or potential harm/negative outcome for F309 related to pain assessment and management may include, but is not limited to:

   - Persisting or recurring pain and discomfort related to failure to recognize, assess, or implement interventions for pain; and
• Decline in function resulting from failure to assess a resident after facility clinical staff became aware of new onset of moderate to severe pain.

2. Degree of harm (actual or potential) related to the non-compliance. 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 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 F309 when related to recognition, assessment and management of pain. 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 for a resident with pain or potential for pain.**

Immediate Jeopardy is a situation in which the facility’s non-compliance 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 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 correct the noncompliance, which allowed or caused the immediate jeopardy.

Level 4 indicates noncompliance that results, or has the potential to result, in expressions (verbal and/or non-verbal) of severe, unrelenting, excruciating, and unrelieved pain; pain has become all-consuming and overwhelms the resident.

Examples may include, but are not limited to:
• Resident experienced continuous, unrelenting, excruciating pain or incapacitating distress because the facility has failed to recognize or address the situation, or failed to develop, implement, monitor, or modify a pain management plan to try to meet the resident’s needs; or

• Resident experienced recurring, episodic excruciating pain or incapacitating distress related to specific situations where pain could be anticipated (e.g., because pain has already been identified during dressing changes or therapies) and the facility failed to attempt pain management strategies to try to minimize the pain.

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 for a resident with pain or potential for pain.

Level 3 indicates non-compliance 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.

Level 3 indicates noncompliance that results in expressions (verbal and non-verbal) of pain that has compromised the resident’s functioning such as diminished level of participation in social interactions and/or ADLs, intermittent crying and moaning, weight loss and/or diminished appetite. Pain has become a central focus of the resident’s attention, but it is not all-consuming or overwhelming (as in Severity Level 4).

Examples may include, but are not limited to:

• The resident experienced pain that compromised his/her function (physical and/or psychosocial) and/or ability to reach his/her highest practicable well-being as a result of the facility’s failure to recognize or address the situation, or failure to develop, implement, monitor, or modify a pain management plan to try to meet the resident’s needs. For example, the pain was intense enough that the resident experienced recurrent insomnia, anorexia with resultant weight loss, reduced ability to move and perform ADLs, a decline in mood, or reduced social engagement and participation in activities; or

• The resident experienced significant episodic pain (that was not all-consuming or overwhelming but was greater than minimal discomfort to the resident) related to care/treatment, as a result of the facility’s failure to develop, implement, monitor, or modify pain management interventions. Some examples include lack of pain management interventions prior to dressing changes, wound care, exercise or physical therapy.

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 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 for a resident with pain or potential for pain.

Severity 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.

Level 2 indicates noncompliance that results in feelings and/or complaints of discomfort or moderate pain. The resident may be irritable and/or express discomfort. Examples may include, but are not limited to:

• The resident experienced daily or less than daily discomfort with no compromise in physical, mental, or psychosocial functioning as a result of the facility’s failure to adequately recognize or address the situation, or failure to develop, implement, monitor, or modify a pain management plan to try to meet the resident’s needs; or

• The resident experienced minimal episodic pain or discomfort (that was not significant pain) related to care/treatment, as a result of the facility’s failure to develop, implement, monitor, or modify a pain management plan.

Severity Level 1: No actual harm with potential for no more than minimal harm for a resident with pain or potential for pain.
The failure of the facility to provide appropriate care and services for pain management places the resident at risk for more than minimal harm. Therefore, Severity Level 1 does not apply for this regulatory requirement.

§483.25(a) Activities of Daily Living.
Based on the comprehensive assessment of a resident, the facility must ensure that

Intent §483.25(a)
The intent of this regulation is that the facility must ensure that a resident’s abilities in ADLs do not deteriorate unless the deterioration was unavoidable.

F310
(Rev. 70, Issued: 01-07-11, Effective: 10-01-10 Implementation: 10-01-10)

§483.25(a)(1) A resident’s abilities in activities of daily living do not diminish unless circumstances of the individual’s clinical condition demonstrate that diminution was unavoidable. This includes the resident’s ability to --

(i) Bathe, dress, and groom;

(ii) Transfer and ambulate;

(iii) Toilet;

(iv) Eat; and
(v) Use speech, language, or other functional communication systems.

Interpretive Guidelines §483.25(a)
The mere presence of a clinical diagnosis, in itself, justify a decline in a resident’s ability to perform ADLs. Conditions which may demonstrate unavoidable diminution in ADLs include:

• The natural progression of the resident’s disease;

• Deterioration of the resident’s physical condition associated with the onset of a physical or mental disability while receiving care to restore or maintain functional abilities; and

• The resident’s or his/her surrogate’s or representative’s refusal of care and treatment to restore or maintain functional abilities after aggressive efforts by the facility to counsel and/or offer alternatives to the resident, surrogate, or representative. Refusal of such care and treatment should be documented in the clinical record.

Determine which interventions were identified on the care plan and/or could be in place to minimize or decrease complications. Note also that depression is a potential cause of excess disability and, where appropriate, therapeutic interventions should be initiated.

Appropriate treatment and services includes all care provided to residents by employees, contractors, or volunteers of the facility to maximize the individual’s functional abilities. This includes pain relief and control, especially when it is causing a decline or a decrease in the quality of life of the resident.

If the survey team identifies a pattern of deterioration in ADLs, i.e., a number of residents have deteriorated in more than one ADL or a number of residents have deteriorated in only one ADL (one in bathing, one in eating, one in toileting) and it is determined there is deficient practice, cite at F310.

For evaluating a resident’s ADLs and determining whether a resident’s abilities have declined, improved or stayed the same within the last twelve months, use the following definitions as specified in the State’s RAI:

Independent – Resident completed activity with no help or oversight every time during the 7-day look-back period.

Supervision – Oversight, encouragement or cueing provided 3 or more times during the last 7 days.

Limited Assistance - Resident highly involved in activity and received physical help in guided maneuvering of limb(s) or other non-weight bearing assistance 3 or more times during the last 7-days.

Extensive Assistance - While resident performed part of activity over the last 7 days, help of following type(s) was provided 3 or more times;

a. Weight-bearing support provided 3 or more times; or
b. Full staff performance of activity during part (but not all) of last 7 days.

Total Dependence - Full staff performance of an activity with no participation by resident for any aspect of the ADL activity. Resident was unwilling or unable to perform any part of the activity over entire 7-day look-back period.

§483.25(a)(1)(i) Bathing, Dressing, Grooming
Interpretive Guidelines §483.25(a)(1)(i)

“Bathing” means how resident takes full-body bath, sponge bath, and transfers in/out of tub/shower. Exclude washing of back and hair.

“Dressing” means how resident puts on, fastens, and takes off all items of clothing, including donning/removing prosthesis.

“Grooming” means how resident maintains personal hygiene, including preparatory activities, combing hair, brushing teeth, shaving, applying make-up, washing/drying face, hands and perineum. Exclude baths and showers.

BATHING, DRESSING, GROOMING

Procedures: §483.25(a)(1)(i)
For each sampled resident selected for the comprehensive review or the focused review, as appropriate, determine:

1. Whether the resident’s ability to bathe, dress and/or groom has changed since admission, or over the past 12 months;

2. Whether the resident’s ability to bathe, dress and groom has improved, declined or stayed the same;

3. Whether any deterioration or lack of improvement was avoidable or unavoidable by:

4. Identifying if resident triggers CAAAs for ADL functional/rehabilitation potential.

a. What risk factors for decline of bathing, dressing, and/or grooming abilities did the facility identify?

b. What care did the resident receive to address unique needs to maintain his/her bathing, dressing, and/or grooming abilities (e.g., resident needs a button hook to button his shirt; staff teaches the resident how to use it; staff provides resident with dementia with cues that allow him/her to dress him or herself)?

c. Were individual objectives of the plan of care periodically evaluated, and if the objectives were not met, were alternative approaches developed to encourage maintenance of bathing,
dressing, and/or grooming abilities (e.g., resident now unable to button dress, even with encouragement; will ask family if we may use velcro in place of buttons so resident can continue to dress herself)?

Probes: §483.25(a)(1)(i)
If the resident’s abilities in bathing, dressing, and grooming have been maintained, what evidence is there that the resident could have improved if appropriate treatment and services were provided:

• Identify relevant sections of the MDS and consider whether assessment triggers the CAAs and the CAA process was followed.

• Are there physical and psychosocial deficits that could affect improvement in functional abilities?

• Was the care plan driven by resident strengths identified in the comprehensive assessment?

• Was the care plan consistently implemented?

• What changes were made in treatment if the resident failed to progress or when initial rehabilitation goals were achieved, but additional progress might have been possible?

TRANSFER AND AMBULATION
§483.25(a)(1)(ii)

Interpretive Guidelines: §483.25(a)(1)(ii)

“Transfer” means how resident moves between surfaces - to/from: bed, chair, wheelchair, standing position. (Exclude to/from bath/toilet.)

“Ambulation” means how resident moves between locations in his/her room and adjacent corridor on same floor. If in wheelchair, self-sufficiency once in chair.

Procedures: §483.25(a)(1)(ii)

Determine for each resident selected for a comprehensive review, or a focused review as appropriate, whether the resident’s ability to transfer and ambulate has declined, improved or stayed the same and whether any deterioration or decline in function was avoidable or unavoidable.

Probes: §483.25(a)(1)(ii)

If the resident’s transferring and ambulating abilities have declined, what evidence is there that the decline was unavoidable:

• What risk factors for decline of transferring or ambulating abilities did the facility identify (e.g., necrotic area of foot ulcer becoming larger, postural hypotension)?
• What care did the resident receive to address risk factors and unique needs to maintain transferring or ambulating abilities (e.g., a transfer board is provided to maintain ability to transfer from bed to wheelchair and staff teaches the resident how to use it)?

• What evidence is there that sufficient staff time and assistance are provided to maintain transferring and ambulating abilities?

• Has resident been involved in activities that enhance mobility skills?

• Were individual objectives of the plan of care periodically evaluated, and if goals were not met, were alternative approaches developed to encourage maintenance of transferring and ambulation abilities (e.g., resident remains unsteady when using a cane, returns to walker, with staff encouraging the walker’s consistent use)?

• Identify if resident triggers CAs for ADL functional/rehabilitation potential, psychosocial well-being, or mood state and the CAA process is followed. If the resident’s abilities in transferring and ambulating have been maintained, is there evidence that the resident could have improved if appropriate treatment and services were provided?

• Are there physical and psychosocial deficits that could affect improvement in functional abilities?

• Was the care plan driven by resident strengths identified in the comprehensive assessment?

• Was the care plan consistently implemented? What changes were made in treatment if the resident failed to progress or when initial rehabilitation goals were achieved, but additional progress seemed possible?

TOILETING

§483.25(a)(1)(ii)
Interpretive Guidelines: §483.25(a)(1)(iii)

“Toilet use” means how the resident uses the toilet room (or commode, bedpan, urinal); transfers on/off the toilet, cleanses self, changes pad, manages ostomy or catheter, adjusts clothes.

Procedures: §483.25(a)(1)(iii)

Determine for each resident selected for a comprehensive review, or focused review as appropriate, whether the resident’s ability to use the toilet has improved, declined or stayed the same and whether any deterioration or decline in improvement was avoidable or unavoidable.

Probes: §483.25(a)(1)(iii)

If the resident’s toilet use abilities have declined, what evidence is there that the decline was unavoidable.
• What risk factors for the decline of toilet use abilities did the facility identify (e.g., severe arthritis in hands makes use of toilet paper difficult)?

• What care did resident receive to address risk factors and unique needs to maintain toilet use abilities (e.g., assistive devices to maintain ability to use the toilet such as using a removable elevated toilet seat or wall grab bar to facilitate rising from seated position to standing position)?

• Is there sufficient staff time and assistance provided to maintain toilet use abilities (e.g., allowing residents enough time to use the toilet independently or with limited assistance)?

• Were individual objectives of the plan of care periodically evaluated, and if objectives were not met, were alternative approaches developed to encourage maintaining toilet use abilities (e.g., if resident has not increased sitting stability, seek occupational therapy consult to determine the need for therapy to increase sitting balance, ability to transfer safely and manipulate clothing during the toileting process. For residents with dementia, remind periodically to use the toilet)?

• Identify if resident triggers CAAs for urinary incontinence, and ADL functional/rehabilitation potential and the CAA process was used to assess causal factors for decline or potential for decline or lack of improvement.

If the resident’s toilet use abilities have been maintained, what evidence is there that the resident could have improved if appropriate treatment and services were provided?

• Are there physical and psychosocial deficits that could affect improvement in functional abilities?

• Was the care plan driven by resident strengths identified in the comprehensive assessment?

• Was the care plan consistently implemented? What changes were made to treatment if the resident failed to progress or when initial rehabilitation goals were achieved, but additional progress seemed possible?

• Identify if resident triggers CAAs for mood state and psychosocial well-being.

**EATING**

§483.25(a)(1)(iv)  
Interpretive Guidelines: §483.25(a)(1)(iv)  
“Eating” means how resident ingests and drinks (regardless of self-feeding skill).

Procedures: §483.25(a)(1)(iv)

Determine for each resident selected for a comprehensive review, or focused review, as appropriate, whether the resident’s ability to eat or eating skills has improved, declined, or stayed the same and whether any deterioration or lack of improvement was avoidable or unavoidable.
If the resident’s eating abilities have declined, is there any evidence that the decline was unavoidable?

1. What risk factors for decline of eating skills did the facility identify?
   a. A decrease in the ability to chew and swallow food
   b. Deficit in neurological and muscular status necessary for moving food onto a utensil and into the mouth
   c. Oral health status affecting eating ability
   d. Depression or confused mental state

2. What care did the resident receive to address risk factors and unique needs to maintain eating abilities?
   a. Assistive devices to improve resident’s grasp or coordination;
   b. Seating arrangements to improve sociability;
   c. Seating in a calm, quiet setting for residents with dementia.

3. Is there sufficient staff time and assistance provided to maintain eating abilities (e.g., allowing residents enough time to eat independently or with limited assistance)?

4. Identify if resident triggers CAAs for ADL functional/rehabilitation potential, feeding tubes, and dehydration/fluid maintenance, and the CAA process was used to assess causal reasons for decline, potential for decline or lack of improvement.

5. Were individual objectives of the plan of care periodically evaluated, and if the objectives were not met, were alternative approaches developed to encourage maintaining eating abilities?

   **Probes: §483.25(a)(1)(iv)**
   If the resident’s eating abilities have been maintained, what evidence is there that the resident could have improved if appropriate treatment and services were provided:

   • Are there physical and psychosocial deficits that could affect improvement in functional abilities?

   • Was the care plan driven by resident strengths identified in the comprehensive assessment?

   • Was the care plan consistently implemented? What changes are made to treatment if the resident failed to progress or when initial rehabilitation goals were achieved, but additional progress seemed possible?

   **Interpretive Guidelines: §483.25(a)(1)(v)**
“Speech, language or other functional communication systems” is defined as the ability to effectively communicate requests, needs, opinions, and urgent problems; to express emotion, to listen to others and to participate in social conversation whether in speech, writing, gesture or a combination of these (e.g., a communication board or electronic augmentative communication device).

**USE OF SPEECH, LANGUAGE, OR OTHER FUNCTIONAL COMMUNICATION SYSTEMS**

§483.25(a)(1)(v)

**Procedures: §483.25(a)(1)(v)**

Determine for each resident selected for a comprehensive review, or focused review, as appropriate, if resident’s ability to communicate has declined, improved or stayed the same and whether any deterioration or lack of improvement was avoidable or unavoidable. Identify if resident triggers CAs for communication, psychosocial well-being, mood state, and visual function, and if the CAA process was used to assess causal factors for decline, potential for decline or lack of improvement.

**Probes: §483.25(a)(1)(v)**

If the resident’s communication abilities have diminished, is there any evidence that the decline was unavoidable:

• What risk factors for decline of communication abilities did the facility identify and how did they address them (e.g., dysarthria, poor fitting dentures, few visitors, poor relationships with staff, Alzheimer’s disease)?

• Has the resident received audiologic and vision evaluation? If not, did the resident refuse such services? (See also §483.10(b)(4).)

• What unique resident needs and risk factors did the facility identify (e.g., does the resident have specific difficulties in transmitting messages, comprehending messages, and/or using a variety of communication skills such as questions and commands; does the resident receive evaluation and training in the use of assistive devices to increase and/or maintain writing skills)?

• What care does the resident receive to improve communication abilities (e.g., nurse aides communicate in writing with deaf residents or residents with severe hearing problems; practice exercises with residents receiving speech-language pathology services; increase number of resident’s communication opportunities; non-verbal means of communication; review of the effect of medications on communication ability)?

• Is there sufficient staff time and assistance provided to maintain communication abilities?

• Were individual objectives of the plan of care periodically evaluated, and if the objectives were not met, were alternative approaches developed to encourage maintenance of communication abilities (e.g., if drill-oriented therapy is frustrating the resident, a less didactic approach should be attempted)?
If the resident’s speech, language, and other communication abilities have been maintained, what evidence is there that the resident could have improved if appropriate treatment and services were provided:

• Are there physical and psychosocial deficits that could affect improvement in functional abilities?

• Was the care plan driven by resident strengths identified in the comprehensive assessment?

• Was the care plan consistently implemented?

• What changes were made to treatment if the resident failed to progress or when initial rehabilitation goals were achieved, but additional progress seemed possible?

(2) A resident is given the appropriate treatment and services to maintain or improve his or her abilities specified in paragraph (a)(1) of this section; and

The intent of this regulation is to stress that the facility is responsible for providing maintenance and restorative programs that will not only maintain, but improve, as indicated by the resident’s comprehensive assessment to achieve and maintain the highest practicable outcome.

Use the survey procedures and probes at §483.25(a)(1)(i) through (v) to assist in making this determination.

(3) A resident who is unable to carry out activities of daily living receives the necessary services to maintain good nutrition, grooming, and personal and oral hygiene.

The intent of this regulation is that the resident receives the care and services needed because he/she is unable to do their own ADL care independently.
“Unable to carry out ADLs” means those residents who need extensive or total assistance with maintenance of nutrition, grooming and personal and oral hygiene, receive this assistance from the facility.

Methods for maintenance of good nutrition may include hand feeding of foods served on dishes; tube feedings provided through naso-gastric, gastrostomy, or other external tubes; or total parenteral nutrition provided through a central intravenous line.

“Grooming” - See §483.25(a)(1)(i) for definition.

“Personal hygiene” - Those activities described in dressing and bathing as defined in §483.25(a)(1)(i).

“Oral hygiene” means maintaining the mouth in a clean and intact condition and treating oral pathology such as ulcers of the mucosa. Services to maintain oral hygiene may include brushing the teeth, cleaning dentures, cleaning the mouth and tongue either by assisting the resident with a mouth wash or by manual cleaning with a gauze sponge; and application of medication as prescribed.

Procedures: §483.25(a)(3)

For residents selected for a comprehensive review, or focused review, as appropriate, who are unable to carry out these ADLs without extensive assistance, determine if poor nutritional status, poor grooming, or lack of effective personal and oral hygiene exist. To what extent are these negative outcomes attributable to the lack of receiving necessary services?

Identify if residents trigger CAA s for nutritional status, ADL functional/rehabilitation potential, behavior problems, and dental care. Consider whether the CAA process was used to assess causal factors for decline, potential for decline, or lack of improvement. Determine if the facility proceeded properly with care planning and delivery of care for these residents.

F313
(Rev. 70, Issued: 01-07-11, Effective: 10-01-10 Implementation: 10-01-10)

§483.25(b) Vision and hearing
To ensure that residents receive proper treatment and assistive devices to maintain vision and hearing abilities, the facility must, if necessary, assist the resident --

1. In making appointments, and

2. By arranging for transportation to and from the office of a practitioner specializing in the treatment of vision or hearing impairment or the office of a professional specializing in the provision of vision or hearing assistive devices.

Intent: §483.25(b)
The intent of this regulation is to require a facility to assist residents in gaining access to vision and hearing services by making appointments and arranging for transportation, and assistance with the use of any devices needed to maintain vision and hearing.

**Interpretive Guidelines: §483.25(b)**

Assistive devices to maintain vision include glasses, contact lenses, and magnifying glasses. Assistive devices to maintain hearing include hearing aids.

This requirement does not mean that the facility must provide refractions, glasses, contact lenses, conduct comprehensive audiological evaluations (although screening is a part of the required assessment in §483.20(b)) or provide hearing aids.

The facility’s responsibility is to assist residents and their families in locating and utilizing any available resources (e.g., Medicare or Medicaid program payment, local health organizations offering items and services which are available free to the community) for the provision of the services the resident needs. This includes making appointments and arranging transportation to obtain needed services.

**Probes: §483.25(b)**

- Identify if resident triggers CAA's for visual function, and communication. Consider whether the CAA process was used to assess causal factors for decline, potential for decline or lack of improvement.

- If the resident needs, and/or requests and does not have vision and/or hearing assistive devices, what has the facility done to assist the resident in making appointments and obtaining transportation to obtain these services?

- If the resident has assistive devices but is not using them, why not (e.g., are repairs or batteries needed)?

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F314
*(Rev. 70, Issued: 01-07-11, Effective: 10-01-10 Implementation: 10-01-10)*

**§483.25(c) Pressure Sores**

Based on the comprehensive Assessment of a resident, the facility must ensure that—

1. A resident who enters the facility without pressure sores does not develop pressure sores unless the individual’s clinical condition demonstrates that they were unavoidable; and

2. A resident having pressure sores receives necessary treatment and services to promote healing, prevent infection and prevent new sores from developing.
Intent: (F314) 42 CFR 483.25(c)
The intent of this requirement is that the resident does not develop pressure ulcers unless clinically unavoidable and that the facility provides care and services to:

- Promote the prevention of pressure ulcer development;
- Promote the healing of pressure ulcers that are present (including prevention of infection to the extent possible); and
- Prevent development of additional pressure ulcers.

NOTE: Although the regulatory language refers to pressure sores, the nomenclature widely accepted presently refers to pressure ulcers, and the guidance provided in this document will refer to pressure ulcers.

DEFINITIONS
Definitions are provided to clarify clinical terms related to pressure ulcers and their evaluation and treatment.

- “Pressure Ulcer”- A pressure ulcer is any lesion caused by unrelieved pressure that results in damage to the underlying tissue(s). Although friction and shear are not primary causes of pressure ulcers, friction and shear are important contributing factors to the development of pressure ulcers.

- “Avoidable/Unavoidable” Pressure Ulcers
  o “Avoidable” means that the resident developed a pressure ulcer and that the facility did not do one or more of the following: evaluate the resident’s clinical condition and pressure ulcer risk factors; define and implement interventions that are consistent with resident needs, resident goals, and recognized standards of practice; monitor and evaluate the impact of the interventions; or revise the interventions as appropriate.

  o “Unavoidable” means that the resident developed a pressure ulcer even though the facility had evaluated the resident’s clinical condition and pressure ulcer risk factors; defined and implemented interventions that are consistent with resident needs, goals, and recognized standards of practice; monitored and evaluated the impact of the interventions; and revised the approaches as appropriate.

- “Cleansing/Irrigation”
  o “Cleansing” refers to the use of an appropriate device and solution to clean the surface of the wound bed and to remove the looser foreign debris or contaminants in order to decrease microbial growth.

  o “Irrigation” refers to a type of mechanical debridement, which uses an appropriate solution delivered under pressure to the wound bed to vigorously attempt to remove debris from the wound bed.
• “Colonized/Infected” Wound 4, 5

  o “Colonized” refers to the presence of bacteria on the surface or in the tissue of a wound without the signs and symptoms of an infection.

  o “Infected” refers to the presence of micro-organisms in sufficient quantity to overwhelm the defenses of viable tissues and produce the signs and symptoms of infection.

• “Debridement”- Debridement is the removal of devitalized/necrotic tissue and foreign matter from a wound to improve or facilitate the healing process. 6, 7, 8 Various debridement methods include:

  o “Autolytic debridement” refers to the use of moisture retentive dressings to cover a wound and allow devitalized tissue to self-digest by the action of enzymes present in the wound fluids.

  o “Enzymatic (chemical) debridement” refers to the topical application of substances e.g., enzymes to break down devitalized tissue.

  o “Mechanical debridement” refers to the removal of foreign material and devitalized or contaminated tissue from a wound by physical rather than by chemical or autolytic means.

  o “Sharp or surgical debridement” refers to removal of foreign material or devitalized tissue by a surgical instrument.

  o “Maggot debridement therapy (MDT)” or medicinal maggots refers to a type of sterile intentional biological larval or biosurgical debridement that uses disinfected (sterile) maggots to clean wounds by dissolving the dead and infected tissue and by killing bacteria.9

• “Eschar/Slough”

  o “Eschar” is described as thick, leathery, frequently black or brown in color, necrotic (dead) or devitalized tissue that has lost its usual physical properties and biological activity. Eschar may be loose or firmly adhered to the wound.

  o “Slough” is necrotic/avascular tissue in the process of separating from the viable portions of the body and is usually light colored, soft, moist, and stringy (at times).

• “Exudate”

  o “Exudate” is any fluid that has been forced out of the tissues or its capillaries because of inflammation or injury. It may contain serum, cellular debris, bacteria and leukocytes.

  o “Purulent exudate/drainage/discharge” is any product of inflammation that contains pus (e.g., leukocytes, bacteria, and liquefied necrotic debris).
“Serous drainage or exudate” is watery, clear, or slightly yellow/tan/pink fluid that has separated from the blood and presents as drainage.

- **“Friction/Shearing”**

- **“Friction”** is the mechanical force exerted on skin that is dragged across any surface.

- **“Shearing”** is the interaction of both gravity and friction against the surface of the skin. Friction is always present when shear force is present. Shear occurs when layers of skin rub against each other or when the skin remains stationary and the underlying tissue moves and stretches and angulates or tears the underlying capillaries and blood vessels causing tissue damage.

- **“Granulation Tissue”**

- **“Granulation tissue”** is the pink-red moist tissue that fills an open wound, when it starts to heal. It contains new blood vessels, collagen, fibroblasts, and inflammatory cells.

- **“Tunnel/Sinus Tract/Undermining”**-Tunnel and sinus tract are often used interchangeably.

- **“Tunneling”** is a passageway of tissue destruction under the skin surface that has an opening at the skin level from the edge of the wound.

- **“Sinus tract”** is a cavity or channel underlying a wound that involves an area larger than the visible surface of the wound.

- **“Undermining”** is the destruction of tissue or ulceration extending under the skin edges (margins) so that the pressure ulcer is larger at its base than at the skin surface. Undermining often develops from shearing forces and is differentiated from tunneling by the larger extent of the wound edge involved in undermining and the absence of a channel or tract extending from the pressure ulcer under the adjacent intact skin.

**OVERVIEW**

A pressure ulcer can occur wherever pressure has impaired circulation to the tissue. Critical steps in pressure ulcer prevention and healing include: identifying the individual resident at risk for developing pressure ulcers, identifying and evaluating the risk factors and changes in the resident’s condition, identifying and evaluating factors that can be removed or modified, implementing individualized interventions to attempt to stabilize, reduce or remove underlying risk factors, monitoring the impact of the interventions, and modifying the interventions as appropriate. It is important to recognize and evaluate each resident’s risk factors and to identify and evaluate all areas at risk of constant pressure.

A complete assessment is essential to an effective pressure ulcer prevention and treatment program. A comprehensive individual evaluation helps the facility to:
• Identify the resident at risk of developing pressure ulcers, the level and nature of risk(s); and

• Identify the presence of pressure ulcers.
This information allows the facility to develop and implement a comprehensive care plan that reflects each resident’s identified needs.

The care process should include efforts to stabilize, reduce or remove underlying risk factors; to monitor the impact of the interventions; and to modify the interventions as appropriate.

The facility should have a system/procedure to assure: assessments are timely and appropriate; interventions are implemented, monitored, and revised as appropriate; and changes in condition are recognized, evaluated, reported to the practitioner, and addressed. The quality assessment and assurance committee may help the facility evaluate existing strategies to reduce the development and progression of pressure ulcers, monitor the incidence and prevalence of pressure ulcers within the facility, and ensure that facility policies and procedures are consistent with current standards of practice.

Research into appropriate practices for the prevention, management and treatment of pressure ulcers, continues to evolve. As such, there are many recognized clinical resources regarding the prevention and management of pressure ulcers (including wound care, and complications such as infections and pain). Some of these resources include:

• The Clinical Practice Guidelines from the Agency for Healthcare Research and Quality (AHRQ) www.ahrq.gov (Guideline No. 15: Treatment of Pressure Ulcers and Guideline No.3: Pressure Ulcers in Adults: Prediction and Prevention)(AHRQ was previously known as the Agency for Health Care Policy and Research [AHCPR]);

• The National Pressure Ulcer Advisory Panel (NPUAP) www.npuap.org;

• The American Medical Directors Association (AMDA) www.amda.com (Clinical Practice Guidelines: Pressure Ulcers, 1996 and Pressure Ulcer Therapy Companion, 1999);

• The Quality Improvement Organizations, Medicare Quality Improvement Community Initiatives site at www.medqic.org;

• The Wound, Ostomy, and Continence Nurses Society (WOCN) www.wocn.org; and


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

The citation at 42 CFR 483.25 (c) requires that a resident who is admitted without a pressure ulcer doesn’t develop a pressure ulcer unless clinically unavoidable, and that a resident who has an ulcer receives care and services to promote healing and to prevent additional ulcers.

The first step in prevention is the identification of the resident at risk of developing pressure ulcers. This is followed by implementation of appropriate individualized interventions and monitoring for the effectiveness of the interventions.

ASSESSMENT

An admission evaluation helps identify the resident at risk of developing a pressure ulcer, and the resident with existing pressure ulcer(s) or areas of skin that are at risk for breakdown. Because a resident at risk can develop a pressure ulcer within 2 to 6 hours of the onset of pressure, the at-risk resident needs to be identified and have interventions implemented promptly to attempt to prevent pressure ulcers. The admission evaluation helps define those initial care approaches.

In addition, the admission evaluation may identify pre-existing signs (such as a purple or very dark area that is surrounded by profound redness, edema, or induration) suggesting that deep tissue damage has already occurred and additional deep tissue loss may occur. This deep tissue damage could lead to the appearance of an unavoidable Stage III or IV pressure ulcer or progression of a Stage I pressure ulcer to an ulcer with eschar or exudate within days after admission. Some situations, which may have contributed to this tissue damage, include pressure resulting from immobility during hospitalization or surgical procedures, during prolonged ambulance transport, or while waiting to be discovered or assisted after a debilitating event, such as a fall or a cerebral vascular accident.

Some evidence suggests that because it may be harder to identify erythema in an older adult with darkly pigmented skin, older individuals with darkly pigmented skin may be more at risk for developing pressure ulcers. It may be necessary, therefore, in a darker skinned individual to focus more on other evidence of pressure ulcer development, such as bogginess, induration, coolness, or increased warmth as well as signs of skin discoloration.

Multiple factors, including pressure intensity, pressure duration, and tissue tolerance, significantly affect the potential for the development and healing of pressure ulcers. An individual may also have various intrinsic risks due to aging, for example: decreased subcutaneous tissue and lean muscle mass, decreased skin elasticity, and impaired circulation or innervation.

The comprehensive assessment, which includes the RAI, evaluates the resident’s intrinsic risks, the resident’s skin condition, other factors (including causal factors) which place the resident at risk for developing pressure ulcers and/or experiencing delayed healing, and the nature of the pressure to which the resident may be subjected. The assessment should identify which risk factors can be removed or modified.
The assessment also helps identify the resident who has multi-system organ failure or an end-of-life condition or who is refusing care and treatment. If the resident is refusing care, an evaluation of the basis for the refusal, and the identification and evaluation of potential alternatives is indicated.

This comprehensive assessment should address those factors that have been identified as having an impact on the development, treatment and/or healing of pressure ulcers, including, at a minimum: risk factors, pressure points, under-nutrition and hydration deficits, and moisture and the impact of moisture on skin. Each of these factors is discussed in additional detail in the following sections.

**Risk Factors**

Many studies and professional documents identify risk factors that increase a resident’s susceptibility to develop or to not heal pressure ulcers.\(^{17, 18, 19}\) Examples of these risk factors include, but are not limited to:

- Impaired/decreased mobility and decreased functional ability;
- Co-morbid conditions, such as end stage renal disease, thyroid disease or diabetes mellitus;
- Drugs such as steroids that may affect wound healing;
- Impaired diffuse or localized blood flow, for example, generalized atherosclerosis or lower extremity arterial insufficiency;
- Resident refusal of some aspects of care and treatment;
- Cognitive impairment;
- Exposure of skin to urinary and fecal incontinence;
- Under nutrition, malnutrition, and hydration deficits; and
- A healed ulcer. The history of a healed pressure ulcer and its stage [if known] is important, since areas of healed Stage III or IV pressure ulcers are more likely to have recurrent breakdown. Some residents have many risk factors for developing pressure ulcers, such as diabetic neuropathy, frailty, cognitive impairment, and under nutrition. Not all factors are fully modifiable and some potentially modifiable factors (e.g., under-nutrition) may not be corrected immediately, despite prompt intervention, while other factors such as pressure may be modified promptly. It may be necessary to stabilize, when possible, the underlying causes (e.g., control blood sugars or ensure adequate food and fluid intake).

Although the requirements do not mandate any specific assessment tool, other than the RAI, validated instruments are available to assess risk for developing pressure ulcers. Research has shown that a significant number of pressure ulcers develop within the first four weeks after
admission to a long term care facility. Therefore, many clinicians recommend using a standardized pressure ulcer risk assessment tool to assess a resident’s pressure ulcer risks upon admission, weekly for the first four weeks after admission for each resident at risk, then quarterly, or whenever there is a change in cognition or functional ability. A resident’s risk may increase due to an acute illness or condition change (e.g., upper respiratory infection, pneumonia, or exacerbation of underlying congestive heart failure) and may require additional evaluation.

Regardless of any resident’s total risk score, the clinicians responsible for the resident’s care should review each risk factor and potential cause(s) individually to: a) Identify those that increase the potential for the resident to develop pressure ulcers; b) Decide whether and to what extent the factor(s) can be modified, stabilized, removed, etc., and c) Determine whether targeted management protocols need to be implemented. In other words, an overall risk score indicating the resident is not at high risk of developing pressure ulcers does not mean that existing risk factors or causes should be considered less important or addressed less vigorously than those factors or causes in the resident whose overall score indicates he or she is at a higher risk of developing a pressure ulcer.

**Pressure Points and Tissue Tolerance**

Assessment of a resident’s skin condition helps define prevention strategies. The skin assessment should include an evaluation of the skin integrity and tissue tolerance (ability of the skin and its supporting structures to endure the effects of pressure without adverse effects) after pressure to that area has been reduced or redistributed.

Tissue closest to the bone may be the first tissue to undergo necrosis. Pressure ulcers are usually located over a bony prominence, such as the sacrum, heel, the greater trochanter, ischial tuberosity, fibular head, scapula, and ankle (malleolus).

An at-risk resident who sits too long on a static surface may be more prone to get ischial ulceration. Slouching in a chair may predispose an at-risk resident to pressure ulcers of the spine, scapula, or elbow (elbow ulceration is often related to arm rests or lap boards). Friction and shearing are also important factors in tissue ischemia, necrosis and pressure ulcer formation.

Pressure ulcers may develop at other sites where pressure has impaired the circulation to the tissue, such as pressure from positioning or use of medical devices. For example, pressure ulcers may develop from pressure on an ear lobe related to positioning of the head; pressure or friction on areas (e.g., nares, urinary meatus, extremities) caused by tubes, casts, orthoses, braces, cervical collars, or other medical devices; pressure on the labia or scrotum related to positioning (e.g., against a pommel type cushion); pressure on the foot related to ill-fitting shoes causing blistering; or pressure on legs, arms and fingers due to contractures or deformity resulting from rheumatoid arthritis, etc.

While pressure ulcers on the sacrum remain the most common location, pressure ulcers on the heel are occurring more frequently and are difficult to assess and heal, and require early identification of skin compromise over the heel.
It is, therefore, important for clinical staff to regularly conduct thorough skin assessments on each resident who is at risk for developing pressure ulcers.

**Under-Nutrition and Hydration Deficits**

Adequate nutrition and hydration are essential for overall functioning. Nutrition provides vital energy and building blocks for all of the body’s structures and processes. Any organ or body system may require additional energy or structural materials for repair or function. The skin is the body’s largest organ system. It may affect, and be affected by, other body processes and organs. Skin condition reflects overall body function; skin breakdown may be the most visible evidence of a general catabolic state.

Weight reflects a balance between intake and utilization of energy. Significant unintended weight loss may indicate under-nutrition or worsening health status. Weight stability (in the absence of fluid excess or loss) is a useful indicator of overall caloric balance. Severely impaired organs (heart, lungs, kidneys, liver, etc.) may be unable to use nutrients effectively. A resident with a pressure ulcer who continues to lose weight either needs additional caloric intake or correction (where possible) of conditions that are creating a hypermetabolic state. Continuing weight loss and failure of a pressure ulcer to heal despite reasonable efforts to improve caloric and nutrient intake may indicate the resident is in multi-system failure or an end-stage or end-of-life condition warranting an additional assessment of the resident’s overall condition.

Before instituting a nutritional care plan, it helps to summarize resident specific evidence, including: severity of nutritional compromise, rate of weight loss or appetite decline, probable causes, the individual’s prognosis and projected clinical course, and the resident’s wishes and goals. Because there are no wound-specific nutritional measures, the interdisciplinary team should develop nutritional goals for the whole person. Unless contraindicated, nutritional goals for a resident with nutritional compromise who has a pressure ulcer or is at risk of developing pressure ulcers should include protein intake of approximately 1.2-1.5 gm/kg body weight daily (higher end of the range for those with larger, more extensive, or multiple wounds). A simple multivitamin is appropriate, but unless the resident has a specific vitamin or mineral deficiency, supplementation with additional vitamins or minerals may not be indicated. 

**NOTE:** Although some laboratory tests may help clinicians evaluate nutritional issues in a resident with pressure ulcers, no laboratory test is specific or sensitive enough to warrant serial/repeated testing. Serum albumin, pre-albumin and cholesterol may be useful to help establish overall prognosis; however, they may not correlate well with clinical observation of nutritional status. At his or her discretion, a practitioner may order test(s) that provide useful additional information or help with management of treatable conditions.

Water is essential to maintain adequate body functions. As a major component of blood, water dissolves vitamins, minerals, glucose, amino acids, etc.; transports nutrients into cells; removes waste from the cells; and helps maintain circulating blood volume as well as fluid and electrolyte balance. It is critical that each resident at risk for hydration deficit or imbalance, including the resident with a pressure ulcer or at risk of developing an ulcer, be identified and that hydration needs be addressed.
(The surveyor should refer to the Guidance at 42 CFR 483.25 (i), F325, Nutrition, and 483.25(j), F327 Hydration for investigation of potential non-compliance with the nutrition and hydration requirements. A low albumin level combined with the facility’s lack of supplementation, for example, is not sufficient to cite a pressure ulcer deficiency.)

**Moisture and Its Impact**

Both urine and feces contain substances that may irritate the epidermis and may make the skin more susceptible to breakdown. Some studies have found that fecal incontinence may pose a greater threat to skin integrity, most likely due to bile acids and enzymes in the feces. Irritation or maceration resulting from prolonged exposure to urine and feces may hasten skin breakdown, and moisture may make skin more susceptible to damage from friction and shear during repositioning.

It may be difficult to differentiate dermatitis related to incontinence from partial thickness skin loss (pressure ulcer). This differentiation should be based on the clinical evidence and review of presenting risk factors. A Stage I pressure ulcer usually presents as a localized area of erythema or skin discoloration, while perineal dermatitis may appear as a more diffuse area of erythema or discoloration where the urine or stool has come into contact with the skin. The dermatitis may occur in the area where the incontinence brief or underpad has been used. Also, the dermatitis/rash more typically presents as intense erythema, scaling, itching, papules, weeping and eruptions.

**INTERVENTIONS**

The comprehensive assessment should provide the basis for defining approaches to address residents at risk of developing or already having a pressure ulcer. A determination that a resident is at high risk to develop a pressure ulcer has significant implications for preventive and treatment strategies, but does not by itself indicate that development of a pressure ulcer was unavoidable. Effective prevention and treatment are based upon consistently providing routine and individualized interventions.

In the context of the resident’s choices, clinical condition, and physician input, the resident’s plan of care should establish relevant goals and approaches to stabilize or improve co-morbidities, such as attempts to minimize clinically significant blood sugar fluctuations and other interventions aimed at limiting the effects of risk factors associated with pressure ulcers. Alternatively, facility staff and practitioners should document clinically valid reasons why such interventions were not appropriate or feasible. Repeated hospitalizations or emergency room visits within a 6-month period may indicate overall decline or instability.

**Resident Choice**

In order for a resident to exercise his or her right appropriately to make informed choices about care and treatment or to refuse treatment, the facility and the resident (or the resident's legal representative) must discuss the resident’s condition, treatment options, expected outcomes, and consequences of refusing treatment. The facility is expected to address the resident’s concerns
and offer relevant alternatives, if the resident has refused specific treatments. (See Resident Rights at 42 CFR 483.10(b)(3) and (4), F154 and F155.)

**Advance Directive**

A resident at the end of life, in terminal stages of an illness or having multiple system failures may have written directions for his or her treatment goals (or a decision has been made by the resident’s surrogate or representative, in accordance with state law).

If a resident has a valid Advance Directive, the facility’s care must reflect a resident’s wishes as expressed in the Directive, in accordance with state law. However, the presence of an Advance Directive does not absolve the facility from giving supportive and other pertinent care that is not prohibited by the Advance Directive. If the facility has implemented individualized approaches for end-of-life care in accordance with the resident's wishes, and has implemented appropriate efforts to try to stabilize the resident’s condition (or indicated why the condition cannot or should not be stabilized) and to provide care to prevent or treat the pressure ulcer (including pertinent, routine, lesser aggressive approaches, such as, cleaning, turning, repositioning), then the development, continuation, or progression of a pressure ulcer may be consistent with regulatory requirements.

**NOTE:** The presence of a "Do Not Resuscitate" (DNR) order is not sufficient to indicate the resident is declining other appropriate treatment and services. It only indicates that the resident should not be resuscitated if respirations and/or cardiac function cease.

Based upon the assessment and the resident’s clinical condition, choices and identified needs, basic or routine care should include interventions to: a) Redistribute pressure (such as repositioning, protecting heels, etc); b) Minimize exposure to moisture and keep skin clean, especially of fecal contamination; c) Provide appropriate, pressure-redistributing, support surfaces; d) Provide non-irritating surfaces; and e) Maintain or improve nutrition and hydration status, where feasible. Adverse drug reactions related to the resident's drug regimen may worsen risk factors for development of pressure ulcers or for non-healing pressure ulcers (for example, by causing lethargy or anorexia or creating/increasing confusion) and should be identified and addressed. These interventions should be incorporated into the plan of care and revised as the condition of the resident indicates.

**Repositioning**

Repositioning is a common, effective intervention for an individual with a pressure ulcer or who is at risk of developing one. Assessment of a resident’s skin integrity after pressure has been reduced or redistributed should guide the development and implementation of repositioning plans. Such plans should be addressed in the comprehensive plan of care consistent with the resident’s need and goals. Repositioning is critical for a resident who is immobile or dependent upon staff for repositioning. The care plan for a resident at risk of friction or shearing during repositioning may require the use of lifting devices for repositioning. Positioning the resident on an existing pressure ulcer should be avoided since it puts additional pressure on tissue that is already compromised and may impede healing.
Surveyors should consider the following repositioning issues:

• A resident who can change positions independently may need supportive devices to facilitate position changes. The resident also may need instruction about why repositioning is important and how to do it, encouragement to change positions regularly, and monitoring of frequency of repositioning.

• The care plan for a resident who is reclining and is dependent on staff for repositioning should address position changes to maintain the resident’s skin integrity. This may include repositioning at least every 2 hours or more frequently depending upon the resident’s condition and tolerance of the tissue load (pressure). Depending on the individualized assessment, more frequent repositioning may be warranted for individuals who are at higher risk for pressure ulcer development or who show evidence (e.g., Stage I pressure ulcers) that repositioning at 2-hour intervals is inadequate. With rare exception (e.g., both sacral and ischial pressure ulcers are present) the resident should not be placed directly on the greater trochanter for more than momentary placement. Elevating the head of the bed or the back of a reclining chair to or above a 30 degree angle creates pressure comparable to that exerted while sitting, and requires the same considerations regarding repositioning as those for a dependent resident who is seated.

• Many clinicians recommend a position change “off loading” hourly for dependent residents who are sitting or who are in a bed or a reclining chair with the head of the bed or back of the chair raised 30 degrees or more. Based upon an assessment including evidence of tissue tolerance while sitting (checking for Stage I ulcers as noted above), the resident may not tolerate sitting in a chair in the same position for 1 hour at a time and may require a more frequent position change.

• Postural alignment, weight distribution, sitting balance and stability, and pressure redistribution should all be considered when positioning a resident in a chair. A teachable resident should be taught to shift his/her weight approximately every 15 minutes while sitting in a chair.

• Wheelchairs are often used for transporting residents, but they may severely limit repositioning options and increase the risk of pressure ulcer development. Therefore, wheelchairs with sling seats may not be optimal for prolonged sitting during activities or meals, etc. However, available modifications to the seating can provide a more stable surface and provide better pressure reduction.

• There isn’t evidence that momentary pressure relief followed by return to the same position (that is a “microshift” of five or 10 degrees or a 10-15 second lift from a seated position) is beneficial. This approach does not allow sufficient capillary refill and tissue perfusion for a resident at risk of developing pressure ulcers. Ongoing monitoring of the resident’s skin integrity and tissue tolerance is critical to prevent development or deterioration of pressure ulcers.

**Support Surfaces and Pressure Redistribution**

Pressure redistribution refers to the function or ability to distribute a load over a surface or contact area. Redistribution results in shifting pressure from one area to another and requires
attention to all affected areas. Pressure redistribution has incorporated the concepts of both pressure reduction (reduction of interface pressure, not necessarily below capillary closure pressure) and pressure relief (reduction of interface pressure below capillary closure pressure).

Appropriate support surfaces or devices should be chosen by matching a device’s potential therapeutic benefit with the resident’s specific situation; for example, multiple ulcers, limited turning surfaces, ability to maintain position. The effectiveness of pressure redistribution devices (e.g., 4-inch convoluted foam pads, gels, air fluidized mattresses, and low loss air mattresses) is based on their potential to address the individual resident’s risk, the resident’s response to the product, and the characteristics and condition of the product. For example, an overinflated overlay product, or one that “bottoms out” (completely compressing the overlay, when, for example, the caregiver can feel less than one inch between the resident and support material) is unlikely to effectively reduce the pressure risk. These products are more likely to reduce pressure effectively if they are used in accord with the manufacturer’s instructions. The effectiveness of each product used needs to be evaluated on an ongoing basis. Surveyors should consider the following pressure redistribution issues:

• Static pressure redistribution devices (e.g., solid foam, convoluted foam, gel mattress) may be indicated when a resident is at risk for pressure ulcer development or delayed healing. A specialized pressure redistribution cushion or surface, for example, might be used to extend the time a resident is sitting in a chair; however, the cushion does not eliminate the necessity for periodic repositioning.

• Dynamic pressure reduction surfaces may be helpful when: 1) The resident cannot assume a variety of positions without bearing weight on a pressure ulcer, 2) The resident completely compresses a static device that has retained its original integrity, or 3) The pressure ulcer is not healing as expected, and it is determined that pressure may be contributing to the delay in healing.

• Because the heels and elbows have relatively little surface area, it is difficult to redistribute pressure on these two surfaces. Therefore, it is important to pay particular attention to reducing the pressure on these areas for the resident at risk in accord with resident’s overall goals and condition. Pillows used to support the entire lower leg may effectively raise the heel from contact with the bed, but use of the pillows needs to take into account the resident’s other conditions. The use of donut-type cushions is not recommended by the clinicians.

• A resident with severe flexion contractures also may require special attention to effectively reduce pressure on bony prominences or prevent breakdown from skin-to-skin contact. Some products serve mainly to provide comfort and reduce friction and shearing forces, e.g., sheepskin, heel and elbow protectors. Although these products are not effective at redistributing pressure, they (in addition to pillows, foam wedges, or other measures) may be employed to prevent bony prominences from rubbing together.
MONITORING

At least daily, staff should remain alert to potential changes in the skin condition and should evaluate and document identified changes. For example, a resident’s complaint about pain or burning at a site where there has been pressure or a nursing assistant’s observation during the resident’s bath that there is a change in skin condition should be reported so that the resident may be evaluated further.

After completing a thorough evaluation, the interdisciplinary team should develop a relevant care plan to including prevention and management interventions with measurable goals. Many clinicians recommend evaluating skin condition (e.g., skin color, moisture, temperature, integrity, and turgor) at least weekly, or more often if indicated, such as when the resident is using a medical device that may cause pressure.

The resident should be monitored for condition changes that might increase the risk for breakdown and the defined interventions should be implemented and monitored for effectiveness.

ASSESSMENT AND TREATMENT OF PRESSURE ULCER(S)

It is important that each existing pressure ulcer be identified, whether present on admission or developed after admission, and that factors that influenced its development, the potential for development of additional ulcers or for the deterioration of the pressure ulcer(s) be recognized, assessed and addressed (see discussion under Prevention regarding overall assessment and interventions). Any new pressure ulcer suggests a need to reevaluate the adequacy of the plan for preventing pressure ulcers.

When assessing the ulcer itself, it is important to:

• Differentiate the type of ulcer (pressure-related versus non-pressure-related) because interventions may vary depending on the specific type of ulcer;

• Determine the ulcer’s stage;

• Describe and monitor the ulcer’s characteristics;

• Monitor the progress toward healing and for potential complications;

• Determine if infection is present;

• Assess, treat and monitor pain, if present; and

• Monitor dressings and treatments.
TYPES OF ULCERS

Three of the more common types of ulcers are pressure, vascular insufficiency/ischemia (venous stasis and arterial ischemic ulcers) and neuropathic. See Guidance to Surveyors at 42 CFR 483.25 (F309) for definition and description of ulcer types other than pressure ulcers.

At the time of the assessment, clinicians (physicians, advance practice nurses, physician assistants, and certified wound care specialists, etc.) should document the clinical basis (for example, type of skin injury/ulcer, location, shape, ulcer edges and wound bed, condition of surrounding tissues) for any determination that an ulcer is not pressure-related, especially if the injury/ulcer has characteristics consistent with a pressure ulcer, but is determined not to be one.

ULCER CHARACTERISTICS

It is important that the facility have a system in place to assure that the protocols for daily monitoring and for periodic documentation of measurements, terminology, frequency of assessment, and documentation are implemented consistently throughout the facility.

When a pressure ulcer is present, daily monitoring, (with accompanying documentation, when a complication or change is identified), should include:

• An evaluation of the ulcer, if no dressing is present;

• An evaluation of the status of the dressing, if present (whether it is intact and whether drainage, if present, is or is not leaking);

• The status of the area surrounding the ulcer (that can be observed without removing the dressing);

• The presence of possible complications, such as signs of increasing area of ulceration or soft tissue infection (for example: increased redness or swelling around the wound or increased drainage from the wound); and

• Whether pain, if present, is being adequately controlled.

The amount of observation possible will depend upon the type of dressing that is used, since some dressings are meant to remain in place for several days, according to manufacturers’ guidelines.

With each dressing change or at least weekly (and more often when indicated by wound complications or changes in wound characteristics), an evaluation of the pressure ulcer wound should be documented. At a minimum, documentation should include the date observed and:

• Location and staging;

• Size (perpendicular measurements of the greatest extent of length and width of the ulceration), depth; and the presence, location and extent of any undermining or tunneling/sinus tract;
• Exudate, if present: type (such as purulent/serous), color, odor and approximate amount;

• Pain, if present: nature and frequency (e.g., whether episodic or continuous);

• Wound bed: Color and type of tissue/character including evidence of healing (e.g., granulation tissue), or necrosis (slough or eschar); and

• Description of wound edges and surrounding tissue (e.g., rolled edges, redness, hardness/induration, maceration) as appropriate.

Photographs may be used to support this documentation, if the facility has developed a protocol consistent with accepted standards (e.g., frequency, consistent distance from the wound, type of equipment used, means to assure digital images are accurate and not modified, inclusion of the resident identification/ulcer location/dates/etc. within the photographic image, and parameters for comparison).

STAGES OF PRESSURE ULCERS

The staging system is one method of summarizing certain characteristics of pressure ulcers, including the extent of tissue damage. This is the system used within the RAI. Stage I pressure ulcers may be difficult to identify because they are not readily visible and they present with greater variability. Advanced technology (not commonly available in nursing homes) has shown that a Stage I pressure ulcer may have minimal to substantial tissue damage in layers beneath the skin's surface, even when there is no visible surface penetration. The Stage I indicators identified below will generally persist or be evident after the pressure on the area has been removed for 30-45 minutes.

The definitions for the stages of pressure ulcers identified below are from the *Long-Term Care Facility Resident Assessment Instrument User’s Manual, Version 3.0*.

• “**Stage I**” - An observable, pressure-related alteration of intact skin, whose indicators as compared to an adjacent or opposite area on the body may include changes in one or more of the following parameters:
  
  o Skin temperature (warmth or coolness);

  o Tissue consistency (firm or boggy);

  o Sensation (pain, itching); and/or

  o A defined area of persistent redness in lightly pigmented skin, whereas in darker skin tones, the ulcer may appear with persistent red, blue, or purple hues.

• “**Stage II**” - Partial thickness loss of *dermis* presenting as a shallow open ulcer with a red-pink *wound bed* without *slough*. May also present as an intact or open/ruptured *blister*.
“Stage III” - Full thickness tissue loss. Subcutaneous fat may be visible but bone, tendon or muscle is not exposed. Slough may be present but does not obscure the depth of tissue loss. May include undermining or tunneling.

"Stage IV" - Full thickness tissue loss with exposed bone, tendon or muscle. Slough or eschar may be present on some parts of the wound bed. Often includes undermining and tunneling.

THE HEALING PRESSURE ULCER
Ongoing evaluation and research have indicated that pressure ulcers do not heal in a reverse sequence, that is, the body does not replace the types and layers of tissue (e.g., muscle, fat and dermis) that were lost during the pressure ulcer development.

There are different types of clinical documentation to describe the progression of the healing pressure ulcer(s). The regulation at 42 CFR 483.20(b)(1), F272, requires that facilities use the RAI. Directions on describing pressure ulcer(s) according to the RAI can be found in the RAI manual – these are intended for coding purposes of the MDS. (NOTE: For information on coding pressure ulcers for the MDS, see Chapter 3 of the Long-Term Care Facility Resident Assessment Instrument User’s Manual, Version 3.0, effective 10/1/2010, which is located on the CMS MDS 3.0 website [http://www.cms.gov/NursingHomeQualityInitiatives/45_NHQIMDS30TrainingMaterials.asp#TopOfPage].

Some clinicians utilize validated instruments to describe the healing of a pressure ulcer.

Although such instruments are appropriate for making treatment decisions, the coding system for the MDS must be used for completion of the RAI.

The 1994 AHCPR Guidelines and current literature indicate that a clean pressure ulcer with adequate blood supply and innervation should show evidence of stabilization or some healing within 2-4 weeks. Evidence accumulating since 1962 indicates that management of wound exudate coupled with a clean, moist wound environment allows a chronic wound (e.g., pressure ulcer) to lay down healthy granulating tissue more efficiently.

If a pressure ulcer fails to show some evidence of progress toward healing within 2-4 weeks, the pressure ulcer (including potential complications) and the resident’s overall clinical condition should be reassessed. Re-evaluation of the treatment plan including determining whether to continue or modify the current interventions is also indicated. Results may vary depending on the resident’s condition and interventions/treatments used. The complexity of the resident’s condition may limit responsiveness to treatment or tolerance for certain treatment modalities.

The clinicians, if deciding to retain the current regimen, should document the rationale for continuing the present treatment (for example, why some, or all, of the plan’s interventions remain relevant despite little or no apparent healing).

Pressure ulcers may progress or may be associated with complications such as infection of the soft tissues around the wound (cellulitis), infection of the bone (osteomyelitis), infection of a
joint (septic arthritis), abscess, spread of bacteria into the bloodstream (bacteremia/septicemia), chronic infection, or development of a sinus tract. Sometimes these complications may occur despite apparent improvement in the pressure ulcer itself. The physician’s involvement is integral whenever significant changes in the nature of the wound or overall resident condition are identified.

**INFECTIONS RELATED TO PRESSURE ULCERS**

Current literature reports that all Stage II, III, and IV pressure ulcers are colonized with bacteria but may not be infected. Identification, diagnosis and treatment of infection, when present, are critical to healing a pressure ulcer. The infection occurs when the bacteria have invaded the tissue surrounding or within the pressure ulcer.

As with any infection, classic signs and symptoms of infection may include purulent exudate, peri-wound warmth, swelling, induration or erythema (erythema may not be readily determined in individuals with dark skin pigmentation), increasing pain or tenderness around the site or delayed wound healing. These classic signs may not be as evident in someone with a granulating, chronic wound or an immuno-compromised or aged resident. Some infections may present primarily with pain or delayed healing without other typical clinical signs of infection.

Clinicians have developed some tools, which may facilitate identifying and assessing an infection and documenting progress toward healing.

Wounds may be classified as infected if the signs and symptoms of infection are present and/or a wound culture (obtained in accord with accepted standards, such as sterile tissue aspirate, a “quantitative surface swab” using the Levine technique or semi-quantitative swab) contains 100,000 (10^5) or greater micro-organisms per gram of tissue. A superficial swab may show the presence of bacteria, but is not a reliable method to identify infection.

Findings such as an elevated white blood cell count, bacteremia, sepsis, or fever may signal an infection related to a pressure ulcer area or a co-existing infection from a different source.

**PAIN**

The assessment and treatment of a resident’s pain are integral components of pressure ulcer prevention and management. “The goal of pain management in the pressure ulcer patient is to eliminate the cause of pain, to provide analgesia, or both.” Pain that interferes with movement and/or affects mood may contribute to immobility and contribute to the potential for developing a pressure ulcer or for delayed healing or non-healing of an already existing ulcer.

It may be difficult to assess the degree of pain in a resident who is cognitively impaired. Some strategies and tools exist to help determine the presence and characteristics of pain (e.g., nature, intensity and frequency). Recent research suggests that a resident with a Stage IV pressure ulcer can feel as much pain as those with a Stage I or II ulcer. The relationship of pain to the pressure ulcer healing process is not yet clear. Pain is an individual perception and response and an individual’s report of pain is a generally valid indicator of pain. One resident may experience pain of varying intensity and frequency (e.g., continually or periodically) or episodically in
association with treatments (e.g., debridement, dressing changes) or movement or infection, while another resident may not have or report pain.

**DRESSINGS AND TREATMENTS**

Research has found that chronic wounds such as pressure ulcers heal differently from acute wounds, primarily because of differing biochemical and cellular characteristics.

Current clinical practice indicates that Stage III and Stage IV ulcers should be covered.

Determination of the need for a dressing for a Stage I or Stage II ulcer is based upon the individual practitioner’s clinical judgment and facility protocols based upon current clinical standards of practice. No particular dressing promotes healing of all pressure ulcers within an ulcer classification.46

For those pressure ulcers with significant exudate, management of the exudate is critical for healing. A balance is needed to assure that the wound is moist enough to support healing but not too moist to interfere with healing.47 Since excess wound exudate generally impairs wound healing, selecting an appropriate absorptive dressing is an important part of managing chronic wound exudate.

Product selection should be based upon the relevance of the specific product to the identified pressure ulcer(s) characteristics, the treatment goals, and the manufacturer's recommendations for use. Current literature does not indicate significant advantages of any single specific product over another, but does confirm that not all products are appropriate for all pressure ulcers.

Wound characteristics should be assessed throughout the healing process to assure that the treatments and dressings being used are appropriate to the nature of the wound.

Present literature suggests that pressure ulcer dressing protocols may use clean technique rather than sterile, but that appropriate sterile technique may be needed for those wounds that recently have been surgically debrided or repaired.48

Debridement of non-viable tissue is frequently performed to reduce the amount of wound debris or non-viable tissue and to reduce the risk of sepsis. A variety of debridement methods (e.g., mechanical, sharp or surgical, enzymatic, autolytic, MDT) are available. Removal of necrotic tissue should enhance wound healing. Ongoing monitoring (and timely intervention in case of change in the character of the wound) is critical for areas with eschar and those areas that have been debrided.49 Many clinicians believe that stable, dry, adherent and intact eschar on the foot/heel should not be debrided, unless signs and symptoms of local infection or instability are detected.50

Some facilities may use “wet to dry gauze dressings” or irrigation with chemical solutions to remove slough. The use of wet-to-dry dressings or irrigations may be appropriate in limited circumstances, but repeated use may damage healthy granulation tissue in healing ulcers and may lead to excessive bleeding and increased resident pain.
A facility should be able to show that its treatment protocols are based upon current standards of practice and are in accord with the facility’s policies and procedures as developed with the medical director’s review and approval.

ENDNOTES

(For more information on the references below, visit the CMS Sharing Innovations in Quality website: www.cms.hhs.gov/medicaid/survey-cert/siqhome.asp.
activated gelatinases are increased in chronic wounds. Journal of Investigative Dermatology, 106(2), 335-341.


INVESTIGATIVE PROTOCOL

PRESSURE ULCER

Objectives
• To determine if the identified pressure ulcer(s) is avoidable or unavoidable; and
• To determine the adequacy of the facility’s interventions and efforts to prevent and treat pressure ulcers.

Use
Use this protocol for a sampled resident having—or at risk of developing—a pressure ulcer. If the resident has an ulcer, determine if it was identified as non-pressure related, e.g., vascular insufficiency or a neuropathic ulcer. If record review, staff and/or physician interview, and observation (unless the dressing protocol precludes observing the wound) support the conclusion that the ulcer is not pressure related, do not proceed with this protocol unless the resident is at risk for developing, or also has, pressure ulcers. Evaluate care and services regarding non-pressure related ulcers at F309, Quality of Care.

**Procedures**
Briefly review the assessment, care plan and orders to identify facility interventions and to guide observations to be made. For a newly admitted resident either at risk or with a pressure ulcer, the staff is expected to assess and provide appropriate care from the day of admission. Corroborate observations by interview and record review.

1. **Observation**
   Observe whether staff consistently implements the care plan over time and across various shifts. During observations of the interventions, note and/or follow up on deviations from the care plan as well as potential negative outcomes, including but not limited to the following:

   • Erythema or color changes on areas such as the sacrum, buttocks, trochanters, posterior thigh, popliteal area, or heels when moved off an area:
     o If erythema or color change are noted, return approximately ½ - ¾ hours later to determine if the changes or other Stage I characteristics persist;
     o If the changes persist and exhibit tenderness, hardness, or alteration in temperature from surrounding skin, ask staff how they determine repositioning schedules and how they evaluate and address a potential Stage I pressure ulcer;
   • Previously unidentified open areas;
   • Whether the positioning avoids pressure on an existing pressure ulcer(s);
   • Measures taken to prevent or reduce the potential for shearing or friction during transfers, elevation, and repositioning; and
   • Whether pressure-redistributing devices for the bed and/or chair, such as gel-type surfaces or overlays are in place, working, and used according to the manufacturer’s recommendations.

**Observation of Existing Ulcer/Wound Care**
If a dressing change is scheduled during the survey, observe the wound care to determine if the record reflects the current status of the ulcer(s) and note:

• Characteristics of the wound and surrounding tissues such as presence of granulation tissue, the Stage, presence of exudates, necrotic tissue such as eschar or slough, or evidence of erythema or swelling around the wound;
• The form or type of debridement, if used;

• Whether treatment and infection control practices reflect current standards of practice; and

• Based on location, steps taken to cleanse and protect the wound from likely contamination by urine or fecal incontinence.

  If unable to observe the dressing change due to the dressing protocol, observe the area surrounding the ulcer(s). For ulcers with dressings that are not scheduled to be changed, the surveyor may request that the dressing be removed to observe the wound and surrounding area if other information suggests a possible treatment or assessment problem.

  If the resident expresses (or appears to be in) pain related to the ulcer or treatment, determine if the facility:

• Assessed for pain related to the ulcer, addressed and monitored interventions for effectiveness; and/or

• Assessed and took preemptive measures for pain related to dressing changes or other treatments, such as debridement/irrigations, and monitored for effectiveness.

2. Resident/Staff Interviews

  Interview the resident, family or responsible party to the degree possible to identify:

• Involvement in care plan, choices, goals, and if interventions reflect preferences;

• Awareness of approaches, such as pressure redistribution devices or equipment, turning/repositioning, weight shifting to prevent or address pressure ulcer(s);

• Presence of pain, if any, and how it is managed;

• If treatment(s) was refused, whether counseling on alternatives, consequences, and/or other interventions was offered; and

• Awareness of current or history of an ulcer(s). For the resident who has or has had a pressure ulcer, identify, as possible, whether acute illness, weight loss or other condition changes occurred prior to developing the ulcer.

  Interview staff on various shifts to determine:

• Knowledge of prevention and treatment, including facility-specific guidelines/protocols and specific interventions for the resident;

• If nursing assistants know what, when, and to whom to report changes in skin condition; and

• Who monitors for the implementation of the care plan, changes in the skin, the development of pressure ulcers, and the frequency of review and evaluation of an ulcer.

3. Record Review
**Assessment**

Review the RAI and other documents such as physician orders, progress notes, nurses’ notes, pharmacy or dietary notes regarding the assessment of the resident’s overall condition, risk factors and presence of a pressure ulcer(s) to determine if the facility identified the resident at risk and evaluated the factors placing the resident at risk:

- For a resident who was admitted with an ulcer or who developed one within 1 to 2 days, review the admission documentation regarding the wound site and characteristics at the time of admission, the possibility of underlying tissue damage because of immobility or illness prior to admission, skin condition on or within a day of admission, history of impaired nutrition; and history of previous pressure ulcers; and

- For a resident who subsequently developed or has an existing pressure ulcer, review documentation regarding the wound site, characteristics, progress and complications including reassessment if there were no signs of progression towards healing within 2 to 4 weeks. In considering the appropriateness of a facility’s response to the presence, progression, or deterioration of a pressure ulcer, take into account the resident’s condition, complications, time needed to determine the effectiveness of a treatment, and the facility’s efforts, where possible, to remove, modify, or stabilize the risk factors and underlying causal factors.

**Care Plan**

For the resident at risk for developing or who has a pressure ulcer, determine if the facility developed an individualized care plan that addresses prevention, care and treatment of any existing pressure ulcers, including specific interventions, measurable objectives and approximate time frames.

If the facility’s care of a specific resident refers to a treatment protocol that contains details of the treatment regimen, the care plan should refer to that protocol. The care plan should clarify any major deviations from, or revisions to, that protocol in a specific resident. A specific care plan intervention for risk of pressure ulcers is not needed if other components of the care plan address related risks adequately. For example, the risk of skin breakdown posed by fecal/urinary incontinence might be addressed in that part of the care plan that deals with incontinence management.

If the resident refuses or resists staff interventions to reduce risk or treat existing pressure ulcers, determine if the care plan reflects efforts to seek alternatives to address the needs identified in the assessment.

**Revision of the Care Plan**

Determine if the staff have been monitoring the resident's response to interventions for prevention and/or treatment and have evaluated and revised the care plan based on the resident’s response, outcomes, and needs. Review the record and interview staff for information and/or evidence that:
• Continuing the current approaches meets the resident’s needs, if the resident has experienced recurring pressure ulcers or lack of progression toward healing and staff did not revise the care plan; and

• The care plan was revised to modify the prevention strategies and to address the presence and treatment of a newly developed pressure ulcer, for the resident who acquired a new ulcer.

4. Interviews with Health Care Practitioners and Professionals

If the interventions defined or care provided appear not to be consistent with recognized standards of practice, interview one or more health care practitioners and professionals as necessary (e.g., physician, charge nurse, director of nursing) who, by virtue of training and knowledge of the resident, should be able to provide information about the causes, treatment and evaluation of the resident’s condition or problem. Depending on the issue, ask about:

• How it was determined that chosen interventions were appropriate;

• Risks identified for which there were no interventions;

• Changes in condition that may justify additional or different interventions; or

• How they validated the effectiveness of current interventions.

If the attending physician is unavailable, interview the medical director, as appropriate.

DETERMINATION OF COMPLIANCE (Task 6, Appendix P)

Synopsis of Regulation (F314)

The pressure ulcer requirement has two aspects. The first aspect requires the facility to prevent the development of pressure ulcer(s) in a resident who is admitted without pressure ulcer(s), unless the development is clinically unavoidable. The second aspect requires the facility to provide necessary treatment and services to promote healing, prevent infection and prevent new ulcers from developing. A facility may have non-compliance in either or both aspects of this requirement.

Criteria for Compliance

• Compliance with 42 CFR 483.25(c)(1), F314, Pressure Sore
  ○ For a resident who developed a pressure ulcer after admission, the facility is in compliance with this requirement, if staff have:

  • Recognized and assessed factors placing the resident at risk for developing a pressure ulcer, including specific conditions, causes and/or problems, needs and behaviors;
• Defined and implemented interventions for pressure ulcer prevention in accordance with resident needs, goals and recognized standards of practice;

• Monitored and evaluated the resident’s response to preventive efforts; and

• Revised the approaches as appropriate.

If not, the development of the pressure ulcer is avoidable, cite at F314.

• Compliance with 42 CFR 483.25(c)(2), F314, Pressure Sore

  o For a resident who was admitted with a pressure ulcer, who has a pressure ulcer that is not healing, or who is at risk of developing subsequent pressure ulcers, the facility is in compliance with this requirement if they:

  • Recognized and assessed factors placing the resident at risk of developing a new pressure ulcer or experiencing non-healing or delayed healing of a current pressure ulcer, including specific conditions, causes and/or problems, needs and behaviors;

  • Defined and implemented interventions for pressure ulcer prevention and treatment in accordance with resident needs, goals and recognized standards of practice;

  • Addressed the potential for infection;

  • Monitored and evaluated the resident’s response to preventive efforts and treatment interventions; and

  • Revised the approaches as appropriate.

If not, cite at F314.

**Non-compliance for F314**

After completing the Investigative Protocol, analyze the data in order to determine whether or not noncompliance with the regulation exists. Non-compliance for F314 may include (but is not limited to) one or more of the following, including failure to:

• Accurately or consistently assess a resident's skin integrity on admission and as indicated thereafter;

• Identify a resident at risk of developing a pressure ulcer(s);

• Identify and address risk factors for developing a pressure ulcer, or explain adequately why they could not or should not do so;

• Implement preventive interventions in accord with the resident’s need and current standards of practice;
• Provide clinical justification for the unavoidable development or non-healing/ delayed healing or deterioration of a pressure ulcer;

• Provide appropriate interventions, care and treatment to an existing pressure ulcer to minimize infections and to promote healing;

• Implement interventions for existing wounds;

• Notify the physician of the resident’s condition or changes in the resident's wound(s);

• Adequately implement pertinent infection management practices in relation to wound care; and

• Identify or know how to apply relevant policies and procedures for pressure ulcer prevention and treatment.

**Potential Tags for Additional Investigation**

During the investigation of F314, the surveyor may have determined that concerns may also be present with related outcome, process and/or structure requirements. The surveyor is cautioned to investigate these related requirements before determining whether non-compliance may be present. Some examples of related requirements that should be considered include the following:

• 42 CFR 483.10(b)(11)(i)(B)&(C), F157, Notification of Changes
  
  o Determine if staff notified the physician of significant changes in the resident’s condition or failure of the treatment plan to prevent or heal pressure ulcers; or the resident’s representative (if known) of significant changes in the resident’s condition in relation to the development of a pressure ulcer or a change in the progression of healing of an existing pressure ulcer.

• 42 CFR 483.20(b)(1), F272, Comprehensive Assessments
  
  o Determine if the facility comprehensively assessed the resident’s skin condition, including existing pressure ulcers, and resident-specific risk factors (including potential causative factors) for the development of a pressure ulcer or non-healing of the ulcer.

• 42 CFR 483.20(k)(1), F279, Comprehensive Care Plans
  
  o Determine if the facility developed a care plan that was consistent with the resident’s specific conditions, risks, needs, behaviors, and preferences and current standards of practice and included measurable objectives and timetables, specific interventions/services to prevent the development of pressure ulcers and/or to treat existing pressures ulcers.

• 42 CFR 483.20(k)(2)(iii), F280, Comprehensive Care Plan Revision
• Determine if the care plan was periodically reviewed and revised as necessary to prevent the development of pressure ulcers and to promote the healing of existing pressure ulcers.

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

• Determine if pressure ulcer care was provided in accordance with accepted professional standards.

42 CFR 483.25, F309, Quality of Care

• Determine if staff identified and implemented appropriate measures for the management of pain as indicated as related to pressure ulcers and pressure ulcer treatment.

42 CFR 482.30(a), F353, Sufficient Staff

• Determine if the facility had qualified staff in sufficient numbers to assure the resident was provided necessary care and services, based upon the comprehensive assessment and care plan, to prevent or treat pressure ulcers.

42 CFR 483.40(a)(1), F385, Physician Supervision

• Determine if the physician has assessed and developed a treatment regimen relevant to preventing or healing a pressure ulcer and responded appropriately to the notice of changes in condition.

42 CFR 483.75(i)(2), F501, Medical Director

• Determine whether the medical director assisted the facility in the development and implementation of policies and procedures for pressure ulcer prevention and treatment, and that these are based on current standards of practice; and whether the medical director interacts with the physician supervising the care of the resident if requested by the facility to intervene on behalf of the resident with a pressure ulcer(s).

V. DEFICIENCY CATEGORIZATION (Part V, Appendix P)

Once the team has completed its investigation, analyzed the data, reviewed the regulatory requirement, and identified the deficient practices that demonstrate that the facility failed to provide care and treatment to prevent or treat pressure ulcers and that non-compliance exists, the team must determine the severity of the deficient practice(s) and the resultant harm or potential for harm to the resident. The key elements for severity determination for F314 are as follows:

1. Presence of harm/negative outcome(s) or potential for negative outcomes because of lack of appropriate treatment and care. Actual or potential harm/negative outcome for F314 may include but is not limited to:

• Potential for development of, occurrence or recurrence of (an) avoidable pressure ulcer(s);
Complications such as sepsis or pain related to the presence of avoidable pressure ulcer(s); and/or

Pressure ulcers that fail to improve as anticipated or develop complications such as sepsis or pain because of the lack of appropriate treatment and care.

2. **Degree of harm (actual or potential) related to the non-compliance**
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 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 non-compliance 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 F314. 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 non-compliance:

- 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 of possible avoidable negative outcomes may include:

- Development of avoidable Stage IV pressure ulcer(s): As a result of the facility’s non-compliance, permanent tissue damage (whether or not healing occurs) has compromised the resident, increasing the potential for serious complications including osteomyelitis and sepsis.

- Admitted with a Stage IV pressure ulcer(s) that has shown no signs of healing or shows signs of deterioration: As a result of the facility’s non-compliance, a Stage IV pressure ulcer has shown signs of deterioration or a failure to progress towards healing with an increased potential for serious complications including osteomyelitis and sepsis.

- Stage III or IV pressure ulcers with associated soft tissue or systemic infection: As a result of the facility’s failure to assess or treat a resident with an infectious complication of a pressure
ulcer. (See discussion in guidelines and definitions that distinguishes colonization from infection.)

• Extensive failure in multiple areas of pressure ulcer care: As a result of the facility’s extensive noncompliance in multiple areas of pressure ulcer care, the resident developed recurrent and/or multiple, avoidable Stage III or Stage IV pressure ulcer(s).

**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 can include but may not be limited to clinical compromise, decline, or the resident’s ability to maintain and/or reach his/her highest practicable well-being.

Examples of avoidable negative outcomes may include but are not limited to:

• The development of avoidable Stage III pressure ulcer(s): As a result of the facility’s non-compliance, Stage III pressure ulcers occurred, which are open wounds in which damage has occurred into the subcutaneous level and may be painful.

• The development of recurrent or multiple avoidable Stage II pressure ulcer(s): As a result of the facility’s non-compliance, the resident developed multiple and/or recurrent avoidable Stage II ulcers.

• Failure to implement the comprehensive care plan for a resident who has a pressure ulcer: As a result of a facility’s failure to implement a portion of an existing plan related to pressure ulcer care, such as failure to provide for pressure redistribution, or inappropriate treatment/dressing changes, a wound increased in size or failed to progress towards healing as anticipated, or the resident experienced untreated pain.

**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 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 of avoidable negative outcomes may include but are not limited to:
• The development of a single avoidable Stage II pressure ulcer that is receiving appropriate
treatment: As a result of the facility’s non-compliance, a resident developed an avoidable Stage
II pressure ulcer.

• The development of an avoidable Stage I pressure ulcer: As a result of the facility’s non-
compliance, a resident developed an avoidable Stage I pressure ulcer.

• Failure to implement an element of the care plan for a resident who has a pressure ulcer
however, there has been no evidence of decline or failure to heal.

• Failure to recognize or address the potential for developing a pressure ulcer: As a result of the
facility’s non-compliance, staff failed to identify the risks, develop a plan of care and/or
consistently implement a plan that has been developed to prevent pressure ulcers.

Severity Level 1: No Actual Harm with Potential for Minimal Harm
The failure of the facility to provide appropriate care and services to prevent pressure ulcers or
heal existing pressure ulcers is more than minimal harm. Therefore, Severity Level 1 doesn't
apply for this regulatory requirement.

F315
(Rev. 70, Issued: 01-07-11, Effective: 10-01-10 Implementation: 10-01-10)

§483.25(d) Urinary Incontinence
Based on the resident’s comprehensive assessment, the facility must ensure that --

§483.25(d) (1) A resident who enters the facility without an indwelling catheter is not
catheterized unless the resident’s clinical condition demonstrates that catheterization was
necessary; and

§483.25(d) (2) A resident who is incontinent of bladder receives appropriate treatment and
services to prevent urinary tract infections and to restore as much normal bladder function
as possible.

INTENT: (F315) 42 CFR 483.25 (d) (1) and (2) Urinary Incontinence and Catheters
The intent of this requirement is to ensure that:

• Each resident who is incontinent of urine is identified, assessed and provided appropriate
treatment and services to achieve or maintain as much normal urinary function as possible;

• An indwelling catheter is not used unless there is valid medical justification;

• An indwelling catheter for which continuing use is not medically justified is discontinued as
soon as clinically warranted;
• Services are provided to restore or improve normal bladder function to the extent possible, after the removal of the catheter; and

• A resident, with or without a catheter, receives the appropriate care and services to prevent infections to the extent possible.

**DEFINITIONS**
Definitions are provided to clarify clinical terms related to evaluation and treatment of urinary incontinence and catheter use.

• “Bacteremia” is the presence of bacteria in the bloodstream.

• “Bacteriuria” is defined as the presence of bacteria in the urine.

• “Urinary Incontinence” is the involuntary loss or leakage of urine. There are several types of urinary incontinence, and the individual resident may experience more than one type at a time. Some of the more common types include:
  o “Functional Incontinence” refers to loss of urine that occurs in residents whose urinary tract function is sufficiently intact that they should be able to maintain continence, but who cannot remain continent because of external factors (e.g., inability to utilize the toilet facilities in time);
  o “Mixed Incontinence” is the combination of stress incontinence and urge incontinence;
  o “Overflow Incontinence” is associated with leakage of small amounts of urine when the bladder has reached its maximum capacity and has become distended;
  o “Stress Incontinence” (Outlet incompetence) is associated with impaired urethral closure (malfunction of the urethral sphincter) which allows small amounts of urine leakage when intra-abdominal pressure on the bladder is increased by sneezing, coughing, laughing, lifting, standing from a sitting position, climbing stairs, etc.;
  o “Transient Incontinence” refers to temporary episodes of urinary incontinence that are reversible once the cause(s) of the episode(s) is (are) identified and treated; and
  o “Urge Incontinence” (overactive bladder) is associated with detrusor muscle overactivity (excessive contraction of the smooth muscle in the wall of the urinary bladder resulting in a sudden, strong urge (also known as urgency) to expel moderate to large amounts of urine before the bladder is full).

• “Urinary Retention” is the inability to completely empty the urinary bladder by micturition.

• “Urinary Tract Infection” (UTI) is a clinically detectable condition associated with invasion by disease causing microorganisms of some part of the urinary tract, including the urethra (urethritis), bladder (cystitis), ureters (ureteritis), and/or kidney (pyelonephritis). An infection of
the urethra or bladder is classified as a lower tract UTI and infection involving the ureter or kidney is classified as an upper tract UTI.

• “Urosepsis” refers to the systemic inflammatory response to infection (sepsis) that appears to originate from a urinary tract source. It may present with symptoms such as fever, hypotension, reduced urine output, or acute change in mental status.

OVERVIEW

Urinary incontinence is not normal. Although aging affects the urinary tract and increases the potential for urinary incontinence, urinary incontinence is not a normal part of aging. In the younger person, urinary incontinence may result from a single cause. In the older individual, urinary incontinence generally involves psychological, physiological, pharmacological and/or pathological factors or co-morbid conditions (e.g., later stages of dementia, diabetes, prostatectomy, medical conditions involving dysfunction of the central nervous system, urinary tract infections, etc.). Because urinary incontinence is a symptom of a condition and may be reversible, it is important to understand the causes and to address incontinence to the extent possible. If the underlying condition is not reversible, it is important to treat or manage the incontinence to try to reduce complications.

Many older adults are incontinent of urine prior to admission to a nursing home. Urinary incontinence and related loss of independence are prominent reasons for a nursing home admission. Articles and data currently available, including CMS data (e.g., MDS Active Resident Information Report (Item H0300) at http://www.cms.gov/MDSPubQIandResRep/04_activeresreport.asp?isSubmitted=res3&var=H1&date=31), indicate that more than 50% of the nursing home population experience some degree of urinary incontinence. Whether the resident is incontinent of urine on admission or develops incontinence after admission, the steps of assessment, monitoring, reviewing, and revising approaches to care (as needed) are essential to managing urinary incontinence and to restoring as much normal bladder function as possible.

Various conditions or situations may aggravate the severity of urinary incontinence in nursing home residents. In addition, urinary incontinence may be associated with changes in skin integrity, skin irritation or breakdown, urinary tract infections, falls and fractures, sleep disturbances, and psychosocial complications including social withdrawal, embarrassment, loss of dignity, feelings of isolation, and interference with participation in activities.

Various factors common to elderly individuals may increase the risk of infection including: underlying diseases (e.g., diabetes mellitus), medications that affect immune responses to infection (e.g., steroids and chemotherapy, history of multiple antibiotic usage), conditions that cause incontinence, and indwelling urinary catheters.

The urinary tract is a common source of bacteremia in nursing home residents. Urinary tract infection (UTI) is one of the most common infections occurring in nursing homes and is often
related to an indwelling urinary catheter. Without a valid clinical rationale for an indwelling catheter, its use is not an acceptable approach to manage urinary incontinence. Although UTIs can result from the resident’s own flora, they may also be the result of microorganisms transmitted by staff when handling the urinary catheter drainage system and/or providing incontinence care. Hand washing remains one of the most effective infection control tools available.

Resources

It is important for the facility to have in place systems/procedures to assure: assessments are timely and appropriate; interventions are defined, implemented, monitored, and revised as appropriate in accordance with current standards of practice; and changes in condition are recognized, evaluated, reported to the practitioner, and addressed. The medical director and the quality assessment and assurance committee may help the facility evaluate existing strategies for identifying and managing incontinence, catheter use, and UTIs, and ensure that facility policies and procedures are consistent with current standards of practice.

Research into appropriate practices to prevent, manage, and treat urinary incontinence, urinary catheterization, and UTI continues to evolve. Many recognized clinical resources on the prevention and management of urinary incontinence, infection, and urinary catheterization exist. Some of these resources include:

• The American Medical Directors Association (AMDA) at www.amda.com (Clinical Practice Guidelines: Clinical Practice Guidelines, 1996);

• The Quality Improvement Organizations, Medicare Quality Improvement Community Initiatives at www.medqic.org;

• The CMS Sharing Innovations in Quality website at www.cms.hhs.gov/medicaid/survey-cert/siqhome.asp;

• Association for Professionals in Infection Control and Epidemiology (APIC) at www.apic.org;

• Centers for Disease Control at www.cdc.gov;

• The Annals of Long Term Care publications at www.mmhc.com;

• American Foundation for Urologic Disease, Inc. at www.afud.org; and

• The American Geriatrics Society at www.americangeriatrics.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.
Resident Choice

In the course of developing and implementing care plan interventions for treatment and services related to achieving the highest practicable level of urinary continence, preventing and treating urinary tract infections, and avoiding the use of indwelling catheters without medical justification, it is important to involve the resident and/or her or his surrogate in care decisions and to consider whether the resident has an advance directive in place.

In order for a resident to exercise his or her right appropriately to make informed choices about care and treatment or to refuse treatment, the facility and the resident (or the resident’s legal representative) must discuss the resident’s condition, treatment options, expected outcomes, and consequences of refusing treatment. The facility should address the resident’s concerns and offer relevant alternatives, if the resident has refused specific treatments. (See Resident Rights 483.10(b) (3) and (4) (F154 and F155).)

Advance Directive. A resident who is at the end of life or in terminal stages of an illness or who has multiple organ system failures may have written directions for his or her treatment goals (or a decision has been made by the resident’s surrogate or representative, in accordance with State law).

Although a facility’s care must reflect a resident’s wishes as expressed in the Directive, in accordance with State law, the presence of an Advance Directive does not absolve the facility from giving supportive and other pertinent care that is not prohibited by the Advance Directive.

The presence of a “Do Not Resuscitate” (DNR) order does not indicate that the resident is declining appropriate treatment and services. It only indicates that the resident should not be resuscitated if respirations and/or cardiac function cease.

If the facility has implemented individualized approaches for end-of-life care in accordance with the resident’s wishes, and has implemented appropriate efforts to try to stabilize the resident’s condition (or indicated why the condition cannot or should not be stabilized), and has provided care based on the assessed needs of the resident, then the development, continuation, or progression of urinary incontinence; the insertion and prolonged use of an indwelling urinary catheter; the development of infection or skin-related complications from urine or an indwelling catheter may be consistent with regulatory requirements.

URINARY INCONTINENCE

42 CFR 483.25 (d) (2) Urinary Incontinence requires that a resident who is incontinent of bladder receives appropriate treatment and services to prevent urinary tract infections and to restore as much normal bladder function as possible.

Urinary incontinence generally involves a number of transitory or chronic progressive factors that affect the bladder and/or the urethral sphincter. Any condition, medication, or factor that affects lower urinary tract function, bladder capacity, urination, or the ability to toilet can predispose residents to urinary incontinence and may contribute to incomplete bladder emptying.
The first steps toward assuring that a resident receives appropriate treatment and services to restore as much bladder function as possible or to treat and manage the incontinence are to identify the resident already experiencing some level of incontinence or at risk of developing urinary incontinence and to complete an accurate, thorough assessment of factors that may predispose the resident to having urinary incontinence. This is followed by implementing appropriate, individualized interventions that address the incontinence, including the resident’s capabilities and underlying factors that can be removed, modified, or stabilized, and by monitoring the effectiveness of the interventions and modifying them, as appropriate. The practitioner, may at his or her option, refer residents to various practitioners who specialize in diagnosing and treating conditions that affect urinary function.

**Assessment**

Factors contributing to urinary incontinence sometimes may be resolved after a careful examination and review of history. In addition, for a resident who is incontinent of urine, determining the type of urinary incontinence can allow staff to provide more individualized programming or interventions to enhance the resident’s quality of life and functional status. A resident should be evaluated at admission and whenever there is a change in cognition, physical ability, or urinary tract function. This evaluation is to include identification of individuals with reversible and irreversible (e.g., bladder tumors and spinal cord disease) causes of incontinence.

If the resident has urinary incontinence that has already been investigated, documented, and determined to be irreversible or not significantly improvable, additional studies may be of limited value, unless there has been advancement in available treatments.

Documentation of assessment information may be found throughout the medical record, such as in an admission assessment, hospital records, history and physical, and the RAI. The location of RAI assessment information is identified on the **CAA Summary form**. It is important that staff, when completing the comprehensive assessment, consider the following:

- Prior history of urinary incontinence, including onset, duration and characteristics, precipitants of urinary incontinence, associated symptoms (e.g., dysuria, polyuria, hesitancy) and previous treatment and/or management, including the response to the interventions and the occurrence of persistent or recurrent UTI;

- Voiding patterns (such as frequency, volume, nighttime or daytime, quality of stream) and, for those already experiencing urinary incontinence, voiding patterns over several days;

- Medication review, particularly those that might affect continence, such as medications with anticholinergic properties (may cause urinary retention and possible overflow incontinence), sedative/hypnotics (may cause sedation leading to functional incontinence), diuretics (may cause urgency, frequency, overflow incontinence), narcotics, alpha-adrenergic agonists (may cause urinary retention in men) or antagonists (may cause stress incontinence in women) calcium channel blockers (may cause urinary retention);
• Patterns of fluid intake, such as amounts, time of day, alterations and potential complications, such as decreased or increased urine output;

• Use of urinary tract stimulants or irritants (e.g., frequent caffeine intake);

• Pelvic and rectal examination to identify physical features that may directly affect urinary incontinence, such as prolapsed uterus or bladder, prostate enlargement, significant constipation or fecal impaction, use of a urinary catheter, atrophic vaginitis, distended bladder, or bladder spasms;

• Functional and cognitive capabilities that could enhance urinary continence and limitations that could adversely affect continence, such as impaired cognitive function or dementia, impaired immobility, decreased manual dexterity, the need for task segmentation, decreased upper and lower extremity muscle strength, decreased vision, pain with movement;

• Type and frequency of physical assistance necessary to assist the resident to access the toilet, commode, urinal, etc. and the types of prompting needed to encourage urination;

• Pertinent diagnoses such as congestive heart failure, stroke, diabetes mellitus, obesity, and neurological disorders (e.g., Multiple Sclerosis, Parkinson’s Disease or tumors that could affect the urinary tract or its function);

• Identification of and/or potential of developing complications such as skin irritation or breakdown;

• Tests or studies indicated to identify the type(s) of urinary incontinence (e.g., post-void residual(s) for residents who have, or are at risk of, urinary retention, results of any urine culture if the resident has clinically significant systemic or urinary symptoms), or evaluations assessing the resident’s readiness for bladder rehabilitation programs; and

• Environmental factors and assistive devices that may restrict or facilitate a resident's ability to access the toilet (e.g., grab bars, raised or low toilet seats, inadequate lighting, distance to toilet or bedside commodes, availability of urinals, use of bed rails or restraints, or fear of falling).

Types of Urinary Incontinence

Identifying the nature of the incontinence is a key aspect of the assessment and helps identify the appropriate program/interventions to address incontinence.

• Urge Incontinence is characterized by abrupt urgency, frequency, and nocturia (part of the overactive bladder diagnosis). It may be age-related or have neurological causes (e.g., stroke, diabetes mellitus, Parkinson’s Disease, multiple sclerosis) or other causes such as bladder infection, urethral irritation, etc. The resident can feel the need to void, but is unable to inhibit voiding long enough to reach and sit on the commode. It is the most common cause of urinary incontinence in elderly persons.
• Stress Incontinence is the loss of a small amount of urine with physical activity such as coughing, sneezing, laughing, walking stairs or lifting. Urine leakage results from an increase in intra-abdominal pressure on a bladder that is not over distended and is not the result of detrusor contractions. It is the second most common type of urinary incontinence in older women.

• Mixed Incontinence is the combination of urge incontinence and stress incontinence. Many elderly persons (especially women) will experience symptoms of both urge and stress called mixed incontinence.

• Overflow Incontinence occurs when the bladder is distended from urine retention. Symptoms of overflow incontinence may include: weak stream, hesitancy, or intermittency; dysuria; nocturia; frequency; incomplete voiding; frequent or constant dribbling. Urine retention may result from outlet obstruction (e.g., benign prostatic hypertrophy (BPH), prostate cancer, and urethral stricture), hypotonic bladder (detrusor under activity) or both. Hypotonic bladder may be caused by outlet obstruction, impaired or absent contractility of the bladder (neurogenic bladder) or other causes. Neurogenic bladder may also result from neurological conditions such as diabetes mellitus, spinal cord injury, or pelvic nerve damage from surgery or radiation therapy. In overflow incontinence, post void residual (PVR) volume (the amount of urine remaining in the bladder within 5 to 10 minutes following urination) exceeds 200 milliliters (ml). Normal PVR is usually 50 ml or less. A PVR of 150 to 200 may suggest a need for retesting to determine if this finding is clinically significant. Overflow incontinence may mimic urge or stress incontinence but is less common than either of those.

• Functional Incontinence refers to incontinence that is secondary to factors other than inherently abnormal urinary tract function. It may be related to physical weakness or poor mobility/dexterity (e.g., due to poor eyesight, arthritis, deconditioning, stroke, contracture), cognitive problems (e.g., confusion, dementia, unwillingness to toilet), various medications (e.g., anti-cholinergics, diuretics) or environmental impediments (e.g., excessive distance of the resident from the toilet facilities, poor lighting, low chairs that are difficult to get out of, physical restraints and toilets that are difficult to access). Refer to 42 CFR 483.15(e) (1) for issues regarding unmet environmental needs (e.g., handicap toilet, lighting, assistive devices). NOTE: Treating the physiological causes of incontinence, without attending to functional components that may have an impact on the resident’s continence, may fail to solve the incontinence problem.

• Transient Incontinence refers to temporary or occasional incontinence that may be related to a variety of causes, for example: delirium, infection, atrophic urethritis or vaginitis, some pharmaceuticals (such as sedatives/hypnotics, diuretics, anticholinergic agents), increased urine production, restricted mobility or fecal impaction. The incontinence is transient because it is related to a potentially improvable or reversible cause.

Interventions

It is important that the facility follow the care process (accurate assessment, care planning, consistent implementation and monitoring of the care plan with evaluation of the effectiveness of
the interventions, and revision, as appropriate). Recording and evaluating specific information (such as frequency and times of incontinence and toileting and response to specific interventions) is important for determining progress, changes, or decline.

A number of factors may contribute to the decline or lack of improvement in urinary continence, for example: underlying medical conditions, an inaccurate assessment of the resident’s type of incontinence (or lack of knowledge about the resident’s voiding patterns) may contribute to inappropriate interventions or unnecessary use of an indwelling catheter. Facility practices that may promote achieving the highest practicable level of functioning, may prevent or minimize a decline or lack of improvement in degree of continence include providing treatment and services to address factors that are potentially modifiable, such as:

- Managing pain and/or providing adaptive equipment to improve function for residents suffering from arthritis, contractures, neurological impairments, etc;
- Removing or improving environmental impediments that affect the resident’s level of continence (e.g., improved lighting, use of a bedside commode or reducing the distance to the toilet);
- Treating underlying conditions that have a potentially negative impact on the degree of continence (e.g., delirium causing urinary incontinence related to acute confusion);
- Possibly adjusting medications affecting continence (e.g., medication cessation, dose reduction, selection of an alternate medication, change in time of administration); and
- Implementing a fluid and/or bowel management program to meet the assessed needs.

Options for managing urinary incontinence in nursing home residents include primarily behavioral programs and medication therapy. Other measures and supportive devices used in the management of urinary incontinence and/or urinary retention may include intermittent catheterization; pelvic organ support devices (pessaries); the use of incontinence products, garments and an external collection system for men and women; and environmental accommodation and/or modification.

**Behavioral Programs**

Interventions involving the use of behavioral programs are among the least invasive approaches to address urinary incontinence and have no known adverse complications. Behavior programs involve efforts to modify the resident’s behavior and/or environment. Critical aspects of a successful behavioral program include education of the caregiver and the resident, availability of the staff and the consistent implementation of the interventions. **NOTE:** It is important for the comprehensive assessment to identify the essential skills the resident must possess to be successful with specific interventions being attempted. These skills include the resident’s ability to: comprehend and follow through on education and instructions; identify urinary urge sensation; learn to inhibit or control the urge to void until reaching a toilet; contract the pelvic floor muscle (Kegel exercises) to lessen urgency and/or urinary leakage; and/or respond to prompts to void.4 Voiding records help detect urinary patterns or intervals.
between incontinence episodes and facilitate planning care to avoid or reduce the frequency of episodes.

Programs that require the resident’s cooperation and motivation in order for learning and practice to occur include the following:

- “Bladder Rehabilitation/Bladder Retraining” is a behavioral technique that requires the resident to resist or inhibit the sensation of urgency (the strong desire to urinate), to postpone or delay voiding, and to urinate according to a timetable rather than to the urge to void. Depending upon the resident’s successful ability to control the urge to void, the intervals between voiding may be increased progressively. Bladder training generally consists of education, scheduled voiding with systematic delay of voiding, and positive reinforcement. This program is difficult to implement in cognitively impaired residents and may not be successful in frail, elderly, or dependent residents. The resident who may be appropriate for a bladder rehabilitation (retraining) program is usually fairly independent in activities of daily living, has occasional incontinence, is aware of the need to urinate (void), may wear incontinence products for episodic urine leakage, and has a goal to maintain his/her highest level of continence and decrease urine leakage. Successful bladder retraining usually takes at least several weeks. Residents who are assessed with urge or mixed incontinence and are cognitively intact may be candidates for bladder retraining; and

- “Pelvic Floor Muscle Rehabilitation,” also called Kegel and pelvic floor muscle exercise, is performed to strengthen the voluntary periurethral and perivaginal muscles that contribute to the closing force of the urethra and the support of the pelvic organs. These exercises are helpful in dealing with urge and stress incontinence. Pelvic floor muscle exercises (PFME) strengthen the muscular components of urethral supports and are the cornerstone of noninvasive treatment of stress urinary incontinence. PFME requires residents who are able and willing to participate and the implementation of careful instructions and monitoring provided by the facility. Poor resident adherence to the exercises may occur even with close monitoring.

Programs that are dependent on staff involvement and assistance, as opposed to resident function, include the following:

- “Prompted Voiding” is a behavioral technique appropriate for use with dependent or more cognitively impaired residents. Prompted voiding techniques have been shown to reduce urinary incontinence episodes up to 40% for elderly incontinent nursing home residents, regardless of their type of urinary incontinence or cognitive deficit—provided that they at least are able to say their name or reliably point to one of two objects. Prompted voiding has three components: regular monitoring with encouragement to report continence status; prompting to toilet on a scheduled basis; and praise and positive feedback when the resident is continent and attempts to toilet. These methods require training, motivation and continued effort by the resident and caregivers to ensure continued success. Prompted voiding focuses on teaching the resident, who is incontinent, to recognize bladder fullness or the need to void, to ask for help, or to respond when prompted to toilet.

Residents who are assessed with urge or mixed incontinence and are cognitively impaired may be candidates for prompted voiding. As the resident’s cognition changes, the facility should
consider other factors, such as mobility, when deciding to conduct a voiding trial to determine feasibility of an ongoing toileting program; and

- “Habit Training/Scheduled Voiding” is a behavioral technique that calls for scheduled toileting at regular intervals on a planned basis to match the resident’s voiding habits. Unlike bladder retraining, there is no systematic effort to encourage the resident to delay voiding and resist urges. Habit training includes timed voiding with the interval based on the resident’s usual voiding schedule or pattern. Scheduled voiding is timed voiding, usually every three to four hours while awake. Residents who cannot self-toilet may be candidates for habit training or scheduled voiding programs.

**Intermittent Catheterization**
Sterile insertion and removal of a catheter through the urethra every 3-6 hours for bladder drainage may be appropriate for the management of acute or chronic urinary retention. See additional discussion below in “Catheterization”.

**Medication Therapy**
Medications are often used to treat specific types of incontinence, including stress incontinence and those categories associated with an overactive bladder, which may involve symptoms including urge incontinence, urinary urgency, frequency and nocturia. The current literature identifies classifications and names of medications used for various types of incontinence. When using medications, potentially problematic anticholinergic and other side effects must be recognized. The use of medication therapy to treat urinary incontinence may not be appropriate for some residents because of potential adverse interactions with their other medications or other co-morbid conditions. Therefore, it is important to weigh the risks and benefits before prescribing medications for continence management and to monitor for both effectiveness and side effects. As with all approaches attempting to improve control or management of incontinence, the education and discussion with the resident (or the resident’s surrogate) regarding the benefits and risks of pharmacologic therapies is important.

**Pessary**
A pessary is an intra-vaginal device used to treat pelvic muscle relaxation or prolapse of pelvic organs. Women whose urine retention or urinary incontinence is exacerbated by bladder or uterine prolapse may benefit from placement of a pessary. Female residents may be admitted to the nursing home with a pessary device. The assessment should note whether the resident has a pessary in place or has had a history of successful pessary use. If a pessary is to be used, it is important to develop a plan of care for ongoing management and for the prevention of and monitoring for complications.

**Absorbent Products, Toileting Devices, and External Collection Devices**
Absorbent incontinence products include perineal pads or panty liners for slight leakage, undergarments and protective underwear for moderate to heavy leakage, guards and drip collection pouches for men, and products (called adult briefs) for moderate or heavy loss. Absorbent products can be a useful, rational way to manage incontinence; however, every absorbent product has a saturation point. Factors contributing to the selection of the type of product to be used should include the severity of incontinence, gender, fit, and ease of use.
Advantages of using absorbent products to manage urinary incontinence include the ability to contain urine (some may wick the urine away from the skin), provide protection for clothing, and preserve the resident’s dignity and comfort.

**NOTE:** Although many residents have used absorbent products prior to admission to the nursing home and the use of absorbent products may be appropriate, absorbent products should not be used as the primary long term approach to continence management until the resident has been appropriately evaluated and other alternative approaches have been considered. The potential disadvantages of absorbent products are the impact on the resident’s dignity, cost, the association with skin breakdown and irritation, and the amount of time needed to check and change them.6

It is important that residents using various toileting devices, absorbent products, external collection devices, etc., be checked (and changed as needed) on a schedule based upon the resident’s voiding pattern, accepted standards of practice, and the manufacturer’s recommendations.

**Skin-Related Complications**
Skin problems associated with incontinence and moisture can range from irritation to increased risk of skin breakdown. Moisture may make the skin more susceptible to damage from friction and shear during repositioning.

One form of early skin breakdown is maceration or the softening of tissue by soaking. Macerated skin has a white appearance and a very soft, sometimes “soggy” texture.

The persistent exposure of perineal skin to urine and/or feces can irritate the epidermis and can cause severe dermatitis or skin erosion. Skin erosion is the loss of some or all of the epidermis (comparable to a deep chemical peel) leaving a slightly depressed area of skin.

One key to preventing skin breakdown is to keep the perineal skin clean and dry. Research has shown that a soap and water regimen alone may be less effective in preventing skin breakdown compared with moisture barriers and no-rinse incontinence cleansers.7 Because frequent washing with soap and water can dry the skin, the use of a perineal rinse may be indicated. Moisturizers help preserve the moisture in the skin by either sealing in existing moisture or adding moisture to the skin. Moisturizers include creams, lotions or pastes. However, moisturizers should be used sparingly—if at all—on already macerated or excessively moist skin.

**CATHETERIZATION**
42 CFR 483.25 (d) (1) Urinary Incontinence requires that a resident who enters the facility without an indwelling catheter is not catheterized unless the resident’s clinical condition demonstrates that catheterization was necessary. Some residents are admitted to the facility with indwelling catheters that were placed elsewhere (e.g., during a recent acute hospitalization). The facility is responsible for the assessment of the resident at risk for urinary catheterization and/or the ongoing assessment for the resident who currently has a catheter. This is followed by implementation of appropriate individualized interventions and monitoring for the effectiveness of the interventions.
**Assessment**
A resident may be admitted to the facility with or without an indwelling urinary catheter (urethral or suprapubic) and may be continent or incontinent of urine. Regardless of the admission status, a comprehensive assessment should address those factors that predispose the resident to the development of urinary incontinence and the use of an indwelling urinary catheter.

An admission evaluation of the resident’s medical history and a physical examination helps identify the resident at risk for requiring the use of an indwelling urinary catheter. This evaluation is to include detection of reversible causes of incontinence and identification of individuals with incontinence caused by conditions that may not be reversible, such as bladder tumors and spinal cord diseases. (See the assessment factors discussed under incontinence.) The assessment of continence/incontinence is based upon an interdisciplinary review. The comprehensive assessment should include underlying factors supporting the medical justification for the initiation and continuing need for catheter use, determination of which factors can be modified or reversed (or rationale for why those factors should not be modified), and the development of a plan for removal. The clinician’s decision to use an indwelling catheter in the elderly should be based on valid clinical indicators.

For the resident with an indwelling catheter, the facility’s documented assessment and staff knowledge of the resident should include information to support the use of an indwelling catheter. Because of the risk of substantial complications with the use of indwelling urinary catheters, they should be reserved primarily for short-term decompression of acute urinary retention. The assessment should include consideration of the risks and benefits of an indwelling (suprapubic or urethral) catheter; the potential for removal of the catheter; and consideration of complications resulting from the use of an indwelling catheter, such as symptoms of blockage of the catheter with associated bypassing of urine, expulsion of the catheter, pain, discomfort and bleeding.

**Intermittent Catheterization**
Intermittent catheterization can often manage overflow incontinence effectively. Residents who have new onset incontinence from a transient, hypotonic/tonic bladder (usually seen following indwelling catheterization in the hospital) may benefit from intermittent bladder catheterization until the bladder tone returns (e.g., up to approximately 7 days). A voiding trial and post void residual can help identify when bladder tone has returned.

**Indwelling Catheter Use**
The facility’s documented assessment and staff approach to the resident should be based on evidence to support the use of an indwelling catheter. Appropriate indications for continuing use of an indwelling catheter beyond 14 days may include:

- Urinary retention that cannot be treated or corrected medically or surgically, for which alternative therapy is not feasible, and which is characterized by:
  - Documented post void residual (PVR) volumes in a range over 200 milliliters (ml);
• Inability to manage the retention/incontinence with intermittent catheterization; and

• Persistent overflow incontinence, symptomatic infections, and/or renal dysfunction.

• Contamination of Stage III or IV pressure ulcers with urine which has impeded healing, despite appropriate personal care for the incontinence; and

• Terminal illness or severe impairment, which makes positioning or clothing changes uncomfortable, or which is associated with intractable pain.

**Catheter-Related Complications**

An indwelling catheter may be associated with significant complications, including bacteremia, febrile episodes, bladder stones, fistula formation, erosion of the urethra, epididymitis, chronic renal inflammation and pyelonephritis. In addition, indwelling catheters are prone to blockage.

Risk factors for catheter blockage include alkaline urine, poor urine flow, proteinuria, and preexisting bladder stones. In the absence of evidence indicating blockage, catheters need not be changed routinely as long as monitoring is adequate. Based on the resident’s individualized assessment, the catheter may need to be changed more or less often than every 30 days.

Some residents with indwelling catheters experience persistent leakage around the catheter.

Examples of factors that may contribute to leakage include irritation by a large balloon or by catheter materials, excessive catheter diameter, fecal impaction, and improper catheter positioning. Because leakage around the catheter is frequently caused by bladder spasm, leakage should generally not be treated by using increasingly larger catheter sizes, unless medically justified. Current standards indicate that catheterization should be accomplished with the narrowest, softest tube that will serve the purpose of draining the bladder. Additional care practices related to catheterization include:

• Educating the resident or responsible party on the risks and benefits of catheter use;

• Recognizing and assessing for complications and their causes, and maintaining a record of any catheter-related problems;

• Attempts to remove the catheter as soon as possible when no indications exist for its continuing use;

• Monitoring for excessive post void residual, after removing a catheter that was inserted for obstruction or overflow incontinence;

• Keeping the catheter anchored to prevent excessive tension on the catheter, which can lead to urethral tears or dislodging the catheter; and

• Securing the catheter to facilitate flow of urine.
Research has shown that catheterization is an important, potentially modifiable, risk factor for UTI. By the 30th day of catheterization, bacteriuria is nearly universal. The potential for complications can be reduced by:

- Identifying specific clinical indications for the use of an indwelling catheter;
- Assessing whether other treatments and services would appropriately address those conditions; and
- Assessing whether residents are at risk for other possible complications resulting from the continuing use of the catheter, such as obstruction resulting from catheter encrustation, urethral erosion, bladder spasms, hematuria, and leakage around the catheter.

**URINARY TRACT INFECTIONS**

**Catheter-Related Bacteriuria and UTIs/Urosepsis**

Most individuals with indwelling catheters for more than 7 days have bacteriuria. Bacteriuria alone in a catheterized individual should not be treated with antibiotics.

A long term indwelling catheter (>2 to 4 weeks) increases the chances of having a symptomatic UTI and urosepsis. The incidence of bacteremia is 40 times greater in individuals with a long term indwelling catheter than in those without one. For suspected UTIs in a catheterized individual, the literature recommends removing the current catheter and inserting a new one and obtaining a urine sample via the newly inserted catheter.

**Clinical Evidence That May Suggest UTI**

Clinically, an acute deterioration in stable chronic symptoms may indicate an acute infection. Multiple co-existing findings such as fever with hematuria are more likely to be from a urinary source.

No one lab test alone proves that a UTI is present. For example, a positive urine culture will show bacteriuria but that alone is not enough to diagnose a symptomatic UTI. However, several test results in combination with clinical findings can help to identify UTIs such as the presence of pyuria (more than minimal white cells in the urine) on microscopic urinalysis, or a positive urine dipstick test for leukocyte esterase (indicating significant pyuria) or for nitrites (indicating the presence of Enterobacteriaceae). A negative leukocyte esterase or the absence of pyuria strongly suggests that a UTI is not present. A positive leukocyte esterase test alone does not prove that the individual has a UTI.

In someone with nonspecific symptoms such as a change in function or mental status, bacteriuria alone does not necessarily warrant antibiotic treatment. Additional evidence that could confirm a UTI may include hematuria, fever (which could include a variation from the individual’s normal or usual temperature range), or evidence of pyuria (either by microscopic examination or by dipstick test). In the absence of fever, hematuria, pyuria, or local urinary tract symptoms, other
potential causes of nonspecific general symptoms, such as fluid and electrolyte imbalance or adverse drug reactions, should be considered instead of, or in addition to, a UTI. Although sepsis, including urosepsis, can cause dizziness or falling, there is not clear evidence linking bacteriuria or a localized UTI to an increased fall risk.12

**Indications to Treat a UTI**
Because many residents have chronic bacteriuria, the research-based literature suggests treating only symptomatic UTIs. Symptomatic UTIs are based on the following criteria:13

- Residents without a catheter should have at least three of the following signs and symptoms:
  - Fever (increase in temperature of >2 degrees F (1.1 degrees C) or rectal temperature >99.5 degrees F (37.5 degrees C) or single measurement of temperature >100 degrees F (37.8 degrees C));14
  - New or increased burning pain on urination, frequency or urgency;
  - New flank or suprapubic pain or tenderness;
  - Change in character of urine (e.g., new bloody urine, foul smell, or amount of sediment) or as reported by the laboratory (new pyuria or microscopic hematuria); and/or
  - Worsening of mental or functional status (e.g., confusion, decreased appetite, unexplained falls, incontinence of recent onset, lethargy, decreased activity).15

- Residents with a catheter should have at least two of the following signs and symptoms:
  - Fever or chills;
  - New flank pain or suprapubic pain or tenderness;
  - Change in character of urine (e.g., new bloody urine, foul smell, or amount of sediment) or as reported by the laboratory (new pyuria or microscopic hematuria); and/or
  - Worsening of mental or functional status. Local findings such as obstruction, leakage, or mucosal trauma (hematuria) may also be present.16

**Follow-Up of UTIs**
The goal of treating a UTI is to alleviate systemic or local symptoms, not to eradicate all bacteria. Therefore, a post-treatment urine culture is not routinely necessary but may be useful in select situations. Continued bacteriuria without residual symptoms does not warrant repeat or continued antibiotic therapy. Recurrent UTIs (2 or more in 6 months) in a noncatheterized individual may warrant additional evaluation (such as a determination of an abnormal post void residual (PVR) urine volume or a referral to a urologist) to rule out structural abnormalities such as enlarged prostate, prolapsed bladder, periurethral abscess, strictures, bladder calculi, polyps and tumors.
Recurrent symptomatic UTIs in a catheterized or noncatheterized individual should lead the facility to check whether perineal hygiene is performed consistently to remove fecal soiling in accordance with accepted practices. Recurrent UTIs in a catheterized individual should lead the facility to look for possible impairment of free urine flow through the catheter, to re-evaluate the techniques being used for perineal hygiene and catheter care, and to reconsider the relative risks and benefits of continuing the use of an indwelling catheter.

Because the major factors (other than an indwelling catheter) that predispose individuals to bacteriuria, including physiological aging changes and chronic comorbid illnesses, cannot be modified readily, the facility should demonstrate that they:

- Employ standard infection control practices in managing catheters and associated drainage system;
- Strive to keep the resident and catheter clean of feces to minimize bacterial migration into the urethra and bladder (e.g., cleaning fecal material away from, rather than towards, the urinary meatus);
- Take measures to maintain free urine flow through any indwelling catheter; and
- Assess for fluid needs and implement a fluid management program (using alternative approaches as needed) based on those assessed needs.

ENDNOTES

INVESTIGATIVE PROTOCOL
URINARY CONTINENCE AND CATHETERS

Objectives
• To determine whether the initial insertion or continued use of an indwelling catheter is based upon clinical indication for use of a urinary catheter;
• To determine the adequacy of interventions to prevent, improve and/or manage urinary incontinence; and
• To determine whether appropriate treatment and services have been provided to prevent and/or treat UTIs.

Use
Use this protocol for a sampled resident with an indwelling urinary catheter or for a resident with urinary incontinence.

Procedures
Briefly review the assessment, care plan and orders to identify facility interventions and to guide observations to be made. Staff are expected to assess and provide appropriate care from the day of admission, for residents with urinary incontinence or a condition that may contribute to incontinence or the presence of an indwelling urinary catheter (including newly admitted residents). Corroborate observations by interview and record review.

NOTE: Criteria established in this protocol provide general guidelines and best practices which should be considered when making a determination of compliance, and is not an exhaustive list of mandatory elements.
1. Observation
Observe whether staff consistently implemented care plan interventions across various shifts. During observations of the interventions, note and/or follow up on deviations from the care plan or from current standards of practice, as well as potential negative outcomes.

Observe whether staff make appropriate resident accommodations consistent with the assessment, such as placing the call bell within reach and responding to the call bell, in relation to meeting toileting needs; maintaining a clear pathway and ready access to toilet facilities; providing (where indicated) elevated toilet seats, grab bars, adequate lighting, and assistance needed to use devices such as urinals, bedpans and commodes.

Observe whether assistance has been provided to try to prevent incontinence episodes, such as whether prompting, transfer, and/or stand-by assist to ambulate were provided as required for toileting.

For a resident who is on a program to restore continence or is on a prompted void or scheduled toileting program, note:
• The frequency of breakthrough or transient incontinence;
• How staff respond to the incontinence episodes; and
• Whether care is provided in accord with standards of practice (including infection control practices) and with respect for the resident’s dignity.

For a resident who has been determined by clinical assessment to be unable to participate in a program to restore continence or in a scheduled toileting program and who requires care due to incontinence of urine, observe:
• Whether the resident is on a scheduled check and change program; and
• Whether staff check and change in a timely fashion.

For a resident who has experienced an incontinent episode, observe:
• The condition of the pads/sheets/clothing (a delay in providing continence care may be indicated by brown rings/circles, saturated linens/clothing, odors, etc.);
• The resident's physical condition (such as skin integrity, maceration, erythema, erosion);
• The resident's psychosocial outcomes (such as embarrassment or expressions of humiliation, resignation, about being incontinent);
• Whether staff implemented appropriate hygiene measures (e.g., cleansing, rinsing, drying and applying protective moisture barriers or barrier films as indicated) to try to prevent skin breakdown from prolonged exposure of the skin to urine; and
• Whether the staff response to incontinence episodes and the provision of care are consistent with standards of practice (including infection control practices) and with respect for the resident’s dignity.

For a resident with an indwelling catheter, observe the delivery of care to evaluate:
• Whether staff use appropriate infection control practices regarding hand washing, catheter care, tubing, and the collection bag;
• Whether staff recognize and assess potential evidence of symptomatic UTI or other related changes in urine condition (such as onset of bloody urine, cloudiness, or oliguria, if present);
• How staff manage and assess urinary leakage from the point of catheter insertion to the bag, if present;
• If the resident has catheter-related pain, how staff assess and manage the pain; and
• What interventions (such as anchoring the catheter, avoiding excessive tugging on the catheter during transfer and care delivery) are being used to prevent inadvertent catheter removal or tissue injury from dislodging the catheter.

For a resident experiencing incontinence and who has an indwelling or intermittent catheter, observe whether the resident is provided and encouraged to take enough fluids to meet the resident's hydration needs, as reflected in various measures of hydration status (approximately 30ml/kg/day or as indicated based on the resident’s clinical condition). For issues regarding hydration, see Guidance at 42 CFR 483.25(j), F327.

2. Interviews
Interview the resident, family or responsible party to the degree possible to identify:
• Their involvement in care plan development including defining the approaches and goals, and whether interventions reflect preferences and choices;
• Their awareness of the existing continence program and how to use devices or equipment;
• If timely assistance is provided as needed for toileting needs, hydration and personal hygiene and if continence care and/or catheter care is provided according to the care plan;
• If the resident comprehends and applies information and instructions to help improve or maintain continence (where cognition permits);
• Presence of urinary tract-related pain, including causes and management;
• If interventions were refused, whether consequences and/or other alternative approaches were presented and discussed; and
• Awareness of any current UTI, history of UTIs, or perineal skin problems.

If the resident has a skin problem that may be related to incontinence, or staff are not following the resident's care plan and continence/catheter care program, interview the nursing assistants to determine if they:
• Are aware of, and understand, the interventions specific to this resident (such as the bladder or bowel restorative/management programs);
• Have been trained and know how to handle catheters, tubing and drainage bags and other devices used during the provision of care; and
• Know what, when, and to whom to report changes in status regarding bowel and bladder function, hydration status, urine characteristics, and complaints of urinary-related symptoms.

3. Record Review

Assessment and Evaluation. Review the RAI, the history and physical, and other information such as physician orders, progress notes, nurses’ notes, pharmacist reports, lab reports and any flow sheets or forms the facility uses to document the resident’s voiding history, including the assessment of the resident’s overall condition, risk factors and information about the resident’s continence status, rationale for using a catheter, environmental factors related to continence programs, and the resident’s responses to catheter/continence services. Request staff assistance, if the information is not readily available.
Determine if the facility assessment is consistent with or corroborated by documentation within the record and comprehensively reflects the status of the resident for:

- Patterns of incontinent episodes, daily voiding patterns or prior routines;
- Fluid intake and hydration status;
- Risks or conditions that may affect urinary continence;
- Use of medications that may affect continence and impaired continence that could reflect adverse drug reactions;
- Type of incontinence (stress, urge, overflow, mixed, functional, or transient incontinence) and contributing factors;
- Environmental factors that might facilitate or impede the ability to maintain bladder continence, such as access to the toilet, call bell, type of clothing and/or continence products, ambulation devices (walkers, canes), use of restraints, side rails;
- Type and frequency of physical assistance necessary to facilitate toileting;
- Clinical rationale for use of an indwelling catheter;
- Alternatives to extended use of an indwelling catheter (if possible); and
- Evaluation of factors possibly contributing to chronically recurring or persistent UTIs.

**Care Plan.** If the care plan refers to a specific facility treatment protocol that contains details of the treatment regimen, the protocol must be available to the direct care staff, so that they may be familiar with it and use it. The care plan should clarify any significant deviations from such a protocol for a specific resident. If care plan interventions that address aspects of continence and skin care related to incontinence are integrated within the overall care plan, the interventions do not need to be repeated in a separate continence care plan.

Review the care plan to determine if the plan is based upon the goals, needs and strengths specific to the resident and reflects the comprehensive assessment. Determine if the plan:

- Identifies quantifiable, measurable objectives with time frames to be able to assess whether the objectives have been met;
- Identifies interventions specific enough to guide the provision of services and treatment (e.g., toilet within an hour prior to each meal and within 30 minutes after meals, or check for episodes of incontinence within 30 minutes after each meal or specific times based upon the assessment of voiding patterns);
- Is based upon resident choices and preferences;
- Promotes maintenance of resident dignity;
- Addresses potential psychosocial complications of incontinence or catheterization such as social withdrawal, embarrassment, humiliation, isolation, resignation;
- Includes a component to inform the resident and representative about the risks and benefits of catheter use, on continence management approaches, medications selected, etc.;
- Addresses measures to promote sufficient fluid intake, including alternatives such as food substitutes that have a high liquid content, if there is reduced fluid intake;
- Defines interventions to prevent skin breakdown from prolonged exposure to urine and stool;
- Identifies and addresses the potential impact on continence of medication and urinary tract stimulants or irritants (e.g., caffeine) in foods and beverages;
- Identifies approaches to minimize risk of infection (personal hygiene measures and catheter/tubing/bag care); and
• Defines environmental approaches and devices needed to promote independence in toileting, to maintain continence, and to maximize independent functioning.

For the resident who is not on a scheduled toileting program or a program to restore normal bladder function to the extent possible, determine if the care plan provides specific approaches for a check and change program.

For the resident who is on a scheduled toileting or restorative program (e.g., retraining, habit training, scheduled voiding, prompted voiding, toileting devices), determine whether the care plan:
• Identifies the type of urinary incontinence and bases the program on the resident’s voiding/elimination patterns; and
• Has been developed by considering the resident’s medical/health condition, cognitive and functional ability to participate in a relevant continence program, and needed assistance.

For the resident with a catheter, determine whether the care plan:
• Defines the catheter, tubing and bag care, including indications, according to facility protocol, for changing the catheter, tubing or bag;
• Provides for assessment and removal of the indwelling catheter when no longer needed; and
• Establishes interventions to minimize catheter-related injury, pain, encrustation, excessive urethral tension, accidental removal, or obstruction of urine outflow.

**Care Plan Revision.** Determine if the resident’s condition and effectiveness of the care plan interventions have been monitored and care plan revisions were made (or justifications for continuing the existing plan) based upon the following:
• The outcome and/or effects of goals and interventions;
• A decline or lack of improvement in continence status;
• Complications associated with catheter usage;
• Resident failure to comply with a continence program and alternative approaches that were offered to try to maintain or improve continence, including counseling regarding the potential consequences of not following the program;
• Change in condition, ability to make decisions, cognition, medications, behavioral symptoms or visual problems;
• Input by the resident and/or the responsible person; and
• An evaluation of the resident’s level of participation in, and response to, the continence program.

**4. Interviews with Health Care Practitioners and Professionals**

If inconsistencies in care or potential negative outcomes have been identified, or care is not in accord with standards of practice, interview the nurse responsible for coordinating or overseeing the resident’s care. Determine:

• How the staff monitor implementation of the care plan, changes in continence, skin condition, and the status of UTIs;
• If the resident resists toileting, how staff have been taught to respond;
• Types of interventions that have been attempted to promote continence (i.e., special clothing, devices, types and frequency of assistance, change in toileting schedule, environmental modifications);
• If the resident is not on a restorative program, how it was determined that the resident could not benefit from interventions such as a scheduled toileting program;

• For the resident on a program of toileting, whether the nursing staff can identify the programming applicable to the resident, and:
  o The type of incontinence;
  o The interventions to address that specific type;
  o How it is determined that the schedule and program is effective (i.e., how continence is maintained or if there has been a decline or improvement in continence, how the program is revised to address the changes); and
  o Whether the resident has any physical or cognitive limitations that influence potential improvement of his/her continence;

• For residents with urinary catheters, whether the nursing staff:
  o Can provide appropriate justification for the use of the catheter;
  o Can identify previous attempts made (and the results of the attempts) to remove a catheter; and
  o Can identify a history of UTIs (if present), and interventions to try to prevent recurrence.

If the interventions defined or care provided do not appear to be consistent with recognized standards of practice, interview one or more health care practitioners and professionals as necessary (e.g., physician, charge nurse, director of nursing) who, by virtue of training and knowledge of the resident, should be able to provide information about the causes, treatment and evaluation of the resident’s condition or problem. Depending on the issue, ask about:

• How it was determined that the chosen interventions were appropriate;
• Risks identified for which there were no interventions;
• Changes in condition that may justify additional or different interventions; or how they validated the effectiveness of current interventions; and
• How they monitor the approaches to continence programs (e.g., policies/procedures, staffing requirements, how staff identify problems, assess the toileting pattern of the resident, develop and implement continence-related action plans, how staff monitor and evaluate resident’s responses, etc.).

If the attending physician is unavailable, interview the medical director, as appropriate.

DETERMINATION OF COMPLIANCE (Task 6, Appendix P)

Synopsis of regulation (F315)
The urinary incontinence requirement has three aspects. The first aspect requires that a resident who does not have an indwelling urinary catheter does not have one inserted unless the resident’s clinical condition demonstrates that it was necessary. The second aspect requires the facility to provide appropriate treatment and services to prevent urinary tract infections; and the third is that the facility attempt to assist the resident to restore as much normal bladder function as possible.

Criteria for Compliance
• Compliance with 42 CFR 483.25(d)(1) and (2), F315, Urinary Incontinence
For a resident who was admitted with an indwelling urinary catheter or who had one placed after admission, the facility is in compliance with this requirement, if staff have: Recognized and assessed factors affecting the resident’s urinary function and identified the medical justification for the use of an indwelling urinary catheter; Defined and implemented pertinent interventions to try to minimize complications from an indwelling urinary catheter, and to remove it if clinically indicated, consistent with resident conditions, goals, and recognized standards of practice; Monitored and evaluated the resident’s response to interventions; and Revised the approaches as appropriate. If not, the use of an indwelling urinary catheter is not medically justified, and/or the ongoing treatment and services for catheter care were not provided consistent with the resident’s needs. Cite F315.

For a resident who is incontinent of urine, the facility is in compliance with this requirement if they: Recognized and assessed factors affecting the risk of symptomatic urinary tract infections and impaired urinary function; Defined and implemented interventions to address correctable underlying causes of urinary incontinence and to try to minimize the occurrence of symptomatic urinary tract infections in accordance with resident needs, goals, and recognized standards of practice; Monitored and evaluated the resident’s response to preventive efforts and treatment interventions; and Revised the approaches as appropriate. If not, the facility is not in compliance with the requirement to assist the resident to maintain or improve the continence status, and/or prevent the decline of the condition of urinary incontinence for the resident. Cite F315.

For a resident who has or has had a symptomatic urinary tract infection, the facility is in compliance with this requirement if they have: Recognized and assessed factors affecting the risk of symptomatic urinary tract infections and impaired urinary function; Defined and implemented interventions to try to minimize the occurrence of symptomatic urinary tract infections and to address correctable underlying causes, in accordance with resident needs, goals, and recognized standards of practice; Monitored and evaluated the resident’s responses to preventive efforts and treatment interventions; and Revised the approaches as appropriate.
If not, the development of a symptomatic urinary tract infection, and/or decline of the resident with one, was not consistent with the identified needs of the resident. Cite F315.

**Noncompliance for F315**
After completing the Investigative Protocol, analyze the data in order to determine whether or not noncompliance with the regulation exists. Noncompliance for F315 may include (but is not limited to) one or more of the following, including failure to:

- Provide care and treatment to prevent incontinence and/or improve urinary continence and restore as much normal bladder function as possible;
- Provide medical justification for the use of a catheter or provide services for a resident with a urinary catheter;
- Assess, prevent (to the extent possible) and treat a symptomatic urinary tract infection (as indicated by the resident’s choices, clinical condition and physician treatment plan);
- Accurately or consistently assess a resident's continence status on admission and as indicated thereafter;
- Identify and address risk factors for developing urinary incontinence;
- Implement interventions (such as bladder rehabilitative programs) to try to improve bladder function or prevent urinary incontinence, consistent with the resident’s assessed need and current standards of practice;
- Provide clinical justification for developing urinary incontinence or for the failure of existing urinary incontinence to improve;
- Identify and manage symptomatic urinary tract infections, or explain adequately why they could or should not do so;
- Implement approaches to manage an indwelling urinary catheter based upon standards of practice;
- Identify and apply relevant policies and procedures to manage urinary incontinence, urinary catheters and/or urinary tract infections;
- Notify the physician of the resident’s condition or changes in the resident’s continence status or development of symptoms that may represent a symptomatic UTI (in contrast to asymptomatic bacteriuria).

**Potential Tags for Additional Investigation**
During the investigation of 42 CFR 483.25(d)(1) and (2), the surveyor may have identified concerns related to outcome, process and/or structure requirements. The surveyor should investigate these requirements before determining whether noncompliance may be present. The following are examples of related outcome, process and/or structure requirements that should be considered:

- 42 CFR 483.10(b)(11), F157, Notification of Changes
  - Determine if staff notified the physician of significant changes in the resident’s continence, catheter usage, or the development, treatment and/or change in symptomatic UTIs; or notified the resident or resident’s representative (where one exists) of significant changes as noted above.
• 42 CFR 483.15(a), F241, Dignity
  o Determine if staff provide continence care and/or catheter care to the resident in a manner that respects his/her dignity, strives to meet needs in a timely manner, monitors and helps the resident who cannot request assistance, and strives to minimize feelings of embarrassment, humiliation and/or isolation related to impaired continence.

• 42 CFR 483.20(b)(1), F272, Comprehensive Assessments
  o Determine if the facility comprehensively assessed the resident’s continence status and resident-specific risk factors (including potential causes), and assessed for the use of continence-related devices, including an indwelling catheter.

• 42 CFR 483.20(k), F279, Comprehensive Care Plans
  o Determine if the facility developed a care plan (1) that was consistent with the resident’s specific conditions, risks, needs, behaviors, and preferences and with current standards of practice and (2) that includes measurable objectives, approximate timetables, specific interventions and/or services needed to prevent or address incontinence, provide catheter care; and to prevent UTIs to the extent possible.

• 42 CFR 483.20(k)(2)(iii), F280, Comprehensive Care Plan Revision
  o Determine if the care plan was reviewed and revised periodically, as necessary, related to preventing, managing, or improving incontinence, managing an indwelling urinary catheter, possible discontinuation of an indwelling catheter, and attempted prevention and management of UTIs.

• 42 CFR 483.20(k)(3)(i), F281, Services Provided Meet Professional Standards
  o Determine if services and care were provided for urinary incontinence, catheter care and/or symptomatic UTIs in accordance with accepted professional standards.

• 42 CFR 483.25, F309, Quality of Care
  o Determine if staff identified and implemented appropriate measures to address any pain related to the use of an indwelling urinary catheter or skin complications such as maceration, and to provide the necessary care and services in accordance with the comprehensive assessment plan of care.

• 42 CFR 483.25 (a)(3) F312, Quality of Care
  o Determine if staff identified and implemented appropriate measures to provide good personal hygiene for the resident who cannot perform relevant activities of daily living, and who has been assessed as unable to achieve and/or restore normal bladder function.

• 42 CFR 483.40(a), F385, Physician Supervision
  o Determine if the physician has evaluated and addressed, as indicated, medical issues related to preventing or managing urinary incontinence, catheter usage, and symptomatic UTIs.

• 42 CFR 483.65(b)(3), F444, Infection Control: Hand Washing
  o Determine if staff wash their hands after providing incontinence care, and before and after providing catheter care.
• 42 CFR 483.75(f), F498, Proficiency of Nurse Aides  
  o Determine if nurse aides correctly deliver continence and catheter care, including practices to try to minimize skin breakdown, UTIs, catheter-related injuries, and dislodgement.

• 42 CFR 483.30(a), F353, Sufficient Staff  
  o Determine if the facility had qualified staff in sufficient numbers to provide necessary care and services on a 24-hour basis, based upon the comprehensive assessment and care plan, to prevent, manage and/or improve urinary incontinence where possible.

• 42 CFR 483.75(i)(2), F501, Medical Director  
  o Determine whether the medical director, in collaboration with the facility and based on current standards of practice, has developed policies and procedures for the prevention and management of urinary incontinence, for catheter care, and for the identification and management of symptomatic urinary tract infections; and whether the medical director interacts, if requested by the facility, with the physician supervising the care of the resident related to the management of urinary incontinence, catheter or infection issues.

V. DEFICIENCY CATEGORIZATION (Part V, Appendix P)  
Once the team has completed its investigation, analyzed the data, reviewed the regulatory requirements, and determined that non-compliance 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 F315 are as follows:

1. Presence of harm/negative outcome(s) or potential for negative outcomes because of lack of appropriate treatment and care. Actual or potential harm/negative outcome for F315 may include, but is not limited to:  
   • Development, recurrence, persistence, or increasing frequency of urinary incontinence, which is not the result of underlying clinical conditions;  
   • Complications such as urosepsis or urethral injury related to the presence of an indwelling urinary catheter that is not clinically justified;  
   • Significant changes in psychosocial functioning, such as isolation, withdrawal, or embarrassment, related to the presence of un-assessed or unmanaged urinary incontinence and/or a decline in continence, and/or the use of a urinary catheter without a clinically valid medical justification; and  
   • Complications such as skin breakdown that are related to the failure to manage urinary incontinence;

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 the potential for serious injury, impairment, death, or compromise or discomfort to occur to the resident; and
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 F315. 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, 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/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 preventative or corrective measures.

Examples of possible negative outcomes as a result of the facility’s deficient practices may include:

• **Complications resulting from utilization of urinary appliance(s) without medical justification:** As a result of incorrect or unwarranted (i.e., not medically indicated) utilization of a urinary catheter, pessary, etc., the resident experiences injury or trauma (e.g., urethral tear) that requires surgical intervention or repair.

• **Extensive failure in multiple areas of incontinence care and/or catheter management:** As a result of the facility’s noncompliance in multiple areas of continence care or catheter management, the resident developed urosepsis with complications leading to prolonged decline or death.

**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 can include but may not be limited to clinical compromise, decline, or the resident’s ability to maintain and/or reach his/her highest practicable well-being.

Examples of avoidable negative outcomes may include, but are not limited to:

• **The development of a symptomatic UTI:** As a result of the facility’s noncompliance, the resident developed a symptomatic UTI, without long term complications, associated with the use of an indwelling catheter for which there was no medical justification.

• **The failure to identify, assess and manage urinary retention:** As a result of the facility’s noncompliance, the resident had persistent overflow incontinence and/or developed recurrent symptomatic UTIs.
• **The failure to provide appropriate catheter care:** As a result of the facility’s noncompliance, the catheter was improperly managed, resulting in catheter-related pain, bleeding, urethral tears or urethral erosion.

• **Medically unjustified use of an indwelling catheter with complications:** As a result of the facility’s noncompliance, a resident who was admitted with a urinary catheter had the catheter remain for an extended period of time without a valid medical justification for its continued use, or a urinary catheter was inserted after the resident was in the facility and used for an extended time without medical justification, during which the resident experienced significant complications such as recurrent symptomatic UTIs.

• **Decline or failure to improve continence status:** As a result of the facility’s failure to assess and/or re-assess the resident’s continence status, utilize sufficient staffing to implement continence programs and provide other related services based on the resident’s assessed needs, and/or to evaluate the possible adverse effects of medications on continence status, the resident failed to maintain or improve continence status.

• **Complications due to urinary incontinence:** As a result of the facility’s failure to provide care and services to a resident who is incontinent of urine, in accordance with resident need and accepted standards of practice, the resident developed skin maceration and/or erosion or declined to attend or participate in social situations (withdrawal) due to embarrassment or humiliation related to unmanaged urinary incontinence.

**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 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 of potentially avoidable negative outcomes may include, but are not limited to:

• **Medically unjustified use of an indwelling catheter:** As a result of the facility’s noncompliance, the resident has the potential for experiencing complications, such as symptomatic UTIs, bladder stones, pain, etc.

• **Complications associated with inadequate care and services for an indwelling catheter:** As a result of the facility’s noncompliance, the resident has developed potentially preventable non-life-threatening problems related to the catheter, such as leaking of urine due to blockage of urine outflow, with or without skin maceration and/or dermatitis.

• **Potential for decline or complications:** As a result of the facility’s failure to consistently implement a scheduled voiding program defined in accordance with the assessed needs, the
resident experiences repeated episodes of incontinence but has not demonstrated a decline or developed complications.

**Severity Level 1: No actual harm with potential for minimal harm**
The failures of the facility to provide appropriate care and services to improve continence, manage indwelling catheters, and minimize negative outcome places residents at risk for more than minimal harm. Therefore, Severity Level 1 does not apply for this regulatory requirement.

§483.25(e) Range of motion.
Based on the comprehensive assessment of a resident, the facility must ensure that (see Tag F318 for intent, guidelines, procedures, and probes for §483.25(e))

F317
§483.25(e)(1) A resident who enters the facility without a limited range of motion does not experience reduction in range of motion unless the resident’s clinical condition demonstrates that a reduction in range of motion is unavoidable; and SEE INTERPRERTIVE GUIDELINES AT TAG F318

F318
(Rev. 70, Issued: 01-07-11, Effective: 10-01-10 Implementation: 10-01-10)

§483.25(e)(2) A resident with a limited range of motion receives appropriate treatment and services to increase range of motion and/or to prevent further decrease in range of motion

**Intent §483.25(e)**
The intent of this regulation is to ensure that the resident reaches and maintains his or her highest level of range of motion and to prevent avoidable decline of range of motion.

**Interpretive Guidelines §483.25(e)**

“Range of motion (ROM)” is defined as the extent of movement of a joint.
The clinical condition that may demonstrate that a reduction in ROM is unavoidable is: limbs or digits immobilized because of injury or surgical procedures (e.g., surgical adhesions).

Adequate preventive care may include active ROM performed by the resident’s passive ROM performed by staff; active-assistive ROM exercise performed by the resident and staff; and application of splints and braces, if necessary.

Examples of clinical conditions that are the primary risk factors for a decreased range of motion are:
• Immobilization (e.g., bedfast);
• Deformities arising out of neurological deficits (e.g., strokes, multiple sclerosis, cerebral palsy, and polio); and
• Pain, spasms, and immobility associated with arthritis or late state Alzheimer’s disease.
This clinical condition may demonstrate that a reduction in ROM is unavoidable only if adequate assessment, appropriate care planning, and preventive care was provided, and resulted in limitation in ROM or muscle atrophy.

**Procedures §483.25(e)**
For each resident selected for a comprehensive review, or focused review, as appropriate, who needs routine preventive care:
• Observe staff providing routine ROM exercises. Are they done according to the care plan?

**Probes: §483.25(e)**
Is there evidence that there has been a decline in sampled residents’ ROM or muscle atrophy that was avoidable?
• Was the resident at risk for decline in ROM? If so, why?
• What care did the facility provide, including routine preventive measures that addressed the resident’s unique risk factors (e.g., use muscle strengthening exercises in residents with muscle atrophy)?
• Was this care provided consistently?
For all sampled residents who have limited ROM, what is the facility doing to prevent further declines in ROM?
• Are passive ROM exercises provided and active ROM exercises supervised per the plan of care?
• Have care plan objectives identified resident’s needs and has resident progress been evaluated?
• Is there evidence that care planning is changed as the resident’s condition changes?
• Identify if resident triggers **CAAs** for ADL functional/rehabilitation potential, visual function, and communication. Consider whether the **CAA process was** used to assess causal factors for decline, potential for decline or lack of improvement.

**§483.25(f) Mental and Psychosocial Functioning**
Based on the comprehensive assessment of a resident, the facility must ensure that—
(See Tag **F319** for intent, guidelines, and probes for §483.25(f))

**F319**
*(Rev. 70, Issued: 01-07-11, Effective: 10-01-10 Implementation: 10-01-10)*

**§483.25(f)(1)** A resident who displays mental or psychosocial adjustment difficulty, receives appropriate treatment and services to correct the assessed problem; and
Intent §483.25(f)
The intent of this regulation is that the resident receives care and services to assist him or her to reach and maintain the highest level of mental and psychosocial functioning.

Interpretive Guidelines §483.25(f)

“Mental and psychosocial adjustment difficulties” refer to problems residents have in adapting to changes in life’s circumstances. The former focuses on internal thought processes; the latter, on the external manifestations of these thought patterns.

Mental and psychosocial adjustment difficulties are characterized primarily by an overwhelming sense of loss of one’s capabilities; of family and friends; of the ability to continue to pursue activities and hobbies; and of one’s possessions. This sense of loss is perceived as global and uncontrollable and is supported by thinking patterns that focus on helplessness and hopelessness; that all learning and essentially all meaningful living ceases once one enters a nursing home. A resident with a mental adjustment disorder will have a sad or anxious mood, or a behavioral symptom such as aggression.

The “Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM/IV),” specifies that adjustment disorders develop within 3 months of a stressor (e.g., moving to another room) and are evidenced by significant functional impairment. Bereavement with the death of a loved one is not associated with adjustment disorders developed within 3 months of a stressor.

Other manifestations of mental and psychosocial adjustment difficulties may, over a period of time, include:

- Impaired verbal communication;
- Social isolation (e.g., loss or failure to have relationships);
- Sleep pattern disturbance (e.g., disruptive change in sleep/rest pattern as related to one’s biological and emotional needs);
- Spiritual distress (disturbances in one’s belief system);
- Inability to control behavior and potential for violence (aggressive behavior directed at self or others); and
- Stereotyped response to any stressor (i.e., the same characteristic response, regardless of the stimulus).

Appropriate treatment and services for psychosocial adjustment difficulties may include providing residents with opportunities for self-governance; systematic orientation programs; arrangements to keep residents in touch with their communities, cultural heritage, former lifestyle, and religious practices; and maintaining contact with friends and family. Appropriate treatment for mental adjustment difficulties may include crisis intervention services; individual, group or family psychotherapy, drug therapy and training in monitoring of drug therapy and other rehabilitative services. (See §483.45(a).)

Clinical conditions that may produce apathy, malaise, and decreased energy levels that can be mistaken for depression associated with mental or psychosocial adjustment difficulty are: (This list is not all inclusive.)
Metabolic diseases (e.g., abnormalities of serum glucose, potassium, calcium, and blood urea nitrogen, hepatic dysfunction);
Endocrine diseases (e.g., hypothyroidism, hyperthyroidism, diabetes, hypoparathyroidism, hyperparathyroidism, Cushing’s disease, Addison’s disease);
Central nervous system diseases (e.g., tumors and other mass lesions, Parkinson’s disease, multiple sclerosis, Alzheimer’s disease, vascular disease);
Miscellaneous diseases (e.g., pernicious anemia, pancreatic disease, malignancy, infections, congestive heart failure);
Over-medication with anti-hypertensive drugs; and
Presence of restraints.

Probes: §483.25(f)(1)
For sampled residents selected for a comprehensive or focused review, determine, as appropriate, for those residents exhibiting difficulties in mental and psychosocial adjustment:

• Is there a complete accurate assessment of resident’s usual and customary routines?
• What evidence is there that the facility makes accommodations for the resident’s usual and customary routines?
• What programs/activities has the resident received to improve and maintain maximum mental and psychosocial functioning?
• Has the resident’s mental and psychosocial functioning been maintained or improved (e.g., fewer symptoms of distress)? Have treatment plans and objectives been re-evaluated?
• Has the resident received a psychological or psychiatric evaluation to evaluate, diagnose, or treat her/his condition, if necessary?
• Identify if resident triggers CAA(s) for activities, mood state, psychosocial well-being, and psychotropic drug use. Consider whether the CAA process was used to assess the causal factors for decline, potential for decline or lack of improvement.
• How are mental and psychosocial adjustment difficulties addressed in the care plan?

See §483.45(a), F406 for health rehabilitative services for mental illness and mental retardation. Psychosocial adjustment difficulty does not display a pattern of decreased social interaction and/or increased withdrawn, angry, or depressive behaviors, unless the resident’s clinical condition demonstrates that such a pattern was unavoidable.

F320
(Rev. 70, Issued: 01-07-11, Effective: 10-01-10 Implementation: 10-01-10)

§483.25(f)(2)

(2) A resident whose assessment did not reveal a mental or psychosocial adjustment difficulty does not display a pattern of decreased social interaction and/or increased withdrawn, angry, or depressive behaviors, unless the resident’s clinical condition demonstrates that such a pattern is unavoidable.

Procedures §483.25(f)(2)
For sampled residents whose assessment did not reveal a mental or psychosocial adjustment difficulty, but who display decreased social interaction or increased withdrawn, angry, or depressed behaviors, determine, as appropriate, was this behavior unavoidable.

Probes: §483.25(f)(2)

- Did the facility attempt to evaluate whether this behavior was attributable to organic causes or other risk factors not associated with adjusting to living in the nursing facility?
- What care did the resident receive to maintain his/her mental or psychosocial functioning?
- Were individual objectives of the plan of care periodically evaluated, and if progress was not made in reducing, maintaining, or increasing behaviors that assist the resident to have his/her needs met, were alternative treatment approaches developed to maintain mental or psychosocial functioning?
- Identify if resident triggers CAA s for behavior problem, cognitive loss/dementia, and psychosocial well-being. Consider whether the CAA process was used to assess causal factors for decline, potential for decline or lack of improvement.
- Did the facility use the CAA process for behavior problems, cognitive loss/dementia, and psychosocial well-being to assess why the behaviors or change in mental or psychosocial functioning was occurring?

§483.25(g) Naso-Gastric Tubes

Based on the comprehensive assessment of a resident, the facility must ensure that --
(See Tag F322 for intent, guidelines, and probes for §483.25(g))

F321
§483.25(g)(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

F322
(Rev: 70, Issued: 01-07-11, Effective: 10-01-10 Implementation: 10-01-10)
§483.25(g)(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 §483.25(g)
The intent of this regulation is that a naso-gastric tube feeding is utilized only after adequate assessment, and the resident’s clinical condition makes this treatment necessary.
Interpretive Guidelines §483.25(g)

This requirement is also intended to prevent the use of tube feeding when ordered over the objection of the resident. Decisions about the appropriateness of tube feeding for a resident are developed with the resident or his/her family, surrogate or representative as part of determining the care plan.

Complications in tube feeding are not necessarily the result of improper care, but assessment for the potential for complications and care and treatment are provided to prevent complications in tube feeding by the facility.

Clinical conditions demonstrating that nourishment via an naso-gastric tube is unavoidable include:

- The inability to swallow without choking or aspiration, i.e., in cases of Parkinson’s disease, pseudobulbar palsy, or esophageal diverticulum;
- Lack of sufficient alertness for oral nutrition (e.g., resident comatose); and
- Malnutrition not attributable to a single cause or causes that can be isolated and reversed. There is documented evidence that the facility has not been able to maintain or improve the resident’s nutritional status through oral intake.

Probes: §483.25(g)

For sampled residents who, upon admission to the facility, were not tube fed and now have a feeding tube, was tube feeding unavoidable? To determine if the tube feeding was unavoidable, assess the following:

- Did the facility identify the resident at risk for malnutrition?
- What did the facility do to maintain oral feeding, prior to inserting a feeding tube? Did staff provide enough assistance in eating? Did staff cue resident as needed, assist with the use of assistive devices, or feed the resident, if necessary?
- Is the resident receiving therapy to improve or enhance swallowing skills, as need, is identified in the comprehensive assessment?
- Was an assessment done to determine the cause of decreased oral intake/weight loss or malnutrition?
- If there was a dietitian consultation, were recommendations followed?
- For all sampled residents who are tube fed:
  - Is the NG tube properly placed?
  - Are staff responsibilities for providing enteral feedings clearly assigned (i.e., who administers the feeding, formula, amount, feeding intervals, flow rate)?
  - Do staff monitor feeding complications (e.g., diarrhea, gastric distension, aspiration) and administer corrective actions to allay complications (e.g., changing rate of formula administration)?
  - Are there negative consequences of tube use (e.g., agitation, depression, self-extubation, infections, aspiration and restraint use without a medical reason for the restraint)?
  - When long term use is anticipated, is G tube placement considered?
Is the potential for complications from feedings minimized by:
• Use of a small bore, flexible naso-gastric tube, unless contraindicated;
• Securely attached the tube to the nose/face;
• Checking for correct tube placement prior to beginning a feeding or administering medications and after episodes of vomiting or suctioning;
• Checking a resident with a newly inserted gastric tube for gastric residual volume every 2-4 hours until the resident has demonstrated an ability to empty his/her stomach;
• Properly elevating the resident’s head;
• Providing the type, rate and volume of the feeding as ordered;
• Using universal precautions and clean technique and as per facility/manufacturer’s directions when stopping, starting, flushing, and giving medications through the tube;
• Using hang time recommendations by the manufacturer to prevent excessive microbial growth;
• Implement the procedures to ensure cleanliness of supplies, e.g. irrigating syringes changed on a regular bases as per facility policy. It is not necessary to change the irrigating syringe each time it is used;
• Using a pump equipped with a functional alarm (if pump used);
• The facility’s criteria for determining that a resident may be able to return to eating by mouth (e.g., a resident whose Parkinson’s symptoms have been controlled);
• There are sampled residents meet these criteria;
• If so, the facility has assisted them in returning to normal eating; and
• Identify if resident triggers CAA s for feeding tubes, nutritional status, and dehydration/fluid maintenance. Consider whether the CAA process was used to assess causal factors for decline, potential for decline and lack of improvement.

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F323
(Rev. 27, Issued: 08-17-07, Effective: 08-17-07 Implementation: 08-17-07)

§483.25(h) Accidents.
The facility must ensure that –

(1) The resident environment remains as free from accident hazards as is possible; and
(2) Each resident receives adequate supervision and assistance devices to prevent accidents.

INTENT: 42 CFR 483.25(H) (1) AND (2) ACCIDENTS AND SUPERVISION
The intent of this requirement is to ensure the facility provides an environment that is free from accident hazards over which the facility has control and provides supervision and assistive devices to each resident to prevent avoidable accidents. This includes:
• Identifying hazard(s) and risk(s);
• Evaluating and analyzing hazard(s) and risk(s);
• Implementing interventions to reduce hazard(s) and risk(s); and
• Monitoring for effectiveness and modifying interventions when necessary.

DEFINITIONS
Definitions are provided to clarify terms related to providing supervision and other interventions to prevent accidents.
• “Accident” refers to any unexpected or unintentional incident, which may result in injury or illness to a resident. This does not include adverse outcomes that are a direct consequence of treatment or care that is provided in accordance with current standards of practice (e.g., drug side effects or reaction).

  o “Avoidable Accident” means that an accident occurred because the facility failed to:
    Identify environmental hazards and individual resident risk of an accident, including the need for supervision; and/or
    Evaluate/analyze the hazards and risks; and/or
    Implement interventions, including adequate supervision, consistent with a resident’s needs, goals, plan of care, and current standards of practice in order to reduce the risk of an accident; and/or
    Monitor the effectiveness of the interventions and modify the interventions as necessary, in accordance with current standards of practice.

  o “Unavoidable Accident” means that an accident occurred despite facility efforts to:
    Identify environmental hazards and individual resident risk of an accident, including the need for supervision; and
    Evaluate/analyze the hazards and risks; and
    Implement interventions, including adequate supervision, consistent with the resident’s needs, goals, plan of care, and current standards of practice in order to reduce the risk of an accident; and
    Monitor the effectiveness of the interventions and modify the interventions as necessary, in accordance with current standards of practice.

• “Assistance Device” or “Assistive Device” refers to any item (e.g., fixtures such as handrails, grab bars, and devices/equipment such as transfer lifts, canes, and wheelchairs, etc.) that is used by, or in the care of a resident to promote, supplement, or enhance the resident’s function and/or safety.

NOTE: The currently accepted nomenclature refers to “assistive devices.” Although the term “assistance devices” is used in the regulation, the Guidance provided in this document will refer to “assistive devices.”

• “Environment” refers to the resident environment. (See definition for “resident environment.”)

• “Fall” refers to unintentionally coming to rest on the ground, floor, or other lower level, but not as a result of an overwhelming external force (e.g., resident pushes another resident). An episode where a resident lost his/her balance and would have fallen, if not for staff intervention, is
considered a fall. A fall without injury is still a fall. Unless there is evidence suggesting otherwise, when a resident is found on the floor, a fall is considered to have occurred.

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

- “Resident environment” includes the physical surroundings to which the resident has access (e.g., room, unit, common use areas, and facility grounds, etc.).

- “Risk” refers to any external factor or characteristic of an individual resident that influences the likelihood of an accident.

- “Supervision/Adequate Supervision” refers to an intervention and means of mitigating the risk of an accident. Facilities are obligated to provide adequate supervision to prevent accidents. Adequate supervision is defined by the type and frequency of supervision, based on the individual resident’s assessed needs and identified hazards in the resident environment. Adequate supervision may vary from resident to resident and from time to time for the same resident.

**OVERVIEW**

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

The facility is responsible for providing care to residents in a manner that helps promote quality of life. This includes respecting residents’ rights to privacy, dignity and self determination, and their right to make choices about significant aspects of their life in the facility.

For various reasons, residents are exposed to some potential for harm. Although hazards should not be ignored, there are varying degrees of potential for harm. It is reasonable to accept some risks as a trade off for the potential benefits, such as maintaining dignity, self-determination, and control over one’s daily life. The facility’s challenge is to balance protecting the resident’s right to make choices and the facility’s responsibility to comply with all regulations.

The responsibility to respect a resident’s choices is balanced by considering the potential impact of these choices on other individuals and on the facility’s obligation to protect the residents from harm. The facility has a responsibility to educate a resident, family, and staff regarding significant risks related to a resident’s choices. Incorporating a resident’s choices into the plan of care can help the facility balance interventions to reduce the risk of an accident, while honoring the resident’s autonomy.
Consent by resident or responsible party alone does not relieve the provider of its responsibility to assure the health, safety, and welfare of its residents, including protecting them from avoidable accidents. While Federal regulations affirm the resident’s right to participate in care planning and to refuse treatment, the regulations do not create the right for a resident, legal surrogate, or representative to demand the facility use specific medical interventions or treatments that the facility deems inappropriate. The regulations hold the facility ultimately accountable for the resident’s care and safety. Verbal consent or signed consent forms do not eliminate a facility’s responsibility to protect a resident from an avoidable accident.

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

- Acknowledges the high-risk nature of its population and setting;
- Develops a reporting system that does not place blame on the staff member for reporting resident risks and environmental hazards;
- Involves all staff in helping identify solutions to ensure a safe resident environment;
- Directs resources to address safety concerns; and
- Demonstrates a commitment to safety at all levels of the organization.

A SYSTEMS APPROACH
Establishing and utilizing a systematic approach to resident safety helps facilities comply with the regulations at 42 CFR §483.25(h)(1) and (2). Processes in a facility’s system approach may include:

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

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

Identifying and addressing risks, including the potential for accidents, includes consideration of the environment, the resident’s risk factors, and the need for supervision, care, and assistive devices. This will allow the facility to communicate information about observed hazards, identify resident-specific information, develop and implement an individualized plan of care to address each resident’s needs and goals, and to monitor the results of the planned interventions. The plan of care should strive to balance the resident’s wishes with the potential impact on other residents.
A systematic approach allows the facility to adjust its responses depending on the urgency of the situation and the hazards identified. The system includes a means for communicating the observations of hazards and the recording of resident specific information. Risks identified by the facility can pertain to individual residents or groups of residents. The facility-centered approach addresses risks for groups of residents; whereas, the resident-directed approach addresses risks for the individual residents.

Identification of Hazards and Risks

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

Evaluation and Analysis

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

Both the facility-centered and resident-directed approaches include evaluating hazard and accident risk data, analyzing potential causes for each hazard and accident risk, and identifying or developing interventions based on the severity of the hazards and immediacy of risk.

Evaluations also look at trends such as time of day, location, etc.

Implementation of Interventions

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

Interventions are based on the results of the evaluation and analysis of information about hazards and risks and are consistent with relevant standards, including evidence-based practice. Development of interim safety measures may be necessary if interventions cannot immediately be implemented fully.
Facility-based interventions may include, but are not limited to, educating staff, repairing the device/equipment, and developing or revising policies and procedures. Resident-directed approaches may include implementing specific interventions as part of the plan of care, supervising staff and residents, etc. Facility records document the implementation of these interventions.

Monitoring and Modification

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

Monitoring and modification processes include:

(1) Ensuring that interventions are implemented correctly and consistently;
(2) Evaluating the effectiveness of interventions;
(3) Modifying or replacing interventions as needed and
(4) Evaluating the effectiveness of new interventions.

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

SUPERVISION
Supervision is an intervention and a means of mitigating accident risk. Facilities are obligated to provide adequate supervision to prevent accidents. Adequacy of supervision is defined by type and frequency, based on the individual resident’s assessed needs, and identified hazards in the resident environment. Adequate supervision may vary from resident to resident and from time to time for the same resident. Tools or items such as personal alarms can help to monitor a resident’s activities, but do not eliminate the need for adequate supervision. The resident environment may contain temporary hazards (e.g., construction, painting, housekeeping activities, etc.) that warrant additional supervision or alternative measures such as barriers to prevent access to affected areas of the resident environment.

Adequate supervision to prevent accidents is enhanced when the facility:

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

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

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

Guidance concerning resident smoking regulations can be found in NFPA 101, the Life Safety Code at 19.7.4, Smoking, including requirements for signage, prohibiting smoking by residents classified as not responsible, and disposal of smoking materials. Refer to the guidance at 42 CFR 483.15(b)(3) [F242] for information about facilities that desire to be smoke-free.

Resident-to-Resident Altercations

NOTE: An incident involving a resident who willfully inflicts injury upon another resident should be reviewed as abuse under the guidance for 42 CFR §483.13(b) at F223. “Willful” means that the individual intended the action itself that he/she knew or should have known could cause physical harm, pain, or mental anguish. Even though a resident may have a cognitive impairment, he/she could still commit a willful act. However, there are instances when a resident’s willful intent cannot be determined. In those cases, a resident-to-resident altercation should be reviewed under this tag, F323.

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

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

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

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

• Providing safe supervised areas for unrestricted movement;
• Eliminating or reducing underlying causes of distressed behavior such as boredom and pain;
• Monitoring environmental influences such as temperatures, lighting, and noise levels;
• Evaluating staffing assignments to ensure consistent staff who are more familiar with the resident and who thus may be able to identify changes in a resident’s condition and behavior;
• Evaluating staffing levels to ensure adequate supervision (if it is adequate, it is meeting the resident’s needs); and
• Ongoing staff training and supervision, including how to approach a resident who may be agitated, combative, verbally or physically aggressive, or anxious, and how and when to obtain assistance in managing a resident with behavior symptoms.

RESIDENT RISKS AND ENVIRONMENTAL HAZARDS

This section discusses common, but not all, potential hazards found in the resident environment. **NOTE:** The information included in the following sections is based on current standards of practice or “best practice” models as described in the industry literature.

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

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

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

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

Resident Vulnerabilities

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

Falls - The MDS defines a fall as unintentionally coming to rest on the ground, floor, or other lower level but not as a result of an overwhelming external force (e.g., resident pushes another resident). An episode where a resident lost his/her balance and would have fallen, if not for staff intervention, is considered a fall. A fall without injury is still a fall. Unless there is evidence suggesting otherwise, when a resident is found on the floor, a fall is considered to have occurred.¹

Some factors that may result in resident falls include (but are not limited to) environmental hazards, underlying medical conditions, medication side effects, and other factors (e.g., lower extremity weakness, balance disorders, poor grip strength, functional and cognitive impairment, visual deficits, etc.).

Older persons have both a high incidence of falls and a high susceptibility to injury.⁴ Falls can have psychological and social consequences, including the loss of self-confidence to try to ambulate. Evaluation of the causal factors leading to a resident fall helps support relevant and consistent interventions to try to prevent future occurrences. Proper actions following a fall include:

• Ascertaining if there were injuries, and providing treatment as necessary;
• Determining what may have caused or contributed to the fall;
• Addressing the factors for the fall; and
• Revising the resident’s plan of care and/or facility practices, as needed, to reduce the likelihood of another fall.

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

Unsafe Wandering or Elopement - Wandering is random or repetitious locomotion. This movement may be goal-directed (e.g., the person appears to be searching for something such as an exit) or may be non-goal-directed or aimless. Non-goal-directed wandering requires a response in a manner that addresses both safety issues and an evaluation to identify root causes to the degree possible. Moving about the facility aimlessly may indicate that the resident is frustrated, anxious, bored, hungry, or depressed. Unsafe wandering and elopement can be associated with falls and related injuries.⁵
Unsafe wandering may occur when the resident at risk enters an area that is physically hazardous or that contains potential safety hazards (e.g., chemicals, tools, and equipment, etc.). Entering into another resident’s room may lead to an altercation or contact with hazardous items.5

While alarms can help to monitor a resident’s activities, staff must be vigilant in order to respond to them in a timely manner. Alarms do not replace necessary supervision.

Elopement occurs when a resident leaves the premises or a safe area without authorization (i.e., an order for discharge or leave of absence) and/or any necessary supervision to do so. A resident who leaves a safe area may be at risk of (or has the potential to experience) heat or cold exposure, dehydration and/or other medical complications, drowning, or being struck by a motor vehicle. Facility policies that clearly define the mechanisms and procedures for monitoring and managing residents at risk for elopement can help to minimize the risk of a resident leaving a safe area without authorization and/or appropriate supervision. In addition, the resident at risk should have interventions in their comprehensive plan of care to address the potential for elopement. Furthermore, a facility’s disaster and emergency preparedness plan should include a plan to locate a missing resident.5

**Physical Plant Hazards**

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

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

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

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

- Chemicals used by the facility staff in the course of their duties (e.g., housekeeping chemicals) and chemicals or other materials brought into the resident environment by staff, other residents, or visitors;
- Drugs and therapeutic agents;
- Plants and other “natural” materials found in the resident environment or in the outdoor environment (e.g., poison ivy).

One source of information concerning the hazards of a material that a facility may obtain is its Material Safety Data Sheet (MSDS).6 The Occupational Safety and Health Administration
(OSHA) requires employers to have an MSDS available for all hazardous materials that staff use while performing their duties. MSDSs are available on-line for numerous chemicals and non-toxic materials, and should be reviewed carefully to determine if the material is toxic and poses a hazard. Poison control centers are another source of information for potential hazards, including non-chemical hazards such as plants.

**NOTE:** Toxicological profiles for a limited number of hazardous materials are accessible on the Agency for Toxic Substances & Disease Registry Web site.

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

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

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

**NOTE:** Burns can occur even at water temperatures below those identified in the table, depending on an individual’s condition and the length of exposure. Based upon the time of the exposure and the temperature of the water, the severity of the harm to the skin is identified by the degree of burn, as follows.

- First-degree burns involve the top layer of skin (e.g., minor sunburn). These may present as red and painful to touch, and the skin will show mild swelling.
- Second-degree burns involve the first two layers of skin. These may present as deep reddening of the skin, pain, blisters, glossy appearance from leaking fluid, and possible loss of some skin.
- Third-degree burns penetrate the entire thickness of the skin and permanently destroy tissue. These present as loss of skin layers, often painless (pain may be caused by patches of first- and second-degree burns surrounding third-degree burns), and dry, leathery skin. Skin may appear charred or have patches that appear white, brown, or black.
Electrical Safety - Any electrical device, whether or not it needs to be plugged into an electric outlet, can become hazardous to the residents through improper use or improper maintenance.

Electrical equipment such as electrical cords can become tripping hazards. Halogen lamps or heat lamps can cause burns or fires if not properly installed away from combustibles in the resident environment. The Life Safety Code prohibits the use of portable electrical space heaters in resident areas.

Extension cords should not be used to take the place of adequate wiring in a facility. If extension cords are used, the cords should be properly secured and not be placed overhead, under carpets or rugs, or anywhere that the cord can cause trips, falls, or overheat. Extension cords should be connected to only one device to prevent overloading of the circuit. The cord itself should be of a size and type for the expected electrical load and made of material that will not fray or cut easily.

Electrical cords including extension cords should have proper grounding if required and should not have any grounding devices removed or not used if required.

Power strips may not be used as a substitute for adequate electrical outlets in a facility. Power strips may be used for a computer, monitor, and printer. Power strips are not designed to be used with medical devices in patient care areas. Precautions needed if power strips are used include: installing internal ground fault and over-current protection devices; preventing cords from becoming tripping hazards; and using power strips that are adequate for the number and types of devices used. Overload on any circuit can potentially cause overheating and fire. The use of ground fault circuit interruption (GFCIs) may be required in locations near water sources to prevent electrocution of staff or residents.11

The proper use of electric blankets and heating pads is essential to avoid thermal injuries. These items should not be tucked in or squeezed. Constriction can cause the internal wires to break. A resident should not go to sleep with an electric blanket or heating pad turned on. Manufacturer’s instructions for use should be followed closely. Injuries and deaths have been related to burns and fires related to the use of heating pads. Most deaths are attributable to heating pads that generated fires, but most injuries are burns from prolonged use or inappropriate temperature setting. Prolonged use on one area of the body can cause a severe burn, even when the heating pad is at a low temperature setting.12

Lighting - The risk of an accident increases when there is insufficient light or too much light, which often results in glare. Vision among older persons varies widely; therefore, no single level of illumination can ensure safety for all residents. The proper amount of light depends on the resident’s visual needs and the task he/she is performing.

An older person typically needs more light to see. However, a resident with cataracts or glaucoma may be overly sensitive to bright light, and excessive lighting could make it more difficult to see clearly and thereby increase his/her fall risk.13 Creating transitional zones between light and dark spaces helps to improve sight recovery and enable safer mobility. Providing extra visual cues that clearly define needed items or spaces in areas with limited or variable light can
help to enable safe performance of tasks (e.g., turning on a light). Providing supplemental light near beds for patients who are mobile may assist in safe mobility at night.\textsuperscript{14}

**NOTE:** Refer to guidance for 42 CFR 483.15(h)(5) [F256] for lighting issues related to Quality of Life.

### Assistive Devices/Equipment Hazards

Assistive devices also can help to prevent accidents. Assistive devices and equipment can help residents move with increased independence, transfer with greater comfort, and feel physically more secure. However, there are risks associated with the use of such devices and equipment, and these risks need to be balanced with the benefits gained from their use. Training of staff, residents, family members and volunteers on the proper use of assistive devices/equipment is crucial to prevent accidents. It is also important to communicate clearly the approaches identified in the care plan to all staff, including temporary staff. It is important to train staff regarding resident assessment, safe transfer techniques, and the proper use of mechanical lifts including device weight limitations.

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

Assistive Devices for Mobility - Mobility devices include all types of assistive devices, such as, but not limited to, canes, standard and rolling walkers, manual or non-powered wheelchairs, and powered wheelchairs. Three primary factors that may be associated with an increased accident risk related to the use of assistive devices include:

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

2. **Personal Fit and Device Condition.** Devices can pose a hazard if not fitted and/or maintained properly.\textsuperscript{15} Personal fit, or how well the assistive device meets the individual needs of the resident, may influence the likelihood of an avoidable accident; and

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

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

Factors that may influence a resident’s risk of accident during transfer include staff availability, resident abilities, and staff training. The resident’s ability to communicate and identify physical limitations or to aid in the transfer will help determine the need for an assistive device, such as a mechanical lift.

Devices Associated with Entrapment Risks - Devices can be therapeutic and beneficial; however, devices are not necessarily risk free so it is important to weigh the relative risks and benefits of using certain devices. For example, while physical restraints may be used to treat a resident’s medical symptom, the devices may create a risk for entrapment. Physical restraints are defined in the SOM at F221 as any manual method, physical or mechanical device, material, or equipment attached or adjacent to the resident’s body that the individual cannot remove easily and that restricts freedom of movement or normal access to one’s body.

In 1992, the Food and Drug Administration (FDA) issued a Safety Alert entitled “Potential Hazards with Restraint Devices”. Serious injuries, as well as death, have been reported as a result of using physical restraints. Some physical restraints carry a risk of severe injury, strangulation, and asphyxiation. Restrained residents may be injured or die when they try to remove restraints, to ambulate while restrained, or due to an improperly fitted or used device.

Regardless of the purpose for use, bed rails (also referred to as “side rails,” “bed side rails,” and “safety rails”) and other bed accessories (e.g., transfer bar, bed enclosures), while assisting with transfer and positioning, can increase resident safety risk. Bed rails include rails of various sizes (e.g., full length rails, half rails, quarter rails) that may be positioned in various locations on the bed. In 1995, the FDA issued a Safety Alert entitled “Entrapment Hazards with Hospital Bed Side Rails.” Residents most at risk for entrapment are those who are frail or elderly or those who have conditions such as agitation, delirium, confusion, pain, uncontrolled body movement, hypoxia, fecal impaction, acute urinary retention, etc. that may cause them to move about the bed or try to exit from the bed. The timeliness of toileting, appropriateness of positioning, and other care-related activities can contribute to the risk of entrapment.

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

The use of a specialty air-filled mattress or a therapeutic air-filled bed may also present an entrapment risk that is different from rail entrapment with a regular mattress. The high compressibility of an air-filled mattress compared to a regular conventional mattress requires appropriate precautions when used for a resident at risk for entrapment. An air-filled mattress compresses on the side to which a person moves, thus raising the center of the mattress and lowering the side. This may make it easier for a resident to slide off the mattress or against the rail. Mattress compression widens the space between the mattress and rail. When a resident is
between the mattress and rail, the mattress can re-expand and press the chest, neck, or head against the rail. While using air therapy to prevent and treat pressure ulcers, facilities should also take precautions to reduce the risk of entrapment. Precautions may include following manufacturer equipment alerts and increasing supervision.\textsuperscript{20}

**NOTE:** 42 CFR 483.13(a), F221, applies to the use of physical restraints. 42 CFR 483.25(h)(2), F323 applies to assistive devices that create hazards (e.g., devices that are defective; not used properly or according to manufacturer’s specifications; disabled or removed; not provided or do not meet the resident’s needs (poor fit or not adapted); and/or used without adequate supervision when required).

**ENDNOTES**

7 US Dept. of Labor, Occupational Safety and Health Standards, 29 CFR 1910.1200 (g)(1) and (2)
INVESTIGATIVE PROTOCOL
ACCIDENTS AND SUPERVISION

Objectives

- To determine if the facility has identified hazard(s) present in the resident environment and the individual resident’s risks for an avoidable accident posed by those hazards;
- To determine if a resident accident was avoidable or unavoidable;
- To evaluate whether the facility provides an environment that is as free as possible of hazards over which the facility has control, and minimizes the potential for harm; and
- To determine if the facility provides adequate supervision and assistive devices to prevent avoidable accidents.

Use

Use this protocol:

- For a sampled resident who is at risk for, or who has a history of accidents, falls, or unsafe wandering/elopement, to determine if the facility provided care and services, including assistive devices as necessary, to prevent avoidable accidents and to reduce the resident’s risk to the extent possible;
- For a sampled resident who is at risk for accidents or who creates a risk to others, to determine if the facility has provided adequate supervision; and
- For identified hazards/risks, to determine if there are facility practices in place to identify, evaluate and analyze hazards/risks; implement interventions to reduce or eliminate the hazards/risks, to the extent possible; and monitor the effectiveness of the interventions.
**Procedures**

Observe the general environment and sampled resident environment. For a sampled resident, briefly review the assessment and plan of care to determine whether the facility identified resident risks and implemented interventions as necessary to guide observations during the investigation. For a newly admitted resident at risk for avoidable accidents, determine if the staff assessed and provided appropriate care from the day of admission. Corroborate observations through interview and record review.

1. **Observation**

   The survey team should make observations and investigate potential hazards that may be encountered throughout the survey. The existence of hazards may indicate a more serious problem; for example, that the organization lacks an effective system to identify and correct the problem independently. The previous discussion of specific common hazards guides surveyors to look for items indicating a failure or absence of an organization’s systems and processes to enable safety.

   During observation of the facility, the survey team may see individual residents who are smoking tobacco products. Whether or not these residents are part of the sample, the issue of facility fires is important enough that the survey team should determine if the situation is hazardous, requiring further investigation.

   Observe the environment for the presence of potential/actual hazards including, but not limited to, the following:

   - Accessibility of chemicals, toxics or other hazards such as housekeeping chemicals and supplies, medications, sharp utensils/tools, and cigarette lighters/smoking materials;
   - Environmental conditions such as unstable or slippery floor surfaces, loose hand rails, excessive water temperatures, electrical hazards, insufficient or excessive light (glare), arrangement of living spaces, obstacles in corridors, unsupervised access into or egress out of the facility, low or loose toilet seats, defective or non-functioning beds, or malfunctioning wheelchair brakes;
   - Staff responses to verbal calls for help and alarms such as door, personal, and equipment alarms, and call bells;
   - Assistive devices/equipment (e.g., mobility devices, lifts and transfer aids, bed rails, call lights, physical restraints, pumps, belts) that are defective; not used properly or according to manufacturer’s specifications; disabled or removed; not provided or do not meet the resident’s needs (poor fit or not adapted); and/or used without adequate supervision, in relation to the facility’s assessment of the resident; and/or
   - Staff response to potential/actual hazard(s) (e.g., cleaning up spilled liquids in a resident area, keeping residents away from the hazard).

   For a sampled resident at risk, observe whether staff implement the care plan consistently over time and across various shifts. Observe how staff respond to any identified resident hazards. Observe how staff supervise the resident, such as during transfers and/or meals, and if caregivers have removed or modified observed hazards. During observations of the interventions, follow up on deviations from the plan of care, as well as potential negative outcomes.
For a resident who smokes, the facility’s determination regarding the resident’s abilities and capabilities would indicate whether supervision is required. If the resident is found to need supervision for smoking, this information is included in the resident’s plan of care. Observe sampled resident(s) in the facility’s designated smoking area. If the resident’s care plan states supervision is required while smoking, confirm that supervision is provided. For others, note any concerns such as difficulty holding or lighting a cigarette or burned areas in clothing that may indicate the need for supervision.

Observe the resident to determine how the resident’s risk influences his/her vulnerability to the observed potential hazard(s) and potential for an accident. Evaluate how the resident’s risks relate to the observed potential hazards such as:
• The resident’s access to the hazard and the ability to react appropriately; and/or
• The adequacy of the supervision provided for the resident who has been assessed to need supervision in relation to the identified potential hazard(s).

2. Interview

Conduct interviews to determine the relationship between the resident’s risk and hazards. Interview the resident, family, and/or responsible party to the degree possible to identify:

• If the resident and/or responsible party reported, or helped identify the resident’s risks for an accident and significant hazards in the resident’s environment;
• If the resident and/or responsible party was aware of or identified a potential hazard for other residents;
• If the resident and/or responsible party reported a hazard or potential risk to staff; and
• How and when staff responded to a hazard once it was identified.

Interview staff to determine:
• If they were aware of planned interventions to reduce a resident’s risk for an avoidable accident;
• If they reported potential resident risks or environmental hazards to the supervisor or others according to facility policy;
• If they acted to correct an immediate hazard, such as spilled liquids; and
• If they are aware of, and follow facility procedures correctly to remove or reduce hazards.

3. Record Review

Assessment and Evaluation: Review the RAI and other documents such as progress notes, physician orders, and nurses’ and consultants’ notes regarding the assessment of the resident’s overall condition and risk factors to determine if the facility identified the resident’s risk for avoidable accidents, evaluated and analyzed any risks, implemented interventions to try to prevent accidents and reduce the resident’s risks, and monitored and modified interventions as necessary.

Determine if the facility assessment is consistent with or corroborated by documentation within the record and reflects the status of the resident for:
• Behavior such as unsafe wandering, elopement, ingesting nonfood items, altercations with others;
• Hearing, visual, and sensory impairments;
• Impaired physical functioning, balance, or gait problems;
• Diagnoses that could relate to safety awareness and safe practices, such as Alzheimer’s and other dementias, arthritis, Parkinson’s disease, seizure disorder, osteoporosis, cardiovascular/cerebrovascular diseases, depression/psychosis;
• Symptoms/conditions that could affect safety risk, such as vertigo, postural hypotension, or acute illness;
• Use of physical restraints and/or other devices that might limit movement;
• Medications that could affect function, level of consciousness, gait, balance, visual acuity, or cognitive ability, use such as antidepressants, anticholinergic medications, anti-hypertensives, diuretics, psychotropic medications, or initiation of new medication therapy; and
• History of falls.

Plan of Care: Review the plan of care to determine if the facility developed interventions based on the resident’s risks to try to prevent avoidable accidents, and if the plan was modified as needed based on the response, outcomes, and needs of the resident.
If the resident has had an accident, review the record to determine if the accident is:
• The result of an order not being followed; and/or
• A care need not being addressed; and/or
• A plan of care not being implemented.

In addition, determine if the facility (1) investigated the cause of the accident and (2) if indicated, implemented revised interventions to prevent additional avoidable accidents.

Plan of Care Revision: Determine if the facility has monitored a resident’s condition and the effectiveness of the plan of care interventions and has made revisions (or has documented justification for continuing the existing plan) based upon the following:
• The outcome and/or effects of goals and interventions;
• Resident failure to comply with the plan of care and interventions;
• Input by the resident and/or the responsible person; and
• Changes in condition such as the ability to make decisions, cognition, functional impairment, or changes in the medication regimen.

4. Review of Facility Practices
The presence or absence of effective facility practices to provide a safe resident environment can influence the likelihood of an accident occurring and subsequent harm to a resident(s). Hazards that have been allowed to exist for a long time, or a facility history of similar problems, could indicate inadequate or ineffective facility practices.

If, during the tour, surveyors identify care delivery, hazards or potential hazards, or a history of resident accidents, the survey team should share the findings with the entire team and determine who will lead the investigation of the facility’s systems for identifying, evaluating and preventing avoidable accidents or hazards. Review of facility practices may involve a review of policies and procedures, staffing, staff training, and equipment manufacturer’s information, as
well as interviews with staff and management. If there is a pattern of accidents involving one or more residents, determine how the facility evaluates its responses to the accidents. Determine if the facility ensured that the resident environment remained as free of accident hazards as possible and if each resident received adequate supervision and assistive devices to try to prevent accidents by:

- Identifying potential hazards and risks (may require various strategies to gather such information);
- Evaluating and analyzing the information gathered to identify the underlying causes of the hazard and/or risk;
- Implementing interventions that addressed the causes and prioritized actions based on severity of the hazard and immediacy of the risk; and
- Monitoring implementation of interventions and determining if modification is needed.

DETERMINATION OF COMPLIANCE (Task 6, Appendix P)

Synopsis of Regulation
The requirements at 42 CFR 483.25(h)(1) and (2) have three aspects. The first aspect requires that a resident’s environment remains as free of accident hazards as possible; the second aspect requires that the facility provide adequate supervision; and the third is that the facility provides assistive devices to prevent accidents.

Criteria for Compliance
The facility’s responsibility to accommodate individual needs and preferences and abide by the resident’s right to choice and self-determination must be balanced against compliance with F323 to protect the resident. Documentation regarding the resident’s choices will assist the survey team in making compliance decisions.

NOTE: It is important to remember that not all accidents in a facility, regardless of outcome to a resident, are necessarily due to facility noncompliance. A resident can sustain bodily injury as a result of an accident over which the facility had no control (i.e., an unavoidable accident). The survey team needs to review the situation that led to the injury or potential for injury, as well as the facility practices, and resident’s rights, preferences, and choices, to determine if the potential or negative outcome was avoidable or unavoidable.

Compliance with 42 CFR 483.25(h)(1) and (2), F323, Accidents and Supervision

For the resident who has had an accident or was assessed at risk for an avoidable accident, the facility is in compliance with this requirement, if staff have:
- Identified hazards and risk of an avoidable accident based on the facility’s assessment of the resident environment and the resident, including the need for supervision and/or assistive devices;
- Evaluated/analyzed the hazards and risks;
- Implemented interventions, including adequate supervision and/or assistive devices, to reduce the risks of an accident that were consistent with a resident’s needs, goals, plan of care, and current standards of practice;
- Provided assistive devices consistent with a resident’s needs;
• Properly deployed and maintained resident specific equipment (e.g., lifts, canes, wheelchairs, walkers);
• Provided a safe environment, such as by monitoring chemicals, wet floors, cords and other equipment;
• Operated equipment in accordance with manufacturer’s recommendations and resident need;
• Provided and maintain a secure environment (e.g., resident room, unit, common use areas, stairs and windows, facility grounds, etc.) to prevent negative outcomes (e.g., prevent falling/tumbling down stairs or jumping from windows or eloping through exit doors) for residents who exhibit unsafe wandering and/or elopement behavior (regardless of whether ambulatory, in wheelchair or using walker); and
• Monitored the effectiveness of the interventions and modified the interventions as necessary, in accordance with current standards of practice.

If not, cite F323.

Noncompliance for F323

After completing the investigation, determine whether or not compliance with the regulation exists. Noncompliance for F323 may include, but is not limited to, one or more of the following failures to:

• Provide each resident an environment that is as free as possible from hazards over which the facility has control, such as assuring safe storage of toxic chemicals and medications, and safe use of equipment and electrical appliances;
• Provide adequate supervision for a resident who has exhibited unsafe wandering and/or has a risk of and/or a history of elopement;
• Identify and correct hazards such as non-functional alarms or call systems, disabled locks, fire doors that have been propped open, irregular walking surfaces, inadequate lighting or unsafe water temperatures;
• Supervise and monitor a resident who smokes and whose comprehensive assessment and plan of care indicates a need for supervision;
• Provide assistive devices and/or appropriate training for the use of assistive devices, based upon the assessed needs of the resident;
• Monitor for defective or disabled equipment, such as pumps, ventilators or other equipment, or the improper use of assistive devices;
• Assess, develop interventions, and/or revise the plan of care for a resident who has experienced falls, or who is identified as having risk factors for falling; and
• Assess, develop interventions, and/or revise the plan of care for a resident who has exhibited or has a risk for unsafe wandering or elopement.

Potential Tags for Additional Investigation
During the investigation of 42 CFR 483.25(h)(1) and (2), the surveyor may have identified concerns related to outcome, process, and/or structure requirements. The surveyor should investigate these requirements before determining whether noncompliance may be present. The following are examples of related outcome, process, and/or structure requirements that should be considered:
• 42 CFR 483.13(a), F221, Restraints
  o Determine if staff attempted alternative approaches prior to the use of a restraint and if a
    medical indication for its use is present.

• 42 CFR 483.13(b), F223, Abuse
  o Determine if the resident was free from verbal, sexual, physical, and mental abuse, corporal
    punishment, and involuntary seclusion.

• 42 CFR 483.20(b)(1), F272, Comprehensive Assessments
  o Determine if the facility comprehensively assessed resident-specific risk factors (including
    potential causes) and assessed the need for and use of assistive devices.

• 42 CFR 483.20(k)(1), F279, Comprehensive Care Plans
  o Determine if the facility developed a plan of care based on the comprehensive resident
    assessment consistent with the resident’s specific conditions, risks, needs, behaviors, and
    preferences and with current standards of practice, and that includes measurable objectives and
    approximate timetables, specific interventions and/or services including necessary supervision
    and/or any assistive devices needed to prevent accidents to the extent possible.

• 42 CFR 483.20(k)(2), F280, Comprehensive Care Plan Revision
  o Determine if the plan of care was reviewed and revised periodically, as necessary, related to
    preventing accidents, supervision required, and the use of assistive devices.

• 42 CFR 483.20(k)(3)(i), F281, Services Provided Meet Professional Standards
  o Determine if services and care were provided for the use of assistive devices, supervision, and
    prevention of accidents in accordance with accepted professional standards.

• 42 CFR 483.30(a), F353, Sufficient Staff
  o Determine if the facility had qualified staff in sufficient numbers to provide necessary care
    and services, including supervision, based upon the comprehensive assessment and care plan, to
    prevent accidents, as possible.

• 42 CFR 483.75(o), F520, Quality Assessment and Assurance
  o Determine whether the quality assessment and assurance committee has identified issues, and
    developed and implemented appropriate plans of action to correct identified quality deficiencies
    in relation to hazards, accident prevention, and supervision of residents.

V. DEFICIENCY CATEGORIZATION (Part V, 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 F323 are as follows:

1. Presence of harm/negative outcome(s) or potential for negative outcomes because of presence
   of environmental hazards, lack of adequate supervision to prevent accidents, or failure to provide
assistive devices to prevent accidents. Actual or potential harm/negative outcome for F323 may include, but is not limited to:

• Injuries sustained from falls and/or unsafe wandering/elopement;
• Resident-to-resident altercations;
• Thermal burns from spills/immersion of hot water/liquids;
• Falls due to environmental hazards;
• Ingestion of chemical substances; and
• Burns related to smoking materials.

2. Degree of harm (actual or potential) related to the noncompliance. Identify how the facility 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; and
• 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 F323. 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.)

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 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 always remove a finding of Immediate Jeopardy. The facility is required to implement specific actions to correct the noncompliance which allowed or caused the Immediate Jeopardy.

When considering Severity Level 4, the survey team must have already determined noncompliance in the facility practices to provide a safe resident environment. Examples of
negative outcomes that occurred or have the potential to occur as a result of the noncompliance might include the following:

- Esophageal damage due to ingestion of corrosive substances;
- Loss of consciousness related to head injuries;
- 3rd degree burn, or a 2nd degree burn covering a large surface area;
- Fracture or other injury that may require surgical intervention and results in significant decline in mental and/or physical functioning;
- Electric shock due to use of unsafe or improperly maintained equipment;
- Entrapment of body parts, such as limbs, head, neck, or chest that cause injury or death as a result of defective or improperly latched side rails or spaces within side rails, between split rails, between rails and the mattress, between side rails and the bed frame, or spaces between side rails and the head or foot board of the bed;
- Entrapment of body parts, such as limbs, head, neck, or chest that causes or has the potential to cause serious injury, harm, impairment or death as a result of any manual method, physical or mechanical device, material, or equipment;
- Fall(s) that resulted in or had the potential to result in serious injury, impairment, harm or death (e.g. fracture or other injury that may require surgical intervention and/or results in significant decline in mental and/or physical functioning), and the facility had no established measure(s) or practice(s), or ineffective measure(s) or practice(s), that would have prevented the fall or limited the resident’s injury; or
- Unsafe wandering and/or elopement that resulted in or had the potential to result in serious injury, impairment, harm or death (e.g., resident leaves facility or locked unit unnoticed and sustained or had potential to sustain serious injury, impairment, harm or death), and the facility had no established measure(s) or practice(s), or ineffective measure(s) or practice(s), that would have prevented or limited the resident’s exposure to hazards.

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

Severity Level 3 indicates noncompliance that results in actual harm and can include but may not be limited to clinical compromise, decline, or the resident’s ability to maintain and/or reach his/her highest practicable well-being.

When considering Severity Level 3, the survey team must have already determined noncompliance in the facility practices to provide a safe resident environment. As a result of the noncompliance, a negative outcome occurred. Some examples of compromise include:

- Short-term disability;
- Pain that interfered with normal activities;
- 2nd degree burn;
- Fracture or other injury that may require surgical intervention and does not result in significant decline in mental and/or physical functioning;
- Medical evaluation was necessary, and treatment beyond first aid (e.g., sutures) was required;
- Fall(s) that resulted in actual harm (e.g., short-term disability; pain that interfered with normal activities; fracture or other injury that may require surgical intervention and does not result in
significant decline in mental and/or physical functioning; or medical evaluation was necessary, and treatment beyond first aid (e.g., sutures) was required) and the facility had established measure(s) or practice(s) in place that limited the resident’s potential to fall and limited the resident’s injury and prevented the harm from rising to a level of immediate jeopardy; or
• Unsafe wandering and/or elopement that resulted in actual harm and the facility had established measure(s) or practice(s) in place that limited the resident’s exposure to hazards and prevented the harm from rising to a level of immediate jeopardy.

NOTE: Unsafe wandering or elopement that resulted in actual harm and the facility had no established measure(s) or practice(s), or ineffective measure(s) or practice(s) that would have prevented or limited the resident’s exposure to hazards should be cited at Level 4, Immediate Jeopardy.

NOTE: If Severity Level 3 (actual harm that is not immediate jeopardy) has been ruled out based upon the evidence, 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 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.
When considering Severity Level 2, the survey team must have already determined noncompliance in the facility practices to provide a safe resident environment. As a result of the noncompliance, a negative outcome occurred, or the potential for a negative outcome exists, such as the following:
• Bruising, minor skin abrasions, and rashes;
• Pain that does not impair normal activities;
• 1st degree burn;
• Medical evaluation or consultation may or may not have been necessary, and treatment such as first aid may have been required;
• Fall(s) which resulted in no more than minimal harm (e.g., bruising or minor skin abrasions; pain that does not impair normal activities; or medical evaluation or consultation may or may not have been necessary, and/or treatment such as first aid may have been required) because the facility had additional established measure(s) or practice(s) that limited the resident’s potential to fall or limited the injury or potential for injury; or
• Unsafe wandering and/or elopement, which resulted in no more than minimal harm because the facility had additional established measure(s) or practice(s) that limited the resident’s exposure to hazards. For example, a resident with Alzheimer’s disease left the locked unit and was quickly found unharmed on another unit, and the building was considered a safe environment, as there was no way for the resident to leave the building.

Severity Level 1 Considerations: No Actual Harm with Potential for Minimal Harm
The failure of the facility to provide a safe environment and adequate supervision places residents at risk for more than minimal harm. Therefore, Severity Level 1 does not apply for this regulatory requirement.

§483.25(i) Nutrition

Based on a resident’s comprehensive assessment, the facility must ensure that a resident--
§483.25(i)(1) Maintains acceptable parameters of nutritional status, such as body weight and protein levels, unless the resident’s clinical condition demonstrates that this is not possible; and
§483.25(i)(2) Receives a therapeutic diet when there is a nutritional problem.

INTENT: §483.25(i) Nutritional Status

The intent of this requirement is that the resident maintains, to the extent possible, acceptable parameters of nutritional status and that the facility:
• Provides nutritional care and services to each resident, consistent with the resident’s comprehensive assessment;
• Recognizes, evaluates, and addresses the needs of every resident, including but not limited to, the resident at risk or already experiencing impaired nutrition; and
• Provides a therapeutic diet that takes into account the resident’s clinical condition, and preferences, when there is a nutritional indication.

DEFINITIONS

Definitions are provided to clarify clinical terms related to nutritional status.
• “Acceptable parameters of nutritional status” refers to factors that reflect that an individual’s nutritional status is adequate, relative to his/her overall condition and prognosis.
• “Albumin” is the body’s major plasma protein, essential for maintaining osmotic pressure and also serving as a transport protein.
• “Anemia” refers to a condition of low hemoglobin concentration caused by decreased production, increased loss, or destruction of red blood cells.
• “Anorexia” refers to loss of appetite, including loss of interest in seeking and consuming food.
• “Artificial nutrition” refers to nutrition that is provided through routes other than the usual oral route, typically by placing a tube directly into the stomach, the intestine or a vein.
• “Avoidable/Unavoidable” failure to maintain acceptable parameters of nutritional status:
  o “Avoidable” means that the resident did not maintain acceptable parameters of nutritional status and that the facility did not do one or more of the following: evaluate the resident’s clinical condition and nutritional risk factors; define and implement interventions that are consistent with resident needs, goals and recognized standards of practice; monitor and evaluate the impact of the interventions; or revise the interventions as appropriate.
  o “Unavoidable” means that the resident did not maintain acceptable parameters of nutritional status even though the facility had evaluated the resident’s clinical condition and nutritional risk factors; defined and implemented interventions that are consistent with resident needs, goals and recognized standards of practice; monitored and evaluated the impact of the interventions; and revised the approaches as appropriate.
• “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.

- “Current standards of practice” refers to approaches to care, procedures, techniques, treatments, etc., that are based on research 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.
- “Dietary supplements” refers to nutrients (e.g., vitamins, minerals, amino acids, and herbs) that are added to a person’s diet when they are missing or not consumed in enough quantity.
- “Insidious weight loss” refers to a gradual, unintended, progressive weight loss over time.
- “Nutritional Supplements” refers to products that are used to complement a resident’s dietary needs (e.g., total parenteral products, enteral products, and meal replacement products).
- “Parameters of nutritional status” refers to factors (e.g., weight, food/fluid intake, and pertinent laboratory values) that reflect the resident’s nutritional status.
- “Qualified dietitian” refers to one who is qualified based upon either registration by the Commission on Dietetic Registration of the American Dietetic Association or as permitted by State law, on the basis of education, training, or experience in identification of dietary needs, planning, and implementation of dietary programs.
- “Therapeutic diet” refers to a diet ordered by a health care practitioner as part of the treatment for a disease or clinical condition, to eliminate, decrease, or increase certain substances in the diet (e.g., sodium or potassium), or to provide mechanically altered food when indicated.
- “Usual body weight” refers to the resident’s usual weight through adult life or a stable weight over time.

OVERVIEW

Nutrients are essential for many critical metabolic processes, the maintenance and repair of cells and organs, and energy to support daily functioning. Therefore, it is important to maintain adequate nutritional status, to the extent possible.

Other key factors in addition to intake can influence weight and nutritional status. For example, the body may not absorb or use nutrients effectively. Low weight may also pertain to: age-related loss of muscle mass, strength, and function (sarcopenia), wasting (cachexia) that occurs as a consequence of illness and inflammatory processes, or disease causing changes in mental status. Changes in the ability to taste food may accompany later life. Impaired nutritional status is not an expected part of normal aging. It may be associated with an increased risk of mortality and other negative outcomes such as impairment of anticipated wound healing, decline in function, fluid and electrolyte imbalance/dehydration, and unplanned weight change. The early identification of residents with, or at risk for, impaired nutrition, may allow the interdisciplinary team to develop and implement interventions to stabilize or improve nutritional status before additional complications arise. However, since intake is not the only factor that affects nutritional status, nutrition-related interventions only sometimes improve markers of nutritional status such as body weight and laboratory results. While they can often be stabilized or improved, nutritional deficits and imbalances may take time to improve or they may not be fully correctable in some individuals.

A systematic approach can help staff’s efforts to optimize a resident’s nutritional status. This process includes identifying and assessing each resident’s nutritional status and risk factors, evaluating/analyzing the assessment information, developing and consistently implementing pertinent approaches, and monitoring the effectiveness of interventions and revising them as necessary.
ASSESSMENT

According to the American Dietetic Association, “Nutritional assessment is a systematic process of obtaining, verifying and interpreting data in order to make decisions about the nature and cause of nutrition-related problems.” The assessment also provides information that helps to define meaningful interventions to address any nutrition-related problems.

The interdisciplinary team clarifies nutritional issues, needs, and goals in the context of the resident’s overall condition, by using observation and gathering and considering information relevant to each resident’s eating and nutritional status. Pertinent sources of such information may include interview of the resident or resident representative, and review of information (e.g., past history of eating patterns and weight and a summary of any recent hospitalizations) from other sources.

The facility identifies key individuals who should participate in the assessment of nutritional status and related causes and consequences. For example, nursing staff provide details about the resident’s nutritional intake. Health care practitioners (e.g., physicians and nurse practitioners) help define the nature of the problem (e.g., whether the resident has anorexia or sarcopenia), identify causes of anorexia and weight loss, tailor interventions to the resident’s specific causes and situation, and monitor the continued relevance of those interventions. Qualified dietitians help identify nutritional risk factors and recommend nutritional interventions, based on each resident’s medical condition, needs, desires, and goals. Consultant pharmacists can help the staff and practitioners identify medications that affect nutrition by altering taste or causing dry mouth, lethargy, nausea, or confusion.

Although the RAI is the only assessment tool specifically required, a more in-depth nutritional assessment may be needed to identify the nature and causes of impaired nutrition and nutrition-related risks. Completion of the RAI does not remove the facility’s responsibility to document a more detailed resident assessment, where applicable. The in-depth nutritional assessment may utilize existing information from sources, such as the RAI, assessments from other disciplines, observation, and resident and family interviews. The assessment will identify usual body weight, a history of reduced appetite or progressive weight loss or gain prior to admission, medical conditions such as a cerebrovascular accident, and events such as recent surgery, which may have affected a resident’s nutritional status and risks. The in-depth nutritional assessment may also include the following information:

**General Appearance** - General appearance includes a description of the resident’s overall appearance (e.g., robust, thin, obese, or cachectic) and other findings (e.g., level of consciousness, responsiveness, affect, oral health and dentition, ability to use the hands and arms, and the condition of hair, nails, and skin) that may affect or reflect nutritional status.

**Height** - Measuring a resident’s height provides information that is relevant (in conjunction with his or her weight) to his/her nutritional status. There are various ways to estimate height if standing height cannot be readily measured. A protocol for determining height helps to ensure that it will be measured as consistently as possible.

**Weight** - Weight can be a useful indicator of nutritional status, when evaluated within the context of the individual’s personal history and overall condition. When weighing a resident, adjustment for amputations or prostheses may be indicated. Significant unintended changes in weight (loss or gain) or insidious weight loss may indicate a nutritional problem. Current standards of practice recommend weighing the resident on admission or readmission (to establish a baseline weight), weekly for the first 4 weeks after admission and at least monthly thereafter to help identify and document trends such as insidious weight loss. Weighing may also
be pertinent if there is a significant change in condition, food intake has declined and persisted (e.g., for more than a week), or there is other evidence of altered nutritional status or fluid and electrolyte imbalance. In some cases, weight monitoring is not indicated (e.g., the individual is terminally ill and requests only comfort care).

Obtaining accurate weights for each resident may be aided by having staff follow a consistent approach to weighing and by using an appropriately calibrated and functioning scale (e.g., wheelchair scale or bed scale). Since weight varies throughout the day, a consistent process and technique (e.g., weighing the resident wearing a similar type of clothing, at approximately the same time of the day, using the same scale, either consistently wearing or not wearing orthotics or prostheses, and verifying scale accuracy) can help make weight comparisons more reliable. A system to verify weights can help to ensure accuracy. Weights obtained in different settings may differ substantially. For example, the last weight obtained in the hospital may differ markedly from the initial weight upon admission to the facility, and is not to be used in lieu of actually weighing the resident. Approaches to improving the accuracy of weights may include reweighing the resident and recording the current weight, reviewing approaches to obtaining and verifying weight, and modifying those approaches as needed.

Examples of other factors that may impact weight and the significance of apparent weight changes include:
- The resident’s usual weight through adult life;
- Current medical conditions;
- Calorie restricted diet;
- Recent changes in dietary intake; and
- Edema.

**Food and fluid intake** - The nutritional assessment includes an estimate of calorie, nutrient and fluid needs, and whether intake is adequate to meet those needs. It also includes information such as the route (oral, enteral or parenteral) of intake, any special food formulation, meal and snack patterns (including the time of supplement or medication consumption in relation to the meals), dislikes, and preferences (including ethnic foods and form of foods such as finger foods); meal/snack patterns, and preferred portion sizes.

**Fluid loss or retention** can cause short term weight change. Much of a resident’s daily fluid intake comes from meals; therefore, when a resident has decreased appetite, it can result in fluid/electrolyte imbalance. Abrupt weight changes, change in food intake, or altered level of consciousness are some of the clinical manifestations of fluid and electrolyte imbalance. Laboratory tests (e.g., electrolytes, BUN, creatinine and serum osmolality) can help greatly to identify, manage, and monitor fluid and electrolyte status.

**Altered Nutrient intake, absorption, and utilization.** Poor intake, continuing or unabated hunger, or a change in the resident’s usual intake that persists for multiple meals, may indicate an underlying problem or illness. Examples of causes include:
- The inability to consume meals provided (e.g., as a result of the form or consistency of food/fluid, cognitive or functional decline, arthritis-related impaired movement, neuropathic pain, or insufficient assistance);
- Insufficient availability of food and fluid (e.g., inadequate amount of food or fluid or inadequate tube feedings);
- Environmental factors affecting food intake or appetite (e.g., comfort and level of disruption in the dining environment);
- Adverse consequences related to medications; and
Diseases and conditions such as cancer, diabetes mellitus, advanced or uncontrolled heart or lung
disease, infection and fever, liver disease, hyperthyroidism, mood disorders, and repetitive
movement disorders (e.g., wandering, pacing, or rocking).
The use of diuretics and other medications may cause weight loss that is not associated with
nutritional issues, but can also cause fluid and electrolyte imbalance/dehydration that causes a
loss of appetite and weight.
Various gastrointestinal disorders such as pancreatitis, gastritis, motility disorders, small bowel
dysfunction, gall bladder disease, and liver dysfunction may affect digestion or absorption of
food. Prolonged diarrhea or vomiting may increase nutritional requirements due to nutrient and
fluid losses. Constipation or fecal impaction may affect appetite and excretion.
Pressure ulcers and some other wounds and other health impairments may also affect nutritional
requirements. A hypermetabolic state results from an increased demand for energy and protein
and may increase the risk of weight loss or under-nutrition. Examples of causes include
advanced chronic obstructive pulmonary disease (COPD), pneumonia and other infections,
cancer, hyperthyroidism, and fever.
Early identification of these factors, regardless of the presence of any associated weight changes,
can help the facility choose appropriate interventions to minimize any subsequent
complications.10 Often, several of these factors affecting nutrition coexist.

**Chewing abnormalities** - Many conditions of the mouth, teeth, and gums can affect the
resident’s ability to chew foods. For example, oral pain, dry mouth, gingivitis, periodontal
disease, ill-fitting dentures, and broken, decayed or missing teeth can impair oral intake.

**Swallowing abnormalities** - Various direct and indirect causes can affect the resident’s ability
to swallow. These include but are not limited to stroke, pain, lethargy, confusion, dry mouth, and
diseases of the oropharynx and esophagus. Swallowing ability may fluctuate from day to day or
over time. In some individuals, aspiration pneumonia can complicate swallowing
abnormalities.10

**NOTE**: Swallowing studies are not always required in order to assess eating and
swallowing; however, when they are indicated, it is essential to interpret
any such tests in the proper context. A clinical evaluation of swallowing
may be used to evaluate average daily oral function.11

**Functional ability** - The ability to eat independently may be helped by addressing factors that
impair function or by providing appropriate individual assistance, supervision, or assistive
devices. Conditions affecting functional ability to eat and drink include impaired upper extremity
motor coordination and strength or reduced range of motion (any of which may be hampered by
stroke, Parkinson’s disease, multiple sclerosis, tardive dyskinesia, or other neuromuscular
disorders or by sensory limitations (e.g., blindness)). Cognitive impairment may also affect a
resident’s ability to use a fork, or to eat, chew, and swallow effectively.

**Medications** - Medications and nutritional supplements may affect, or be affected by, the intake
or utilization of nutrients (e.g., liquid phenytoin taken with tube feedings or grapefruit juice
taken with some antihyperlipidemics).12 Medications from almost every pharmaceutical class can
affect nutritional status, directly or indirectly; for example, by causing or exacerbating anorexia,
lethargy, confusion, nausea, constipation, impairing taste, or altering gastrointestinal function.
Inhaled or ingested medications can affect food intake by causing pharyngitis, dry mouth,
esophagitis, or gastritis. To the extent possible, consideration of medication/nutrient interactions
and adverse consequences should be individualized.
**Goals and prognosis** - Goals and prognosis refer to a resident’s projected personal and clinical outcomes. These are influenced by the resident’s preferences (e.g., willingness to participate in weight management interventions or desire for nutritional support at end-of-life), anticipated course of a resident’s overall condition and progression of a disease (e.g., end-stage, terminal, or other irreversible conditions affecting food intake, nutritional status, and weight goals), and by the resident’s willingness and capacity to permit additional diagnostic testing, monitoring and treatment.

**Laboratory/Diagnostic Evaluation**

Laboratory tests are sometimes useful to help identify underlying causes of impaired nutrition or when the clinical assessment alone is not enough to define someone’s nutritional status. Abnormal laboratory values may, but do not necessarily, imply that treatable clinical problems exist or that interventions are needed. Confirmation is generally desirable through additional clinical evaluation and evidence such as food intake, underlying medical condition, etc. Abnormal laboratory values may, but do not necessarily, imply that treatable clinical problems exist or that interventions are needed. Confirmation is generally desirable through additional clinical evaluation and evidence such as food intake, underlying medical condition, etc. For example, serum albumin may help establish prognosis but is only sometimes helpful in identifying impaired nutrition or guiding interventions. Serum albumin may drop significantly during an acute illness for reasons unrelated to nutrition; therefore, albumin may not improve, or may fall further, despite consumption of adequate amounts of calories and protein.

The decision to order laboratory tests, and the interpretation of subsequent results, is best done in light of a resident’s overall condition and prognosis. Before ordering laboratory tests it is appropriate for the health care practitioner to determine and indicate whether the tests would potentially change the resident’s diagnosis, management, outcome or quality of life or otherwise add to what is already known. Although laboratory tests such as albumin and pre-albumin may help in some cases in deciding to initiate nutritional interventions, there is no evidence that they are useful for the serial follow-up of undernourished individuals.

**NOTE:** If laboratory tests were done prior to or after admission to the facility and the test results are abnormal, the physician or other licensed health care practitioner, in collaboration with the interdisciplinary team, reviews the information and determines whether to intervene or order additional diagnostic testing.

**ANALYSIS**

Analysis refers to using the information from multiple sources to include, but not limited to, the Resident Assessment Instrument (RAI), and additional nutritional assessments as indicated to determine a resident’s nutritional status and develop an individualized care plan. Resultant conclusions may include, but are not limited to: a target range for weight based on the individual's overall condition, goals, prognosis, usual body weight, etc; approximate calorie, protein, and other nutrient needs; whether and to what extent weight stabilization or improvement can be anticipated; and whether altered weight or nutritional status could be related to an underlying medical condition (e.g., fluid and electrolyte imbalance, medication-related anorexia, or an infection).

Suggested parameters for evaluating significance of unplanned and undesired weight loss are:

<table>
<thead>
<tr>
<th>Interval</th>
<th>Significant Loss</th>
<th>Severe Loss</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 month</td>
<td>5%</td>
<td>Greater than 5%</td>
</tr>
<tr>
<td>3 months</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
7.5%
Greater than 7.5%
6 months
10%
Greater than 10%
The following formula determines percentage of weight loss:
\[
\% \text{ of body weight loss} = \frac{(\text{usual weight} - \text{actual weight})}{(\text{usual weight})} \times 100
\]
Based on analysis of relevant information, the facility identifies a clinically pertinent basis for any conclusions that a resident could not attain or maintain acceptable parameters of nutritional status.

**Specification of the Nutritional Concern**
A clear statement of the nature of the nutritional concern provides the basis for resident-specific interventions. Many residents have multiple coexisting issues. For example:

**Poor food and fluid intake:** The resident has poor intake, is not consuming specific food groups, and has increased nutritional needs specific to clinical conditions. The resident also has lost significant weight over a few days while taking medications that may affect appetite.

**Specific clinical conditions:** The resident has an infection with fever and is in a hyper-metabolic state associated with an increased demand for energy and protein. The resident also has a neuromuscular disorder affecting the ability to eat or swallow, and has impaired cognition affecting attention and appetite.

**CARE PLANNING AND INTERVENTIONS**
The management of nutrition in nursing homes involves various medical, psychosocial, ethical, and functional considerations. Based on information generated by the comprehensive assessment and any pertinent additional nutritional assessment, the interdisciplinary team (including a physician or other licensed health care practitioner and the resident or the resident’s representative) develops an individualized care plan. The care plan addresses, to the extent possible, identified causes of impaired nutritional status, reflects the resident’s goals and choices, and identifies resident-specific interventions and a time frame and parameters for monitoring. The care plan is updated as needed; e.g., as conditions change, goals are met, interventions are determined to be ineffective, or as specific treatable causes of nutrition-related problems (anorexia, impaired chewing, etc.) are identified. If nutritional goals are not achieved, different or additional pertinent approaches are considered and implemented as indicated. Pertinent documentation can help identify the basis (e.g., current resident status, comorbid conditions, prognosis, and resident choices) for nutrition-related goals and interventions.

**Resident Choice**
A resident or resident representative has the right to make informed choices about accepting or declining care and treatment. The facility can help the resident exercise those rights effectively by discussing with the resident (or the resident’s representative) the resident’s condition, treatment options (including related risks and benefits, and expected outcomes), personal preferences, and any potential consequences of accepting or refusing treatment. If the resident declines specific interventions, the facility must address the resident’s concerns and offer relevant alternatives.

The facility’s care reflects a resident’s choices, either as offered by the resident directly or via a valid advance directive, or based on a decision made by the resident’s surrogate or representative in accordance with state law. The presence of care instructions, such as an advance directive, declining some interventions does not necessarily imply that other support and care was declined.
or is not pertinent. When preferences are not specified beforehand, decisions related to the possible provision of supplemental or artificial nutrition should be made in conjunction with the resident or resident’s representative in accordance with state law, taking into account relevant considerations such as condition, prognosis, and a resident’s known values and choices.

**NOTE:** The presence of a “Do Not Resuscitate” (DNR) order does not by itself indicate that the resident is declining other appropriate treatment and services. It only indicates that the resident has chosen not to be resuscitated if cardiopulmonary functions cease.

### Meeting Nutritional Needs

The scope of interventions to meet residents’ nutritional needs depends on many factors, including, but not limited to a resident’s current food intake, the degree of nutritional impairment or risk, resident choices, the response to initial interventions, and the feasibility of addressing underlying conditions and causes. Basic energy needs can generally be met by providing a diet that includes enough calories to stabilize current body weight. Adjustments may be necessary when factors exist such as those discussed within this document. For example, limits on dairy products may be desirable in individuals with lactose intolerance, and additional amounts of nutrients and calories may be needed for individuals with hypermetabolic states (e.g., fever, hyperthyroidism, acute wounds, or heart or lung disease), to try to keep the body from using lean body mass for energy and wound repair.

### Diet Liberalization

Research suggests that a liberalized diet can enhance the quality of life and nutritional status of older adults in long-term care facilities. Thus, it is often beneficial to minimize restrictions, consistent with a resident’s condition, prognosis, and choices before using supplementation. It may also be helpful to provide the residents their food preferences, before using supplementation. This pertains to newly developed meal plans as well as to the review of existing diets.

Dietary restrictions, therapeutic (e.g., low fat or sodium restricted) diets, and mechanically altered diets may help in select situations. At other times, they may impair adequate nutrition and lead to further decline in nutritional status, especially in already undernourished or at-risk individuals. When a resident is not eating well or is losing weight, the interdisciplinary team may temporarily abate dietary restrictions and liberalize the diet to improve the resident’s food intake to try to stabilize their weight.

Sometimes, a resident or resident’s representative decides to decline medically relevant dietary restrictions. In such circumstances, the resident, facility and practitioner collaborate to identify pertinent alternatives.

### Weight-Related Interventions

For many residents (including overweight individuals), the resident’s usual body weight prior to decline or admission is the most relevant basis for weight-related interventions. Basing interventions on ideal body weight can be misleading, because ideal body weight has not been definitively established for the frail elderly and those with chronic illnesses and disabilities.

The care plan includes nutritional interventions that address underlying risks and causes of weight loss (e.g., the need for eating assistance, reduction of medication side effects, and additional food that the resident will eat) or unplanned weight gain. It is important that the care plan address insidious, abrupt, or sudden decline in intake or insidious weight loss that does not trigger review of the Nutritional Status CAA; for example, by intensifying observation of intake...
and eating patterns, monitoring for complications related to poor intake, and seeking underlying cause(s).

Many risk factors and some causes of weight loss can be addressed, at least partially, while others may not be modifiable. In some cases, certain interventions may not be indicated or appropriate, based on individual goals and prognosis. Weight stability, rather than weight gain, may sometimes be the most pertinent short-term or long-term objective for the nutritionally at-risk or compromised resident. After an acute illness or as part of an advanced or end-stage medical condition, the resident’s weight and other nutritional parameters may not return to previous levels and may stabilize at a lower level, sometimes indefinitely.

NOTE: There should be a documented clinical basis for any conclusion that nutritional status or significant weight change are unlikely to stabilize or improve (e.g., physician’s documentation as to why weight loss is medically unavoidable).

**Weight Gain.** Unplanned weight gain in a resident may have significant health implications. Rapid or abrupt increases in weight may also indicate significant fluid excess. After assessing the resident for the cause of the weight gain, care plan interventions may include dietary alterations based on the resident’s medical condition, choices, and needs. If the resident exercises his/her right to choose and declines dietary restrictions, the facility discusses with the resident the benefits of maintaining a lower weight and the possible consequences of not doing so. A health care practitioner can help inform the resident about the rationale for the recommended plan of care.

**Environmental Factors**

Appetite is often enhanced by the appealing aroma, flavor, form, and appearance of food. Resident-specific facility practices that may help improve intake include providing a pleasant dining experience (e.g., flexible dining environments, styles and schedules), providing meals that are palatable, attractive and nutritious (e.g., prepare food with seasonings, serve food at proper temperatures, etc.), and making sure that the environment where residents eat (e.g., dining room and/or resident’s room) is conducive to dining.

**Anorexia**

The facility, in consultation with the practitioner, identifies and addresses treatable causes of anorexia. For example, the practitioner may consider adjusting or stopping medications that may have caused the resident to have dyspepsia or become lethargic, constipated, or confused, and reevaluate the resident to determine whether the effects of the medications are the reasons for the anorexia and subsequent weight loss. Where psychosis or a mood disorder such as depression has been identified as a cause of anorexia or weight change, treatment of the underlying disorder (based on an appropriate diagnostic evaluation) may improve appetite. However, other coexisting conditions or factors instead of, or in addition to, depression, may cause or contribute to anorexia. In addition, the use of antidepressants is not generally considered to be an adequate substitute for appropriately investigating and addressing modifiable risk factors or other underlying causes of anorexia and weight loss.

**Wound Healing**

Healing of acute (e.g., postoperative) and chronic (e.g., pressure ulcer) wounds requires enough calories and protein so that the body will not use lean body mass (muscle) for energy and wound repair. However, to date, no routinely beneficial wound-specific nutritional measures have been identified.
Care plan interventions for a resident who has a wound or is at risk of developing a wound may include providing enough calories to maintain a stable weight and a daily protein intake of approximately 1.2-1.5 gm protein/Kg body weight. The recommended daily protein intake may be adjusted according to clinical need and standards of clinical practice for situations in which more calories and protein are indicated. Sometimes, it may be most appropriate to try to encourage the resident to eat as many calories and as much protein as tolerated, because he/she does not desire or cannot tolerate more aggressive nutritional interventions. Additional strategies for wound healing may be considered when indicated. A multivitamin/mineral supplement may be prescribed, however current evidence does not definitively support any specific dietary supplementation (e.g., Vitamin C and Zinc) unless the resident has a specific vitamin or mineral deficiency.

**Functional Factors**

Based on the comprehensive interdisciplinary assessment, the facility provides the necessary assistance to allow the resident to eat and drink adequately. A resident with functional impairment may need help with eating. Examples of such interventions may include, but are not limited to: ensuring that sensory devices such as eyeglasses, dentures, and hearing aids are in place; providing personal hygiene before and after meals, properly positioning the individual, providing eating assistance where needed, and providing the assistive devices/utensils identified in the assessment. 17

**Chewing and Swallowing**

In deciding whether and how to intervene for chewing and swallowing abnormalities, it is essential to take a holistic approach and look beyond the symptoms to the underlying causes. Pertinent interventions may help address the resident’s eating, chewing, and swallowing problems and optimize comfort and enjoyment of meals. Examples of such interventions may include providing proper positioning for eating; participation in a restorative eating program; use of assistive devices/utensils; and prompt assistance (e.g., supervision, cueing, hand-over-hand) during every meal/snack where assistance is needed. Treating medical conditions (e.g., gastroesophageal reflux disease and oral and dental problems) that can impair swallowing or cause coughing may improve a chewing or swallowing problem. Examples of other relevant interventions include adjusting medications that cause dry mouth or coughing, and providing liquids to moisten the mouth of someone with impaired saliva production.

Excessive modification of food and fluid consistency may unnecessarily decrease quality of life and impair nutritional status by affecting appetite and reducing intake.18 Many factors influence whether a swallowing abnormality eventually results in clinically significant complications such as aspiration pneumonia.19 Identification of a swallowing abnormality alone does not necessarily warrant dietary restrictions or food texture modifications. No interventions consistently prevent aspiration and no tests consistently predict who will develop aspiration pneumonia.20 For example, tube feeding may be associated with aspiration, and is not necessarily a desirable alternative to allowing oral intake, even if some swallowing abnormalities are present.21,22 Decisions to downgrade or alter the consistency of diets must include the resident (or the resident’s representative), consider ethical issues (such as the right to decline treatment), and be based on a careful review of the resident’s overall condition, correctable underlying causes of the risk or problem, the benefits and risks of a more liberalized diet, and the resident’s preferences to accept risks in favor of a more liberalized food intake.

**Medications**
When a resident is eating poorly or losing weight, the immediate need to stabilize weight and improve appetite may supersede long-term medical goals for which medications were previously ordered. It may be appropriate to change, stop, or reduce the doses of medications (e.g., antiepileptics, cholinesterase inhibitors, or iron supplements) that are associated either with anorexia or with symptoms such as lethargy or confusion that can cause or exacerbate weight loss. The medical practitioner in collaboration with the staff and the pharmacist reviews and adjusts medications as appropriate. (For additional Guidance related to medications, refer to 42 CFR 483.25(l)(1), F329, Unnecessary Drugs.)

**Food Fortification and Supplementation**

With any nutrition program, improving intake via wholesome foods is generally preferable to adding nutritional supplements. However, if the resident is not able to eat recommended portions at meal times or to consume between-meal snacks/nourishments, or if he/she prefers the nutritional supplement, supplements may be used to try to increase calorie and nutrient intake. Since some research suggests that caloric intake may increase if nutritional supplements are consumed between meals, and may be less effective when given with meals, the use of nutritional supplements is generally recommended between meals instead of with meals. Taking a nutritional supplement during medication administration may also increase caloric intake without reducing the resident’s appetite at mealtime.

Examples of interventions to improve food/fluid intake include:

- Fortification of foods (e.g., adding protein, fat, and/or carbohydrate to foods such as hot cereal, mashed potatoes, casseroles, and desserts);
- Offering smaller, more frequent meals;
- Providing between-meal snacks or nourishments; or
- Increasing the portion sizes of a resident’s favorite foods and meals; and providing nutritional supplements.

**Maintaining Fluid and Electrolyte Balance**

If a resident has poor intake or abnormal laboratory values related to fluid/electrolyte balance, the care plan addresses the potential for hydration deficits. Examples of interventions include adjusting or discontinuing medications that affect fluid balance or appetite; offering a variety of fluids (water, fruit juice, milk, etc.) between meals, and encouraging and assisting residents as appropriate. Serving (except to those with fluid restrictions) additional beverages with meals will also help increase fluid intake. Examples of ways to encourage fluid intake include maintaining filled water pitchers and drinking cups easily accessible to residents (except those with fluid restrictions) and offering alternate fluid sources such as popsicles, gelatin, and ice cream.

**Use of Appetite Stimulants**

To date, the evidence is limited about benefits from appetite stimulants. While their use may be appropriate in specific circumstances, they are not a substitute for appropriate investigation and management of potentially modifiable risk factors and underlying causes of anorexia and weight loss.

**Feeding Tubes**

Feeding tubes have potential benefits and complications, depending on an individual’s underlying medical conditions and prognosis, and the causes of his or her anorexia or weight loss. Possible feeding tube use, especially for residents with advanced dementia or at the end-of-life, should be considered carefully. The resident’s values and choices regarding artificial nutrition should be identified and considered. The health care practitioner should be involved in reviewing whether potentially modifiable causes of anorexia, weight loss, and eating or
swallowing abnormalities have been considered and addressed, to the extent possible. For residents with dementia, studies have shown that tube feeding does not extend life, prevent aspiration pneumonia, improve function or limit suffering. 27

**End-of-Life**

Resident choices and clinical indications affect decisions about the use of a feeding tube at the end-of-life. A resident at the end of life may have an advance directive addressing his or her treatment goals (or the resident’s surrogate or representative, in accordance with State law, may have made a decision).

Decreased appetite and altered hydration are common at the end of life, and do not require interventions other than for comfort. Multiple organ system failure may impair the body’s capacity to accept or digest food or to utilize nutrients. Thus, the inability to maintain acceptable parameters of nutritional status for someone who is at the end-of-life or in the terminal stages of an illness may be an expected outcome.

Care and services, including comfort measures, are provided based on the resident’s choices and a pertinent nutritional assessment. The facility can help to support intake, to the extent desired and feasible, based on the information from the assessment and on considering the resident’s choices.

If individualized approaches for end-of-life care are provided in accordance with the care plan and the resident's choices, then the failure to maintain acceptable parameters of nutritional status may be an expected outcome for residents with terminal conditions.

**MONITORING**

Monitoring after care plan implementation is necessary for residents with impaired or at-risk nutritional status, as well as for those whose current nutritional status is stable. Monitoring includes a review of the resident-specific factors identified as part of the comprehensive resident assessment and any supplemental nutrition assessment.

Identifying and reporting information about the resident’s nutritional status and related issues such as level of consciousness and function are obtainable through various staff observations. For example, nursing assistants may be most familiar with the resident’s habits and preferences, symptoms such as pain or discomfort, fluctuating appetite, and nausea or other gastrointestinal symptoms. More intensive and frequent monitoring may be indicated for residents with impaired or at-risk nutritional status than for those who are currently nutritionally stable. Such monitoring may include, but is not limited to, observing for and recognizing emergence of new risk factors (e.g., acute medical illness, pressure ulcers, or fever), evaluating consumption of between-meal snacks and nutritional supplements, and reviewing the continued relevance of any current nutritional interventions (e.g., therapeutic diets, tube feeding orders or nutritional supplements).

Evaluating the care plan to determine if current interventions are being followed and if they are effective in attaining identified nutritional and weight goals allows the facility to make necessary revisions. Subsequent adjustment of interventions will depend on, but are not limited to, progress, underlying causes, overall condition and prognosis. The resident’s current nutritional and medical status helps the staff determine the frequency of reweighing the resident. For example, reweighing a resident within a week of initiating or substantially revising nutritional interventions to address anorexia or weight loss assists in monitoring responses to interventions. Monitoring residents who experience unplanned weight loss, including reweighing at least weekly until weight is stable or increasing and then routinely thereafter, helps clarify his/her responses to interventions. However in some residents, subsequent weight monitoring may not be clinically indicated (e.g., palliative care resident).
Nutrition-related goals may need to be modified, depending on factors such as further clarification of underlying causes (e.g., when evidence suggests that unmodifiable factors may prevent improved or stabilized nutritional status) and responses to current interventions. In some cases, the current plan of care may need to be modified and new or additional interventions implemented. The facility explains any decisions to continue current interventions when the resident’s nutritional status continues to decline. For example, because the goal of care for someone with a terminal, advanced, or irreversible condition has changed to palliation.

ENDNOTES

INVESTIGATIVE PROTOCOL

NUTRITIONAL STATUS

Objectives

• To determine if the facility has practices in place to maintain acceptable parameters of nutritional status for each resident based on his/her comprehensive assessment.

• To determine if failure to maintain acceptable parameters of nutritional status for each resident was avoidable or unavoidable (the resident’s clinical condition demonstrates that maintaining acceptable parameters is not possible).

• To determine if the resident has received a therapeutic diet when there is a nutritional indication.

Use

Use this protocol for each sampled resident to determine through interview, observation and record review whether the facility is in compliance with the regulation, specifically:

• To determine if residents maintained acceptable parameters of nutritional status, relative to his/her comprehensive assessment;

• For a resident who did not maintain acceptable parameters of nutritional status, to determine if the facility assessed and intervened (e.g., therapeutic diet) to enable the resident to maintain acceptable parameters of nutritional status, unless the resident’s clinical condition demonstrated that this was not possible; and

• For a resident who is at nutritional risk, to determine if the facility has identified and addressed risk factors for, and causes of, impaired nutritional status, or demonstrated why they could not or should not do so.
Procedures
Briefly review the RAI, care plan, and any additional relevant nutritional assessment information that may be available to identify facility evaluations, conclusions, and interventions to guide subsequent observations.
NOTE: For the purposes of this investigation, conduct record reviews prior to meal observations to note the resident’s therapeutic diet, food texture and level of required assistance with meals.

Observation
Observe residents during the initial tour of the facility and throughout the survey process. To facilitate the investigation, gather appropriate information (e.g., dining style, nourishment list, schedules, and policies).
During observations, surveyors may see non-traditional or alternate approaches to dining services such as buffet, restaurant style or family style dining. These alternate dining approaches may include more choices in meal options, preparations, dining areas and meal times. Such alternate dining approaches are acceptable and encouraged.
While conducting the resident dining observations:
• Observe at least two meals during the survey;
• Observe a resident’s physical appearance for signs that might indicate altered nutritional status (e.g., cachectic) and note any signs of dental and oral problems;
• Observe the delivery of care (such as assistance and encouragement during dining) to determine if interventions are consistent with the care plan;
• Observe the serving of food as planned with attention to portion sizes, preferences, nutritional supplements, prescribed therapeutic diets and between-meal snacks to determine if the interventions identified in the care plan were implemented;
• Follow up and note differences between the care plan and interventions and
• Determine if staff responded appropriately to the resident’s needs (e.g., for assistance, positioning, and supervision).

1. Interview
Interview the resident, family or resident’s representative to identify:
• Whether staff are responsive to the resident’s eating abilities and support needs, including the provision of adaptive equipment and personal assistance with meals as indicated;
• Whether the resident’s food and dining preferences are addressed to the extent possible, e.g., whether the resident is offered substitutions or choices at meal times as appropriate and in accordance with his/her preferences;
• Whether pertinent nutritional interventions, such as snacks, frequent meals, and calorie-dense foods, are provided; and
• If the resident refused needed therapeutic approaches, whether treatment options, related risks and benefits, expected outcomes and possible consequences were discussed with the resident or resident’s representative, and whether pertinent alternatives or other interventions were offered.
Interview interdisciplinary team members on various shifts (e.g., certified nursing assistant, registered dietitian, dietary supervisor/manager, charge nurse, social worker, occupational therapist, attending physician, medical director, etc.) to determine, how:
• Food and fluid intake, and eating ability and weight (and changes to any of these) are monitored and reported;
• Nutrition interventions, such as snacks, frequent meals, and calorie-dense foods are provided to prevent or address impaired nutritional status (e.g., unplanned weight changes);
• Nutrition-related goals in the care plan are established, implemented, and monitored periodically;
• Care plans are modified when indicated to stabilize or improve nutritional status (e.g., reduction in medications, additional assistance with eating, therapeutic diet orders); and
• A health care practitioner is involved in evaluating and addressing underlying causes of nutritional risks and impairment (e.g., review of medications or underlying medical causes).
If the interventions defined, or the care provided, appear to be inconsistent with current standards of practice, interview one or more physicians or other licensed health care practitioners who can provide information about the resident’s nutritional risks and needs.
Examples include, but are not limited to:
• The rationale for chosen interventions;
• How staff evaluated the effectiveness of current interventions;
• How staff managed the interventions;
• How the interdisciplinary team decided to maintain or change interventions; and
• Rationale for decisions not to intervene to address identified needs.
2. Record Review
Review the resident’s medical record to determine how the facility:
• Has evaluated and analyzed nutritional status;
• Has identified residents who are at nutritional risk;
• Has investigated and identified causes of anorexia and impaired nutritional status;
• Has identified and implemented relevant interventions to try to stabilize or improve nutritional status;
• Has identified residents’ triggered RAI for nutritional status;
• Has evaluated the effectiveness of the interventions; and
• Has monitored and modified approaches as indicated.
Documentation
Documentation of findings and conclusions related to nutritional status may be found in various locations in the medical record, including but not limited to interdisciplinary progress notes, nutrition progress notes, the CAA summary, care plan, or resident care conference notes. Review of the documentation will help the surveyor determine how the facility developed approaches to meet each resident’s nutritional needs. This information will help the surveyor determine whether a resident’s decline or failure to improve his/her nutritional status was avoidable or unavoidable.
Assessment and Monitoring
Review information including the RAI, diet and medication orders, activities of daily living worksheets, and nursing, dietitian, rehabilitation, and social service notes.
Determine if the resident’s weight and nutritional status were assessed in the context of his/her overall condition and prognosis, if nutritional requirements and risk factors were identified, and if causes of the resident’s nutritional risks or impairment were sought.
Determine:
• Whether the facility identified a resident’s desirable weight range, and identified weight loss/gain;
• Whether the facility identified the significance of any weight changes, and what interventions were needed;
• Whether there have been significant changes in the resident’s overall intake;
• Whether the reasons for the change were identified and if appropriate interventions were implemented;
• Whether the facility has calculated nutritional needs (i.e., calories, protein and fluid requirements) and identified risk factors for malnutrition;
• Whether the facility met those needs and if not, why;
• Whether the resident’s weight stabilized or improved as anticipated;
• Whether a need for a therapeutic diet was identified and implemented, consistent with the current standards of practice;
• Whether the facility indicated the basis for dietary restrictions;
• Whether the reasons for dietary changes were identified and appropriate interventions implemented;
• Whether the facility accommodated resident choice, individual food preferences, allergies, food intolerances, and fluid restrictions and if the resident was encouraged to make choices;
• Whether the facility identified and addressed underlying medical and functional causes (e.g., oral cavity lesions, mouth pain, decayed teeth, poorly fitting dentures, refusal to wear dentures, gastroesophageal reflux, or dysphagia) of any chewing or swallowing difficulties to the extent possible;
• Whether the facility identified residents requiring any type of assistance to eat and drink (e.g., assistive devices/utensils, cues, hand-over-hand, and extensive assistance), and provided such assistance;
• Whether the facility has identified residents receiving any medications that are known to cause clinically significant medication/nutrient interactions or that may affect appetite, and determined risk/benefit;
• Whether the facility identified and addressed to the extent possible medical illnesses and psychiatric disorders that may affect overall intake, nutrient utilization, and weight stability;
• Whether the facility reviewed existing abnormal laboratory test results and either implemented interventions, if appropriate, or provided a clinical justification for not intervening (see note in Laboratory/Diagnostic Evaluation);
• Whether the resident’s current nutritional status is either at or improving towards goals established by the care team; and
• Whether alternate interventions were identified when nutritional status is not improving or clinical justification is provided as to why current interventions continue to be appropriate.

Care Plan
Review the comprehensive care plan to determine if the plan is based on the comprehensive assessment and additional pertinent nutritional assessment information.
Determine if the facility developed measurable objectives, approximate time frames, and specific interventions to try to maintain acceptable parameters of nutritional status, based on the resident’s overall goals, choices, preferences, prognosis, conditions, assessed risks, and needs.
If care plan concerns, related to nutritional status are noted, interview staff responsible for care planning about the rationale for the current plan of care. If questions remain after reviewing available information including documentation in the medical record, interview the resident’s attending physician or licensed health care practitioner or the facility’s medical director (e.g., if the attending physician or licensed health care practitioner is unavailable) concerning the resident’s plan of care.
NOTE: Because the physician may not be present in the facility and have immediate access to
the resident’s medical record when the surveyor has questions, allow the facility the opportunity
to first provide any pertinent information to the physician before responding to the interview.

**Care Plan Revision**
Determine if the staff has evaluated the effectiveness of the care plan related to nutritional status
and made revisions if necessary based upon the following:
- Evaluation of nutrition-related outcomes;
- Identification of changes in the resident’s condition that require revised goals and care
  approaches; and
- Involvement of the resident or the resident’s representative in reviewing and updating the
  resident’s care plan.

**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 (to include but not limited to
management). If there is a pattern of residents who have not maintained acceptable parameters of
nutritional status without adequate clinical justification, determine if quality assurance activities
were initiated in order to evaluate the facility’s approaches to nutrition and weight issues.

**Interviews with Health Care Practitioners**
If the interventions defined, or the care provided, appear to be inconsistent with recognized
standards of practice, interview one or more health care practitioners as necessary (e.g.,
physician, hospice nurse, dietitian, charge nurse, director of nursing or medical director).
Depending on the issue, ask:
- How it was determined that chosen interventions were appropriate;
- Why identified needs had no interventions;
- How changes in condition that may justify additional or different interventions were addressed;
  and
- How staff evaluated the effectiveness of current interventions.

**DETERMINATION OF COMPLIANCE (Appendix P)**

**Synopsis of Regulation (Tag F325)**
This regulation requires that, based on the resident’s comprehensive assessment, the facility
ensures that each resident maintains acceptable parameters of nutritional status unless the
resident’s clinical condition demonstrates that this is not possible, and that to the extent possible
the resident receives a therapeutic diet when indicated.

**Criteria for Compliance**
The facility is in compliance with 42 CFR 483.25(i), Tag F325, Nutrition, if staff have:
- Assessed the resident’s nutritional status and identified factors that put the resident at risk of
  not maintaining acceptable parameters of nutritional status;
- Analyzed the assessment information to identify the medical conditions, causes and problems
  related to the resident’s condition and needs;
- Provided a therapeutic diet when indicated;
- Defined and implemented interventions to maintain or improve nutritional status that are
  consistent with the resident’s assessed needs, choices, goals, and
  recognized standards of practice, or provided clinical justification why they did not do so; and
- Monitored and evaluated the resident’s response to the interventions; and revised the
  approaches as appropriate, or justified the continuation of current approaches.
If not, failure to maintain acceptable parameters of nutritional status is avoidable, cite at Tag F325.

**Noncompliance with Tag F325**

After completing the investigative protocol, the survey team must analyze the data to determine whether noncompliance with the regulation exists. Noncompliance must be established before determining severity. A clear understanding of the facility’s noncompliance with requirements (i.e., deficient practices) is essential to determine how the deficient practice(s) relates to any actual harm or potential for harm to the resident.

Noncompliance with Tag F325 may include (but is not limited to) one or more of the following, including failure to:

- Accurately and consistently assess a resident’s nutritional status on admission and as needed thereafter;
- Identify a resident at nutritional risk and address risk factors for impaired nutritional status, to the extent possible;
- Identify, implement, monitor, and modify interventions (as appropriate), consistent with the resident’s assessed needs, choices, goals, and current standards of practice, to maintain acceptable parameters of nutritional status;
- Notify the physician as appropriate in evaluating and managing causes of the resident’s nutritional risks and impaired nutritional status;
- Identify and apply relevant approaches to maintain acceptable parameters of residents’ nutritional status; and
- Provide a therapeutic diet when indicated.

**Potential Tags for Additional Investigation**

If noncompliance with 42 CFR 483.25(i) has been identified, the survey team may have determined during the investigation of Tag F325 that concerns may also be present with related process and/or structure requirements. Examples of related process and/or structure requirements related to noncompliance with Tag F325 may include the following:

- 42 CFR 483.10, Tag F150, Resident Rights
  - Determine if the resident’s preferences related to nutrition and food intake were considered.
- 42 CFR §483.20(b)(1), Tag F272, Comprehensive Assessments
  - Determine if the facility assessed the resident’s nutritional status and the factors that put the resident at risk for failure to maintain acceptable parameters of nutritional status.
- 42 CFR §483.20(k), Tag F279, Comprehensive Care Plans
  - Determine if the facility developed a comprehensive care plan for each resident that includes measurable objectives, interventions/services, and time frames to meet the resident’s needs as identified in the resident’s assessment and provided a therapeutic diet when indicated.
- 42 CFR §483.20(k)(2)(iii), Tag F280, Comprehensive Care Plan Revision
  - Determine if the care plan was periodically reviewed and revised as necessary by qualified persons after each assessment to maintain acceptable parameters of nutritional status and provided a therapeutic diet when indicated.
- 42 CFR 483.20(k)(3)(ii), Tag F282, Provision of Care in Accordance with the Care Plan
  - Determine if the services provided or arranged by the facility were provided by qualified persons in accordance with the resident’s written plan of care.
- 42 CFR 483.25(j), Tag F327, Hydration
  - Determine if the facility took measures to maintain proper hydration.
- 42 CFR 483.25(k)(2), F328, Special Needs
o Determine if the facility took measures to provide proper treatment and care for Parenteral and Enteral Fluids.
• 42 CFR 483.25, Tag F329, Unnecessary Medicines
o Determine if food and medication interactions are impacting the residents’ dietary intake.
• 42 CFR 483.30(a), Tag F353, Sufficient Staff
o Determine if the facility had qualified staff in sufficient numbers to provide necessary care and services, including supervision, based upon the comprehensive assessment and care plan.
• 42 CFR 483.35(a)(1)(2), F361, Dietary Services - Staffing
o 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
o Determine if the facility employs sufficient support personnel competent to carry out the functions of the dietary service.
• 42 CFR 483.40(a)(1)(2), Tag F385, Physician Services – Physician Supervision
o Determine if a physician supervised the medical aspects of care of each resident, as indicated, as they relate to medical conditions that affect appetite and nutritional status.
• 42 CFR 483.75(h)(2)(ii), Tag F500, Use of Outsider resources
o If the facility does not employ a qualified dietitian, determine if the professional services of a dietitian are furnished by an outside resource, meet professional standards and principles, and are timely.
• 42 CFR 483.75(i)(2)(ii), Tag F501, Medical Director
o Determine if the medical director helped develop and implement resident care policies as they relate to maintaining acceptable parameters of nutritional status and the provision of therapeutic diets when indicated.
• 42 CFR 483.75(o), Tag F520, Quality Assessment and Assurance
o Related concerns may have been identified that would suggest the need for a review of facility practices. Such activities may involve a review of policies, staffing and staff training, contracts, etc. and interviews with management, for example. If there is a pattern of residents who have not maintained acceptable parameters of nutritional status without adequate clinical justification, determine if quality assurance activities address the facility’s approaches to nutrition and weight issues.

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 F325 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 F325 may include, but are not limited to:
   • Significant unplanned weight change;
   • Inadequate food/fluid intake;
   • Impairment of anticipated wound healing;
   • Failure to provide a therapeutic diet;
   • Functional decline; and
   • Fluid/electrolyte imbalance.
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 Tag F325. 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”.)

**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 avoidable actual or potential resident outcomes that demonstrate severity at Level 4 may include, but are not limited to:
   • Continued weight loss and functional decline resulting from ongoing, repeated systemic failure to assess and address a resident’s nutritional status and needs, and implement pertinent interventions based on such an assessment;
   • Development of life-threatening symptom(s), or the development or continuation of severely impaired nutritional status due to repeated failure to assist a resident who required assistance with meals;
   • Substantial and ongoing decline in food intake resulting in significant unplanned weight loss due to dietary restrictions or downgraded diet textures (e.g., mechanic soft, pureed) provided by the facility against the resident’s expressed preferences; or
   • Evidence of cardiac dysrhythmias or other changes in medical condition due to hyperkalemia, resulting from the facility’s failure to provide a potassium restricted therapeutic diet that was ordered.

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

- Significant unplanned weight change and impaired wound healing (not attributable to an underlying medical condition) due to the facility’s failure to revise and/or implement the care plan to address the resident’s impaired ability to feed him/herself;
- Loss of weight from declining food and fluid intake due to the facility’s failure to assess and address the resident’s use of medications that affect appetite and food intake;
- Unplanned weight change and declining food and/or fluid intake due to the facility’s failure to assess the relative benefits and risks of restricting or downgrading diet and food consistency or to obtain or accommodate resident preferences in accepting related risks;
- Decline in function related to poor food/fluid intake due to the facility’s failure to accommodate documented resident food dislikes and provide appropriate substitutes or
- A resident with known celiac disease (damage to the small intestine related to gluten allergy) develops persistent gastrointestinal symptoms including weight loss, chronic diarrhea, and vomiting, due to the facility's failure to provide a gluten-free diet (i.e., one free of wheat, barley, and rye products) as prescribed by the physician.

**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) (e.g., unplanned weight change, inadequate food/fluid intake, impairment of anticipated wound healing, functional decline, and/or fluid/electrolyte imbalance), due to the facility’s failure to help the resident maintain acceptable parameters of nutritional status.

Examples of avoidable actual or potential resident outcomes that demonstrate severity at Level 2 may include, but are not limited to:

- Failure to obtain accurate weight(s) and to verify weight(s) as needed;
- Poor intake due to the facility’s intermittent failure to provide required assistance with eating, however, the resident met identified weight goals;
- Failure to provide additional nourishment when ordered for a resident, however, the resident did not experience significant weight loss; and
- Failure to provide a prescribed sodium-restricted therapeutic diet (unless declined by the resident or the resident’s representative or not followed by the resident); however, the resident did not experience medical complications such as heart failure related to sodium excess.

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

- The failure of the facility to provide appropriate care and services to maintain acceptable parameters of nutritional status and minimize negative outcomes places residents at risk for more than minimal harm. Therefore, Severity Level 1 does not apply for this regulatory requirement.

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**F327**

*(Rev. 70, Issued: 01-07-11, Effective: 10-01-10 Implementation: 10-01-10)*
§483.25(j) Hydration

§483.25(j) Hydration. The facility must provide each resident with sufficient fluid intake to maintain proper hydration and health

Intent §483.25(j)

The intent of this regulation is to assure that the resident receives sufficient amount of fluids based on individual needs to prevent dehydration.

Interpretive Guidelines §483.25(j)

“Sufficient fluid” means the amount of fluid needed to prevent dehydration (output of fluids far exceeds fluid intake) and maintain health. The amount needed is specific for each resident, and fluctuates as the resident’s condition fluctuates (e.g., increase fluids if resident has fever or diarrhea).

Risk factors for the resident becoming dehydrated are:

• Coma/decreased sensorium;
• Fluid loss and increased fluid needs (e.g., diarrhea, fever, uncontrolled diabetes);
• Fluid restriction secondary to renal dialysis;
• Functional impairments that make it difficult to drink, reach fluids, or communicate fluid needs (e.g., aphasia);
• Dementia in which resident forgets to drink or forgets how to drink;
• Refusal of fluids; and
• Did the MDS trigger any CAAs for dehydration? What action was taken based on this information?

Consider whether assessment triggers CAAs and does the facility assess the causal factors for decline, potential for decline or lack of improvement.

A general guideline for determining baseline daily fluids needs is to multiply the resident’s body weight in kg times 30cc (2.2 lbs = 1kg), except for residents with renal or cardiac distress. An excess of fluids can be detrimental for these residents.

Procedures §483.25(j)

Identify if resident triggers any CAAs for dehydration/fluid maintenance, and cognitive loss.

Probes: §483.25(j)

Do sampled residents show clinical signs of possible insufficient fluid intake (e.g., dry skin and mucous membranes, cracked lips, poor skin turgor, thirst, fever), abnormal laboratory values (e.g., elevated hemoglobin and hematocrit, potassium, chloride, sodium, albumin, transferrin, blood urea nitrogen (BUN), or urine specific gravity)? Has the facility provided residents with adequate fluid intake to maintain proper hydration and health? If not:

• Did the facility identify any factors that put the resident at risk of dehydration?
• What care did the facility provide to reduce those risk factors and ensure adequate fluid intake (e.g., keep fluids next to the resident at all times and assisting or cuing the resident to drink)? Is staff aware of need for maintaining adequate fluid intake?
• If adequate fluid intake is difficult to maintain, have alternative treatment approaches been developed, attempt to increase fluid intake by the use of popsicles, gelatin, and other similar non-liquid foods?

F328
(Rev. 70, Issued: 01-07-11, Effective: 10-01-10 Implementation: 10-01-10)

§483.25(k) Special Needs
The facility must ensure that residents receive proper treatment and care for the following special services

Intent 483.25(k)
The intent of this provision is that the resident receives the necessary care and treatment including medical and nursing care and services when they need the specialized services as listed below.

Interpretive Guidelines §483.25(k)
The non-availability of program funding does not relieve a facility of its obligation to ensure that its residents receive all needed services listed in §1819(b)(4)(A) of the Act for Medicare and §1919(b)(4)(A) of the Act for Medicaid. For services not covered, a facility is required to assist the resident in securing any available resources to obtain the needed services.

§483.25(k)(1) Injections
Probes: §483.25(k)(1)
For sampled residents receiving one or more of these services within 7 days of the survey:
• Is proper administration technique used (i.e., maintenance of sterility; correct needle size, route)?
• Are there signs of redness, swelling, lesions from previous injections?
• If appropriate, is resident observed for adverse reaction after the injection?
• Are syringes and needles disposed of according to facility policy and accepted Practice (e.g., Centers for Disease Control and Prevention and Occupational Safety and Health Administration guidelines)?
• Do nursing notes indicate, as appropriate, the resident’s response to treatment (e.g., side effects/ adverse actions; problems at the injection site(s); relief of pain)?

§483.25(k)(2) Parenteral and Enteral Fluids
Probes: §483.25(k)(2)
Refer to appropriate sections of the MDS, as applicable.
For residents selected for a comprehensive review, or focused review as appropriate, receiving one or more of these services within 7 days of the survey:
• Are there signs of inflammation or infiltration at the insertion site?
• If the IV site, tubing, or bottle/bag is changed, is sterile technique maintained?
• Is the rate of administration that which is ordered by the Physician
• Has the resident received the amount of fluid during the past 24 hours that he/she should have received according to the physician’s orders (allow flexibility up to 150cc unless an exact fluid intake is critical for the resident)?

Procedures §483.25(k)(2)
See §483.25(g) for enteral feedings (includes gastrostomy).

§483.25(k)(3) Colostomy, Ureterostomy, or Ileostomy care
Procedures §483.25(k)(3)
Refer to appropriate sections of the MDS, as applicable.
Identify if resident triggers any CAA(s) for urinary incontinence, nutritional status, pressure ulcers (skin care).
Probes: §483.25(k)(3)
• If appropriate, is the resident provided with self-care instructions?
• Does the staff member observe and respond to any signs of resident’s discomfort about the ostomy or its care?
• Is skin surrounding the ostomy free of excoriation (abrasion, breakdown)?
• If excoriation is present, does the clinical record indicate an onset and a plan of care to treat the excoriation?

§483.25(k)(4) Tracheostomy Care
Procedures §483.25(k)(4) (Includes care of the tracheostomy site)
Refer to appropriate sections of the MDS, as applicable.
Observations for tracheostomy care are most appropriate for residents with new or relatively new tracheostomies, and may not be appropriate for those with tracheostomies of long standing.
Probes: §483.25(k)(4) (Includes care of the tracheostomy site)
• Is the skin around the tracheostomy clean and dry? Are the dressing and the ties clean and dry, with the cannula secure?
• Does the resident have signs of an obstructed airway or need for suctioning (e.g., secretions draining from mouth or tracheotomy; unable to cough to clear chest; audible crackles or wheezes; dyspneic, restless or agitated)?
• If appropriate for a specific resident, is there a suction machine and catheter immediately available?
• Is there an extra cannula of the correct size at the bedside or other place easily accessible if needed in an emergency?

For sampled residents receiving one or more of these services within 7 days of the survey:
• Is suction machine available for immediate use, clean, working, and available to a source of emergency power?
• Is there an adequate supply of easily accessible suction catheters?

§483.25(k)(5) Standard: Tracheal Suctioning
Probes: §483.25(k)(5)
Refer to appropriate sections of the MDS, as applicable.

§483.25(k)(6) Standard: Respiratory Care
Procedures §483.25(k)(6)
Refer to appropriate sections of the MDS, as applicable.
Includes use of respirators/ventilators, oxygen, intermittent positive pressure breathing (IPPB) or other inhalation therapy, pulmonary care, humidifiers, and other methods to treat conditions of the respiratory tract.
Identify if resident triggers any CAA(s) for delirium and dehydration/fluid maintenance.
Probes: §483.25(k)(6)
For sampled residents receiving one or more of these services within 7 days of the survey:
• If oxygen is in use, are precautions observed (e.g., proper storage and handling of oxygen cylinders secured)? Secondary “No Smoking” signs are not required in facilities that prohibit smoking and have signs at all major entrances that the facility does not allow smoking.
• If the survey team observes a treatment being administered, is the resident encouraged and instructed on how to assist in the treatment?
• Is the staff following the facility’s protocol and/or written procedures for ventilators (e.g., functioning alarms); frequency of staff monitoring; monitoring of resident response (e.g., use of accessory muscles to breathe, cleanliness of mouth, skin irritation), and availability of manual resuscitators?
• If the resident is ventilator dependent, is routine machine maintenance and care done (e.g., water changes/tubing changes, safety checks on alarms, and machine functioning checks)?

§483.25(k)(7) Foot Care
Procedures §483.25(k)(7)
Refer to appropriate sections of the MDS, as applicable.
Includes treatment of foot disorders by qualified persons, e.g., podiatrist, Doctor of Medicine, Doctor of Osteopathy), including, but not limited, to corns, neuroma, calluses, bunions, heel spurs, nail disorders, preventive care, to avoid foot problems in diabetic residents and residents with circulatory disorders.

Probes: §483.25(k)(7)
For residents selected for a comprehensive review, or focused review, as appropriate:
• Do nails, corns, calluses, and other foot problems appear unattended; do these foot problems interfere with resident mobility?
• Are residents able to see a qualified person when they want?
• What preventive foot care do staff provide diabetic residents?

§483.25(k)(8) Prostheses
Probes: §483.25(k)(8)
Refer to appropriate sections of the MDS, as applicable.
Includes artificial limbs, eyes, teeth.
For residents selected for a comprehensive review, or focused review, as appropriate:
• Is resident able to put on the prosthesis by himself/herself or with some assistance?
• Are residents wearing their prostheses?
• Does the prosthesis fit correctly?
• Is skin/mucous membrane in contact with the prosthesis free of abrasions, wounds, irritation?

§483.25(l) Unnecessary Drugs
1. General. Each resident’s drug regimen must be free from unnecessary drugs. An unnecessary drug is any drug when used:
   (i) In excessive dose (including duplicate therapy); or
   (ii) For excessive duration; or
   (iii) Without adequate monitoring; or
   (iv) Without adequate indications for its use; or
   (v) In the presence of adverse consequences which indicate the dose should be reduced or discontinued; or
   (vi) Any combinations of the reasons above.
2. Antipsychotic Drugs. Based on a comprehensive assessment of a resident, the facility must ensure that:
   (i) Residents who have not used antipsychotic drugs are not given these drugs unless antipsychotic drug therapy is necessary to treat a specific condition as diagnosed and documented in the clinical record; and
   (ii) Residents who use antipsychotic drugs receive gradual dose reductions, and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs.

INTENT: §483.25(l) Unnecessary drugs
The intent of this requirement is that each resident’s entire drug/medication regimen be managed and monitored to achieve the following goals:
• The medication regimen helps promote or maintain the resident’s highest practicable mental, physical, and psychosocial well-being, as identified by the resident and/or representative(s) in collaboration with the attending physician and facility staff;
• Each resident receives only those medications, in doses and for the duration clinically indicated to treat the resident’s assessed condition(s);
• Non-pharmacological interventions (such as behavioral interventions) are considered and used when indicated, instead of, or in addition to, medication;
• Clinically significant adverse consequences are minimized; and
• The potential contribution of the medication regimen to an unanticipated decline or newly emerging or worsening symptom is recognized and evaluated, and the regimen is modified when appropriate.

NOTE: This guidance applies to all categories of medications including antipsychotic medications.

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

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

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

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

• “Adverse consequence” is 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 consequences. It may be either a secondary effect of a medication that is usually undesirable and different from the therapeutic effect of the medication or any response to a medication that is noxious and unintended and occurs in doses for prophylaxis, diagnosis, or treatment. The term “side effect” is often used interchangeably with ADR; however, side effects are but one of five ADR categories, the others being hypersensitivity, idiosyncratic response, toxic reactions, and adverse medication interactions. A side effect is an expected, well-known reaction that occurs with a predictable frequency and may or may not constitute an adverse consequence.

• “Anticholinergic side effect” is an effect of a medication that opposes or inhibits the activity of the parasympathetic (cholinergic) nervous system to the point of causing symptoms such as dry mouth, blurred vision, tachycardia, urinary retention, constipation, confusion, delirium, or hallucinations.

• “Behavioral interventions” are individualized non-pharmacological approaches (including direct care and activities) that are provided as part of a supportive physical and psychosocial environment, and are directed toward preventing, relieving, and/or accommodating a resident’s distressed behavior.

• “Clinically significant” refers to effects, results, or consequences that materially affect or are likely to affect an individual’s mental, physical, or psychosocial well-being either positively by preventing, stabilizing, or improving a condition or reducing a risk, or negatively by exacerbating, causing, or contributing to a symptom, illness, or decline in status.
“Distressed behavior” is behavior that reflects individual discomfort or emotional strain. It may present as crying, apathetic or withdrawn behavior, or as verbal or physical actions such as: pacing, cursing, hitting, kicking, pushing, scratching, tearing things, or grabbing others.

“Dose” is the total amount/strength/concentration of a medication given at one time or over a period of time. The individual dose is the amount/strength/concentration received at each administration. The amount received over a 24-hour period may be referred to as the daily dose.

- “Excessive dose” means the total amount of any medication (including duplicate therapy) given at one time or over a period of time that is greater than the amount recommended by the manufacturer’s label, package insert, current standards of practice for a resident’s age and condition, or clinical studies or evidence-based review articles that are published in medical and/or pharmacy journals and that lacks evidence of:
  - A review for the continued necessity of the dose;
  - Attempts at, or consideration of the possibility of, tapering a medication; and
  - A documented clinical rationale for the benefit of, or necessity for, the dose or for the use of multiple medications from the same pharmacological class.

“Duplicate therapy” refers to multiple medications of the same pharmacological class/category or any medication therapy that substantially duplicates a particular effect of another medication that the individual is taking.

“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, clinical practice guidelines, clinical studies or evidence-based review articles, and/or without either evidence of additional therapeutic benefit for the resident or clinical evidence that would warrant the continued use of the medication.

“Extrapyramidal symptoms (EPS)” are neurological side effects that can occur at any time from the first few days of treatment to years later. EPS includes various syndromes such as:

- Akathisia, which refers to a distressing feeling of internal restlessness that may appear as constant motion, the inability to sit still, fidgeting, pacing, or rocking.
- Medication-induced Parkinsonism, which refers to a syndrome of Parkinson-like symptoms including tremors, shuffling gait, slowness of movement, expressionless face, drooling, postural unsteadiness and rigidity of muscles in the limbs, neck and trunk.
- Dystonia, which refers to an acute, painful, spastic contraction of muscle groups (commonly the neck, eyes and trunk) that often occurs soon after initiating treatment and is more common in younger individuals.

“Gradual Dose Reduction (GDR)” is the stepwise tapering of a dose to determine if symptoms, conditions, or risks can be managed by a lower dose or if the dose or medication can be discontinued.

“Indications for use” is the identified, documented clinical rationale for administering a medication that is based upon an assessment of the resident’s condition and therapeutic goals and is consistent with manufacturer’s recommendations and/or clinical practice guidelines, clinical standards of practice, medication references, clinical studies or evidence-based review articles that are published in medical and/or pharmacy journals.

“Insomnia” is the inability to sleep characterized by difficulty falling asleep, difficulty staying asleep, early waking, or non-restorative sleep, which may result in impaired physical, social, or cognitive function.
• “Medication Interaction” is the impact of another substance (such as another medication, nutritional supplement including herbal products, 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 by a pharmacist, 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 in collaboration with other members of the interdisciplinary team.51

• “Monitoring” is the ongoing collection and analysis of information (such as observations and diagnostic test results) and comparison to baseline data in order to:
  o Ascertain the individual’s response to treatment and care, including progress or lack of progress toward a therapeutic goal;
  o Detect any complications or adverse consequences of the condition or of the treatments; and
  o Support decisions about modifying, discontinuing, or continuing any interventions.

• “Neuroleptic Malignant Syndrome” (NMS) is a syndrome related to the use of medications, mainly antipsychotics, that typically presents with a sudden onset of diffuse muscle rigidity, high fever, labile blood pressure, tremor, and notable cognitive dysfunction. It is potentially fatal if not treated immediately, including stopping the offending medications.

• “Non-pharmacological interventions” refers to approaches to care that do not involve medications, generally directed towards stabilizing or improving a resident’s mental, physical or psychosocial well-being.

• “Psychopharmacological medication” is any medication used for managing behavior, stabilizing mood, or treating psychiatric disorders.

• “Serotonin Syndrome” is a potentially serious clinical condition resulting from overstimulation of serotonin receptors. It is commonly related to the use of multiple serotonin-stimulating medications (e.g., SSRIs, SNRIs, triptans, certain antibiotics). Symptoms may include restlessness, hallucinations, confusion, loss of coordination, fast heart beat, rapid changes in blood pressure, increased body temperature, overactive reflexes, nausea, vomiting and diarrhea.

• “Tardive dyskinesia” refers to abnormal, recurrent, involuntary movements that may be irreversible and typically present as lateral movements of the tongue or jaw, tongue thrusting, chewing, frequent blinking, brow arching, grimacing, and lip smacking, although the trunk or other parts of the body may also be affected.

OVERVIEW

Medications are an integral part of the care provided to residents of nursing facilities. They are administered to try to achieve various outcomes, such as curing an illness, diagnosing a disease or condition, arresting or slowing a disease process, reducing or eliminating symptoms, or preventing a disease or symptom.

A study of 33,301 nursing facility residents found that an average of 6.7 medications were ordered per resident, with 27 percent of residents taking nine or more medications.52 Analysis of antipsychotic use by 693,000 Medicare nursing home residents revealed that 28.5 percent of the doses received were excessive and 32.2 percent lacked appropriate indications for use. 53

Proper medication selection and prescribing (including dose, duration, and type of medication(s)) may help stabilize or improve a resident’s outcome, quality of life and functional capacity. Any
medication or combination of medications—or the use of a medication without adequate
indications, in excessive dose, for an excessive duration, or without adequate monitoring—may
increase the risk of a broad range of adverse consequences such as medication interactions,
depression, confusion, immobility, falls, and related hip fractures.
Intrinsic factors including physiological changes accompanying the aging process, multiple
comorbidities, and certain medical conditions may affect the absorption, distribution, metabolism
or elimination of medications from the body and may also increase an individual’s risk of
adverse consequences.
While assuring that only those medications required to treat the resident’s assessed condition are
being used, reducing the need for and maximizing the effectiveness of medications are important
considerations for all residents. Therefore, as part of all medication management (including
antipsychotics), it is important for the interdisciplinary team to consider non-pharmacological
approaches. Educating facility staff and providers in addition to implementing non-
pharmacological approaches to resident conditions prior to, and/or in conjunction with, the use of
medications may minimize the need for medications or reduce the dose and duration of those
medications.54
Examples of non-pharmacological interventions may include:
• Increasing the amount of resident exercise, intake of liquids and dietary fiber in conjunction
with an individualized bowel regimen to prevent or reduce constipation and the use of
medications (e.g. laxatives and stool softeners);
• Identifying, addressing, and eliminating or reducing underlying causes of distressed behavior
such as boredom and pain;
• Using sleep hygiene techniques and individualized sleep routines;
• Accommodating the resident’s behavior and needs by supporting and encouraging activities
reminiscent of lifelong work or activity patterns, such as providing early morning activity for a
farmer used to awakening early;
• Individualizing toileting schedules to prevent incontinence and avoid the use of incontinence
medications that may have significant adverse consequences (e.g., anticholinergic effects);
• Developing interventions that are specific to resident’s interests, abilities, strengths and needs,
such as simplifying or segmenting tasks for a resident who has trouble following complex
directions;
• Using massage, hot/warm or cold compresses to address a resident’s pain or discomfort; or
• Enhancing the taste and presentation of food, assisting the resident to eat, addressing food
preferences, and increasing finger foods and snacks for an individual with dementia, to improve
appetite and avoid the unnecessary use of medications intended to stimulate appetite.
The indications for initiating, withdrawing, or withholding medication(s), as well as the use of
non-pharmacological approaches, are determined by assessing the resident’s underlying
condition, current signs and symptoms, and preferences and goals for treatment. This includes,
where possible, the identification of the underlying cause(s), since a diagnosis alone may not
warrant treatment with medication.
Orders from multiple prescribers can increase the resident’s chances of receiving unnecessary
medications. Many residents receive orders for medications from several practitioners, for
example, attending and on-call physicians, consultants, and nurse practitioner(s). It is important
that the facility clearly identify who is responsible for prescribing and identifying the indications
for use of medication(s), for providing and administering the medication(s), and for monitoring
the resident for the effects and potential adverse consequence of the medication regimen. This is
also important when care is delivered or ordered by diverse sources such as consultants, providers, or suppliers (e.g., hospice or dialysis programs).

Staff and practitioner access to current medication references and pertinent clinical protocols helps to promote safe administration and monitoring of medications. One of the existing mechanisms to warn prescribers about risks associated with medications is the Food and Drug Administration (FDA) requirement that manufacturers include within the medication labeling warnings about adverse reactions and potential safety hazards identified both before and after approval of a medication, and what to do if they occur (Visit: www.fda.gov/medwatch/safety.htm). Manufacturers are required to update labels to warn about newly identified safety hazards—regardless of whether causation has been proven and whether the medication is prescribed for a disease or condition that is not included in the “Indications and Usage” section of the labeling (so-called “off-label” or unapproved use). The FDA may require manufacturers to place statements about serious problems in a prominently displayed box (so-called boxed or “black box” warnings), which indicates a need to closely evaluate and monitor the potential benefits and risks of that medication.

The facility’s pharmacist is a valuable source of information about medications. Listings or descriptions of most significant risks, recommended doses, medication interactions, cautions, etc. can be found in widely available, standard references, and computer software and systems that provide up-to-date information. It is important to note that some of the medication information found in many of these references is not specific to older adults or institutionalized individuals.

Clinical standards of practice and clinical guidelines established by professional groups are useful to guide clinicians. Some of the recognized clinical resources available for understanding the overall treatment and management of medical problems, symptoms and medication consequences and precautions include the:

- American Geriatrics Society www.americangeriatrics.org and www.geriatricsatyourfingertips.org;
- American Medical Directors Association www.amda.com;
- American Psychiatric Association www.psych.org;
- American Society of Consultant Pharmacists www.ASCP.com;
- Agency for Healthcare Research and Quality (AHRQ) www.ahrq.gov;
- American Association for Geriatric Psychiatry www.aagp.org;
- Association for Practitioners in Infection Control and Epidemiology www.apic.org;
- CMS Sharing Innovations in Quality Web site maintained at: http://siq.air.org;
- National Guideline Clearinghouse www.guideline.gov;
- Quality Improvement Organizations, Medicare Quality Improvement Community Initiatives www.medqic.org;
- U.S. Department of Health and Human Services, Food and Drug Administration Web site www.fda.gov/medwatch/safety.htm;
- U.S. Department of Health and Human Services, National Institute of Mental Health Web site, which includes publications and clinical research information www.nimh.nih.gov;
- Mace N, Rabins P. The 36-Hour Day: A Family Guide to Caring for Persons with Alzheimer Disease, Related Dementing Illnesses, and Memory Loss in Later Life; and

NOTE: References to non-CMS sources or sites on the Internet included above or later
MEDICATION MANAGEMENT

Medication management is based in the care process and includes recognition or identification of the problem/need, assessment, diagnosis/cause identification, management/treatment, monitoring, and revising interventions, as warranted. The attending physician plays a key leadership role in medication management by developing, monitoring, and modifying the medication regimen in conjunction with residents and/or representative(s) and other professionals and direct care staff (the interdisciplinary team).

When selecting medications and non-pharmacological interventions, members of the interdisciplinary team participate in the care process to identify, assess, address, advocate for, monitor, and communicate the resident’s needs and changes in condition.

This guidance is intended to help the surveyor determine whether the facility’s medication management supports and promotes:

- Selection of medications(s) based on assessing relative benefits and risks to the individual resident;
- Evaluation of a resident’s signs and symptoms, in order to identify the underlying cause(s), including adverse consequences of medications;
- Selection and use of medications in doses and for the duration appropriate to each resident’s clinical conditions, age, and underlying causes of symptoms;
- The use of non-pharmacological interventions, when applicable, to minimize the need for medications, permit use of the lowest possible dose, or allow medications to be discontinued; and
- The monitoring of medications for efficacy and clinically significant adverse consequences.

The resident’s clinical record documents and communicates to the entire team the basic elements of the care process. Information about aspects of the care process related to medications may be found in various locations within the record, such as: hospital discharge summaries and transfer notes, progress notes and interdisciplinary notes, history and physical examination, Resident Assessment Instrument (RAI), plan of care, laboratory reports, professional consults, medication orders, Medication Regimen Review (MRR) reports, and Medication Administration Records (MAR).

Resident Choice – A resident and/or representative(s) has the right to be informed about the resident’s condition; treatment options, relative risks and benefits of treatment, required monitoring, expected outcomes of the treatment; and has the right to refuse care and treatment. If a resident refuses treatment, the facility staff and physician should inform the resident about the risks related to the refusal, and discuss appropriate alternatives such as offering the medication at another time or in another dosage form, or offer an alternative medication or non-pharmacological approach, if available.

Advance Directives – A resident may have written or verbal directions related to treatment choices (or a decision has been made by the resident’s surrogate or representative) in accordance with state law. An advance directive is a means for the resident to communicate his or her wishes, which may include withdrawing or withholding medications. Whether or not a resident
has an advanced directive, the facility is responsible for giving treatment, support, and other care that is consistent with the resident’s condition and applicable care instructions.

NOTE: Choosing not to be resuscitated (reflected in a “Do Not Resuscitate” (DNR) order) indicates that the resident should not be resuscitated if respirations and/or cardiac function cease. A DNR order by itself does not indicate that the resident has declined other appropriate treatment and services.

Under these regulations, medication management includes consideration of:
I. Indications for use of medication (including initiation or continued use of antipsychotic medication);
II. Monitoring for efficacy and adverse consequences;
III. Dose (including duplicate therapy);
IV. Duration;
V. Tapering of a medication dose/gradual dose reduction for antipsychotic medications; and
VI. Prevention, identification, and response to adverse consequences.

I. Indications for Use of Medication (including Initiation or Continued Use of an Antipsychotic Medication)

An evaluation of the resident helps to identify his/her needs, comorbid conditions, and prognosis to determine factors (including medications and new or worsening medical conditions) that are affecting signs, symptoms, and test results. This evaluation process is important when making initial medication/intervention selections and when deciding whether to modify or discontinue a current medication intervention. Regarding “as needed” (PRN) medications, it is important to evaluate and document the indication(s), specific circumstance(s) for use, and the desired frequency of administration. As part of the evaluation, gathering and analyzing information helps define clinical indications and provide baseline data for subsequent monitoring. The evaluation also clarifies:
• Whether other causes for the symptoms (including behavioral distress that could mimic a psychiatric disorder) have been ruled out;
• Whether the signs, symptoms, or related causes are persistent or clinically significant enough (e.g., causing functional decline) to warrant the initiation or continuation of medication therapy;
• Whether non-pharmacological interventions are considered;
• Whether a particular medication is clinically indicated to manage the symptom or condition; and
• Whether the intended or actual benefit is sufficient to justify the potential risk(s) or adverse consequences associated with the selected medication, dose, and duration.

The content and extent of the evaluation may vary with the situation and may employ various assessment instruments and diagnostic tools. Examples of information to be considered and evaluated may include, but are not limited to, the following:
• An appropriately detailed evaluation of mental, physical, psychosocial, and functional status, including comorbid conditions and pertinent psychiatric symptoms and diagnoses and a description of resident complaints, symptoms, and signs (including the onset, scope, frequency, intensity, precipitating factors, and other important features);
• Each resident’s goals and preferences;
• Allergies to medications and foods and potential for medication interactions;
• A history of prior and current medications and non-pharmacological interventions (including therapeutic effectiveness and any adverse consequences);
• Recognition of the need for end-of-life or palliative care; and
The refusal of care and treatment, including the basis for declining it, and the identification of pertinent alternatives.

NOTE: The CAA_s, an integral part of the comprehensive resident assessment, help identify some possible categories of causes of various symptoms including: behavioral symptoms of distress, delirium, and changes in functional status. Refer to 42 CFR 483.20 and the MDS and CAA_s.

Circumstances that warrant evaluation of the resident and medication(s) may include:
- Admission or re-admission;
- A clinically significant change in condition/status;
- A new, persistent, or recurrent clinically significant symptom or problem;
- A worsening of an existing problem or condition;
- An unexplained decline in function or cognition;
- A new medication order or renewal of orders; and
- An irregularity identified in the pharmacist’s monthly medication regimen review.

Specific considerations related to these circumstances may include the following:

** Admission (or Readmission) ** – Some residents may be admitted on medications for an undocumented chronic condition or without a clear indication as to why a medication was begun or should be continued. It is expected that the attending physician, pharmacist, and staff subsequently determine if continuing the medication is justified by evaluating the resident’s clinical condition, risks, existing medication regimen, and related factors. If the indications for continuing the medication are unclear, or if the resident’s symptoms could represent a clinically significant adverse consequence, additional consideration of the rationale for the medication(s) is warranted.

** Multiple prescribers ** – Regardless of who the prescribers are, the continuation of a medication needs to be evaluated to determine if the medication is still warranted in the context of the resident’s other medications and comorbidities. Medications prescribed by a specialist or begun in another care setting, such as the hospital, need to have a clinically pertinent documented rationale.

** New medication order as an emergency measure ** – When a resident is experiencing an acute medical problem or psychiatric emergency (e.g., the resident’s behavior poses an immediate risk to the resident or others), medications may be required. In these situations, it is important to identify and address the underlying causes of the problem or symptoms. Once the acute phase has stabilized, the staff and prescriber consider whether medications are still relevant. Subsequently, the medication is reduced or discontinued as soon as possible or the clinical rationale for continuing the medication is documented. When psychopharmacological medications are used as an emergency measure, adjunctive approaches, such as behavioral interventions and techniques should be considered and implemented as appropriate. Longer term management options should be discussed with the resident and/or representative(s).

** Psychiatric disorders or distressed behavior ** – As with all symptoms, it is important to seek the underlying cause of distressed behavior, either before or while treating the symptom. Examples of potential causes include:
- Delirium;
- Pain;
- Chronic psychiatric illness such as schizophrenia or schizoaffective disorder;
- Acute psychotic illness such as brief reactive psychosis;
- Substance intoxication or withdrawal;
Environmental stressors (e.g., excessive heat, noise, overcrowding);
Psychological stressors (e.g., disruption of the resident’s customary daily routine, grief over nursing home admission or health status, abuse, taunting, intimidation);
Neurological illnesses such as Huntington’s disease or Tourette’s syndrome; or
Medical illnesses such as Alzheimer’s disease, Lewy body disease, vascular dementia, or frontotemporal dementia.
See Table I below in these guidelines for key issues related to indications for use of antipsychotic agents, monitoring, and adverse consequences.

II. Monitoring for Efficacy and Adverse Consequences
The information gathered during the initial and ongoing evaluations is essential to:
• Incorporate into a comprehensive care plan that reflects appropriate medication related goals and parameters for monitoring the resident’s condition, including the likely medication effects and potential for adverse consequences. Examples of this information may include the FDA boxed warnings or adverse consequences that may be rare, but have sudden onset or that may be irreversible. If the facility has established protocols for monitoring specific medications and the protocols are accessible for staff use, the care plan may refer staff to these protocols;
• Optimize the therapeutic benefit of medication therapy and minimize or prevent potential adverse consequences;
• Establish parameters for evaluating the ongoing need for the medication; and
• Verify or differentiate the underlying diagnoses or other underlying causes of signs and symptoms.
The key objectives for monitoring the use of medications are to track progress towards the therapeutic goal(s) and to detect the emergence or presence of any adverse consequences. Effective monitoring relies upon understanding the indications and goals for using the medication, identifying relevant baseline information, identifying the criteria for evaluating the benefit(s) of the medication, and recognizing and evaluating adverse consequences. Monitoring parameters are based on the resident’s condition, the pharmacologic properties of the medication being used and its associated risks, individualized therapeutic goals, and the potential for clinically significant adverse consequences.
Adverse consequences related to medications are common enough to warrant serious attention and close monitoring. For example, a study reported that 338 (42%) of 815 adverse drug events were judged preventable, and that common omissions included inadequate monitoring and either lack of response or a delayed response to signs, symptoms, or laboratory evidence of medication toxicity.55
Sources of information to facilitate defining the monitoring criteria or parameters may include cautions, warnings, and identified adverse consequences from:
• Manufacturers’ package inserts and black-box warnings;
• Facility policies and procedures;
• Pharmacists;
• Clinical practice guidelines or clinical standards of practice;
• Medication references; and
• Clinical studies or evidence-based review articles that are published in medical and/or pharmacy journals.
Monitoring of the resident’s response to any medication(s) is essential to evaluate the ongoing benefits as well as risks of various medications. It is important, for example, to monitor the effectiveness of medications used to address behavioral symptoms (e.g., behavioral monitoring).
or to treat hypertension (e.g., periodic pulse and blood pressure). Monitoring for adverse consequences involves ongoing vigilance and may periodically involve objective evaluation (e.g., assessing vital signs may be indicated if a medication is known to affect blood pressure, pulse rate and rhythm, or temperature). Using quantitative and qualitative monitoring parameters facilitates consistent and objective collection of information by the facility. Examples of tools that may be used by facility staff, practitioners, or consultants to determine baseline status as well as to monitor for effectiveness and potential adverse consequences may include, but are not limited to the following:

**Common Conditions/ Symptoms**

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<tr>
<th>Potential Applications</th>
<th>Examples of Tools</th>
<th>Source/Reference</th>
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<tr>
<td>Common Conditions/ Symptoms</td>
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<tr>
<td>Diabetes</td>
<td>Blood glucose,</td>
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<td>Hemoglobin A1C</td>
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<td>Diagnose diabetes and determine diabetic control</td>
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<tr>
<td>Alzheimer’s Disease / Dementia</td>
<td>Mini Mental Status Exam</td>
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<td>(MMSE)</td>
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<td></td>
<td>Determine degree of cognitive impairment</td>
<td><a href="http://www.emedicine.com/med/topic3358.htm">www.emedicine.com/med/topic3358.htm</a></td>
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<td><a href="http://www.fpnotebook.com/NEU75.htm">www.fpnotebook.com/NEU75.htm</a></td>
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<tr>
<td>Functional Decline</td>
<td>Instrumental Activities of Daily Living (IADL)</td>
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<td>Resident Assessment Instrument (RAI)</td>
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<td></td>
<td>Functional Alzheimer’s Screening Test (FAST)</td>
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<td></td>
<td>Assess functional capabilities</td>
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<td>Assess aspects of nursing home resident’s behavior and function</td>
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<td>Assess level of function in individuals with dementia</td>
<td><a href="http://www.fpnotebook.com/GER3.htm">www.fpnotebook.com/GER3.htm</a></td>
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<td><a href="http://geriatrics.uthscsa.edu/educational/med_students/fastscale_admin.htm">http://geriatrics.uthscsa.edu/educational/med_students/fastscale_admin.htm</a></td>
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<table>
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<tr>
<th>Examples of Tools</th>
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<tr>
<td>Delirium</td>
<td>Confusion Assessment Method (CAM)</td>
</tr>
<tr>
<td></td>
<td>Screen for cognitive impairment and delirium</td>
</tr>
</tbody>
</table>
Bipolar Disorder
Mania Rating Scale
Assess severity of mania
www.brainexplorer.org/factsheets/Psychiatry%20Rating%20Scales.pdf
Pain
List of pain scales
Assess pain characteristics (e.g., intensity, impact, timing)
www.chcr.brown.edu/pcoc/Physical.htm
Depression
Geriatric Depression Scale
Cornell Depression in Dementia Scale
Screen or monitor individuals at risk for depression
Screen or monitor for depression in individuals with cognitive impairment
www.assessmentpsychology.com/geriatricscales.htm
www.hartfordign.org/publications/trythis/issue04.pdf
www.merck.com/mrkshared/mmg/tables/33t4.jsp
www.emoryhealthcare.org/departments/fuqua/CornellScale.pdf
Abnormal Movements
Abnormal Involuntary Movement Scales (AIMS)
Assess presence and severity of involuntary movements that may be due to disease or medications
www.carepaths.com/pages/Instruments_AIMS.asp
Common Conditions/ Symptoms
Examples of Tools
Potential Applications
Source/Reference
Behavioral Symptoms associated with Dementia
Neuro-psychiatric Inventory-Nursing Home Version (NPI-NH)
Behavioral Pathology in Alzheimer’s Disease Rating Scale (Behave AD)
Cohen-Mansfield Agitation Inventory (CMAI)
Screen or monitor for behavior associated with dementia (e.g., hallucinations, agitation or anxiety)
Provide a global rating of non-cognitive symptoms.
Assess/rate distressed behavior in older individuals
www.alzforum.org/dis/dia/tes/neuropsychological.asp
www.researchinstituteonaging.org/assessment.html
www.geriatric-times.com/g010533.html
Monitoring involves several steps, including:
• **Identifying the essential information and how it will be obtained and reported.** It is important to consider who is responsible for obtaining the information, which information should be collected, and how the information will be documented. The information that is collected
depends on therapeutic goals, detection of potential or actual adverse consequences, and
collection of risk factors, such as:
o Medication-medication, medication-food interactions;
o Clinical condition (for example renal disease);
o Properties of the medication;
o Black-box warnings; and
o History of adverse consequences related to a similar medication.

**Determining the frequency of monitoring.** The frequency and duration of monitoring needed
to identify therapeutic effectiveness and adverse consequences will depend on factors such as
clinical standards of practice, facility policies and procedures, manufacturer’s specifications, and
the resident’s clinical condition. Monitoring involves three aspects:
o Periodic planned evaluation of progress toward the therapeutic goals;
o Continued vigilance for adverse consequences; and
o Evaluation of identified adverse consequences.

For example, when monitoring all psychopharmacological medications and sedative/hypnotics,
the facility should review the continued need for them, at least quarterly (i.e., a 3 month period),
and document the rationale for continuing the medication, including evidence that the following
had been evaluated:
• The resident’s target symptoms and the effect of the medication on the severity, frequency, and
other characteristics of the symptoms;
• Any changes in the resident’s function during the previous quarter (e.g., as identified in the
Minimum Data Set); and
• Whether the resident experienced any medication-related adverse consequences during the
previous quarter.

An important aspect of the review would include whether the pharmacological management of
the resident’s medical and/or psychiatric disorder is consistent with recommendations from
relevant clinical practice guidelines, current standards of practice, and/or manufacturer’s
specifications.

**Defining the methods for communicating, analyzing, and acting upon relevant
information.** The monitoring process needs to identify who is to communicate with the
prescriber, what information is to be conveyed, and when to ask the prescriber to evaluate and
consider modifying the medication regimen.

It is important to consider whether a resident’s medications are promoting or maintaining a
resident’s highest practicable level of function. If the therapeutic goals are not being met or the
resident is experiencing adverse consequences, it is essential for the prescriber in collaboration
with facility staff and pharmacist to consider whether current medications and doses continue to
be appropriate or should be reduced, changed, or discontinued.

**Re-evaluating and updating monitoring approaches.** Modification of monitoring may be
necessary when the resident experiences changes, such as:
o Acute onset of signs or symptoms or worsening of chronic disease;
o Decline in function or cognition;
o Addition or discontinuation of medications and/or non-pharmacological interventions;
o Addition or discontinuation of care and services such as enteral feedings; and
o Significant changes in diet that may affect medication absorption or effectiveness or increase
adverse consequences.
Additional examples of circumstances that may indicate a need to modify the monitoring include: changes in manufacturer’s specifications, FDA warnings, pertinent clinical practice guidelines, or other literature about how and what to monitor.

III. Dose (Including Duplicate Therapy)
A prescriber orders medication(s) based on a variety of factors including the resident’s diagnoses, signs and symptoms, current condition, age, coexisting medication regimen, review of lab and other test results, input from the interdisciplinary team about the resident, the type of medication(s), and therapeutic goals being considered or used. Factors influencing the appropriateness of any dose include the resident’s clinical response, possible adverse consequences, and other resident and medication-related variables. Often, lab test results such as serum medication concentrations are only a rough guide to dosing. Significant adverse consequences can occur even when the concentration is within the therapeutic range. Serum concentrations alone may not necessarily indicate a need for dose adjustments, but may warrant further evaluation of a dose or the medication regimen.

The route of administration influences a medication’s absorption and ultimately the dose received. Examples of factors that can affect the absorption of medications delivered by transdermal patches include skin temperature and moisture, and the integrity of the patch. Similarly, the flow rate of intravenous solutions affects the amount received at a given time. Duplicate therapy is generally not indicated, unless current clinical standards of practice and documented clinical rationale confirm the benefits of multiple medications from the same class or with similar therapeutic effects. Some examples of potentially problematic duplicate therapy include:

- Use of more than one product containing the same medication can lead to excessive doses of a medication, such as concomitant use of acetaminophen/hydrocodone and acetaminophen, which may increase the risk of acetaminophen toxicity;
- Use of multiple laxatives to improve or maintain bowel movements, which may lead to abdominal pain or diarrhea;
- Concomitant use of multiple benzodiazepines such as lorazepam for anxiety and temazepam for sleep, which may increase fall risk; or
- Use of medications from different therapeutic categories that have similar effects or properties, such as multiple medications with anticholinergic effects (e.g., oxybutynin and diphenhydramine), which may increase the risk of delirium or excessive sedation.

Documentation is necessary to clarify the rationale for and benefits of duplicate therapy and the approach to monitoring for benefits and adverse consequences. This documentation may be found in various areas of the resident’s clinical record.

IV. Duration
Many conditions require treatment for extended periods, while others may resolve and no longer require medication therapy. For example:

- Acute conditions such as cough and cold symptoms, upper respiratory condition, nausea and/or vomiting, acute pain, psychiatric or behavioral symptoms;
- Proton pump inhibitors (PPIs)/H2 blockers used for prophylaxis during the acute phase of a medical illness should be tapered and possibly discontinued after the acute phase of the illness has resolved, unless there is a valid clinical indication for prolonged use.

Periodic re-evaluation of the medication regimen is necessary to determine whether prolonged or indefinite use of a medication is indicated. The clinical rationale for continued use of a medication(s) may have been demonstrated in the clinical record, or the staff and prescriber may
present pertinent clinical reasons for the duration of use. Common considerations for appropriate duration may include:

- A medication initiated as a result of a time-limited condition (for example, delirium, pain, infection, nausea and vomiting, cold and cough symptoms, or itching) is then discontinued when the condition has resolved, or there is documentation indicating why continued use is still relevant. Failure to review whether the underlying cause has resolved may lead to excessive duration.
- A medication is discontinued when indicated by facility stop order policy or by the prescriber’s order, unless there is documentation of the clinical justification for its extended use. A medication administered beyond the stop date established in the prescriber’s order or by facility policy, without evidence of clinical justification for continued use of the medication, may be considered excessive duration.

V. Tapering of a Medication Dose/Gradual Dose Reduction (GDR)

The requirements underlying this guidance emphasize the importance of seeking an appropriate dose and duration for each medication and minimizing the risk of adverse consequences. The purpose of tapering a medication is to find an optimal dose or to determine whether continued use of the medication is benefiting the resident.

Tapering may be indicated when the resident’s clinical condition has improved or stabilized, the underlying causes of the original target symptoms have resolved, and/or non-pharmacological interventions, including behavioral interventions, have been effective in reducing the symptoms. There are various opportunities during the care process to evaluate the effects of medications on a resident’s function and behavior, and to consider whether the medications should be continued, reduced, discontinued, or otherwise modified. Examples of these opportunities include:

- During the monthly medication regimen review, the pharmacist evaluates resident-related information for dose, duration, continued need, and the emergence of adverse consequences for all medications;
- When evaluating the resident’s progress, the practitioner reviews the total plan of care, orders, the resident’s response to medication(s), and determines whether to continue, modify, or stop a medication; and
- During the quarterly MDS review, the facility evaluates mood, function, behavior, and other domains that may be affected by medications.

Sometimes, the decision about whether to continue a medication is clear; for example, someone with a history of multiple episodes of depression or recurrent seizures may need an antidepressant or anticonvulsant medication indefinitely. Often, however, the only way to know whether a medication is needed indefinitely and whether the dose remains appropriate is to try reducing the dose and to monitor the resident closely for improvement, stabilization, or decline. The time frames and duration of attempts to taper any medication depend on factors including the coexisting medication regimen, the underlying causes of symptoms, individual risk factors, and pharmacologic characteristics of the medications. Some medications (e.g., antidepressants, sedative/hypnotics, opioids) require more gradual tapering so as to minimize or prevent withdrawal symptoms or other adverse consequences.

NOTE: If the resident’s condition has not responded to treatment or has declined despite treatment, it is important to evaluate both the medication and the dose to determine whether the medication should be discontinued or the dosing should be altered, whether or not the facility has implemented GDR as required, or tapering.
**Considerations Specific to Antipsychotics.** The regulation addressing the use of antipsychotic medications identifies the process of tapering as a “gradual dose reduction (GDR)” and requires a GDR, unless clinically contraindicated. Within the first year in which a resident is admitted on an antipsychotic medication or after the facility has initiated an antipsychotic medication, the facility must attempt a GDR in two separate quarters (with at least one month between the attempts), unless clinically contraindicated. After the first year, a GDR must be attempted annually, unless clinically contraindicated.

For any individual who is receiving an antipsychotic medication to treat behavioral symptoms related to dementia, the GDR may be considered clinically contraindicated if:
- The resident’s target symptoms returned or worsened after the most recent attempt at a GDR within the facility; and
- The physician has documented the clinical rationale for why any additional attempted dose reduction at that time would be likely to impair the resident’s function or increase distressed behavior.

For any individual who is receiving an antipsychotic medication to treat a psychiatric disorder other than behavioral symptoms related to dementia (for example, schizophrenia, bipolar mania, or depression with psychotic features), the GDR may be considered contraindicated, if:
- The continued use is in accordance with relevant current standards of practice and the physician has documented the clinical rationale for why any attempted dose reduction would be likely to impair the resident’s function or cause psychiatric instability by exacerbating an underlying psychiatric disorder; or
- The resident’s target symptoms returned or worsened after the most recent attempt at a GDR within the facility and the physician has documented the clinical rationale for why any additional attempted dose reduction at that time would be likely to impair the resident’s function or cause psychiatric instability by exacerbating an underlying medical or psychiatric disorder.

**Attempted Tapering Relative to Continued Indication or Optimal Dose**

As noted, attempted tapering is one way to determine whether a specific medication is still indicated, and whether target symptoms and risks can be managed with a lesser dose of a medication. As noted, many medications in various categories can be tapered safely. The following examples of tapering relate to two common categories of concern: sedatives/hypnotics and psychopharmacologic medications (other than antipsychotic and sedatives/hypnotics medications).

**Tapering Considerations Specific to Sedatives/Hypnotics.**

For as long as a resident remains on a sedative/hypnotic that is used routinely and beyond the manufacturer’s recommendations for duration of use, the facility should attempt to taper the medication quarterly unless clinically contraindicated. Clinically contraindicated means:
- The continued use is in accordance with relevant current standards of practice and the physician has documented the clinical rationale for why any attempted dose reduction would be likely to impair the resident’s function or cause psychiatric instability by exacerbating an underlying medical or psychiatric disorder; or
- The resident’s target symptoms returned or worsened after the most recent attempt at tapering the dose within the facility and the physician has documented the clinical rationale for why any additional attempted dose reduction at that time would be likely to impair the resident’s function or cause psychiatric instability by exacerbating an underlying medical or psychiatric disorder.
Considerations Specific to Psychopharmacological Medications (Other Than Antipsychotics and Sedatives/Hypnotics).

During the first year in which a resident is admitted on a psychopharmacological medication (other than an antipsychotic or a sedative/hypnotic), or after the facility has initiated such medication, the facility should attempt to taper the medication during at least two separate quarters (with at least one month between the attempts), unless clinically contraindicated. After the first year, a tapering should be attempted annually, unless clinically contraindicated. The tapering may be considered clinically contraindicated, if:

- The continued use is in accordance with relevant current standards of practice and the physician has documented the clinical rationale for why any attempted dose reduction would be likely to impair the resident’s function or cause psychiatric instability by exacerbating an underlying medical or psychiatric disorder; or
- The resident’s target symptoms returned or worsened after the most recent attempt at tapering the dose within the facility and the physician has documented the clinical rationale for why any additional attempted dose reduction at that time would be likely to impair the resident’s function or cause psychiatric instability by exacerbating an underlying medical or psychiatric disorder.

VI. Adverse Consequences

Any medication or combination of medications (for example interactions between multiple medications with sedative or anticholinergic effects) can cause adverse consequences. Some adverse consequences occur quickly or abruptly, while others are more insidious and develop over time. Adverse consequences may become evident at any time after the medication is initiated, e.g., when there is a change in dose or after another medication has been added. When reviewing medications used for a resident, it is important to be aware of the medication’s recognized safety profile, tolerability, dosing, and potential medication interactions. Although a resident may have an unanticipated reaction to a medication that is not always preventable, many ADRs can be anticipated, minimized, or prevented. Some adverse consequences may be avoided by:

- Following relevant clinical guidelines and manufacturer’s specifications for use, dose, administration, duration, and monitoring of the medication;
- Defining appropriate indications for use; and
- Determining that the resident:
  - Has no known allergies to the medication;
  - Is not taking other medications, nutritional supplements including herbal products, or foods that would be incompatible with the prescribed medication; and
  - Has no condition, history, or sensitivities that would preclude use of that medication.

Published studies have sought to identify the frequency, severity, and preventability of adverse consequences. Neuropsychiatric, hemorrhagic, gastrointestinal, renal/electrolyte abnormalities and metabolic/endocrine complications were the most common overall and preventable adverse consequences identified in two nursing home studies. Specifically, a study of 18 community-based nursing homes reported that approximately 50 percent (276/546) of all the adverse consequences—and 72 percent of those characterized as fatal, life-threatening, or serious—were considered preventable. A second study of two academic-based nursing homes reported that inadequate monitoring, failure to act on the monitoring, and errors in ordering, including wrong dose, wrong medication, and medication-medication interactions were the most frequent causes for the preventable adverse consequences.
The risk for adverse consequences increases with both the number of medications being taken regularly and with medications from specific pharmacological classes, such as anticoagulants, diuretics, antipsychotics, anti-infectives, and anticonvulsants. See Tables I and II for classes of medications that are associated with frequent or severe adverse consequences. Adverse consequences can range from minimal harm to functional decline, hospitalization, permanent injury, and death.

Delirium (i.e., acute confusional state) is a common medication-related adverse consequence. In many facilities, a majority of the residents have dementia. Individuals who have dementia may be more sensitive to medication effects and may be at greater risk for delirium. Delirium may result from treatable underlying causes including medical conditions and the existing medication regimen. The presence of delirium is associated with higher morbidity and mortality. Some of the classic signs of delirium may be difficult to recognize and may be mistaken for the natural progression of dementia, particularly in the late stages of dementia. Careful observation of the resident (including mental status and level of consciousness), review of the potential causes (e.g., medications, fluid and electrolyte imbalance, infections) of the mental changes and distressed behavior, and appropriate and timely management of delirium are essential.

ENDNOTES

51 Adapted from American Society of Consultant Pharmacists (ASCP) Guidelines for Assessing the Quality of Drug Regimen Review in Long-Term Care Facilities.

TABLE I
MEDICATION ISSUES OF PARTICULAR RELEVANCE
This table lists alphabetically, examples of some categories of medications that have the potential to cause clinically significant adverse consequences, that may have limited indications for use, require specific monitoring, and which warrant careful consideration of relative risks and benefit. Inclusion of a medication in this table does not imply that it is contraindicated for every resident. Medications are identified by generic rather than trade names.

**NOTE:** This table is based on review of a variety of pharmaceutical references. It does not include all categories of medications or all medications within a category, and does not address all issues or considerations related to medication use, such as dosages. Medications other than those listed in this table may present significant issues related to indications, dosage, duration, monitoring, or potential for clinically significant adverse consequences. Since medication issues continue to evolve and new medications are being approved regularly, it is important to refer to a current authoritative source for detailed medication information such as indications and precautions, dosage, monitoring, or adverse consequences.

The listed doses for psychopharmacological medications are applicable to older individuals. The facility is encouraged to initiate therapy with lower doses and, when necessary, only gradually increase doses. The facility may exceed these doses if it provides evidence to show why higher doses were necessary to maintain or improve the resident’s function and quality of life.

### Medication Issues and Concerns

#### Analgesics
- acetaminophen

**Dosage / Adverse Consequences**
- Daily doses greater than 4 grams/day from all sources (alone or as part of combination products) may increase risk of liver toxicity

**Monitoring**
- For doses greater than the maximum recommended daily dose, documented assessment should reflect periodic monitoring of liver function and indicate that benefits outweigh risks

#### Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)
- Non-selective NSAIDs, e.g.,
  - aspirin
  - diclofenac
  - diflunisal
  - ibuprofen
  - indomethacin
  - ketorolac
  - meclofenamate
  - naproxen
  - piroxicam
  - salicylates
  - tolmetin
- Cyclooxygenase-II (COX-2) inhibitors, e.g.,
  - celecoxib

#### Indications
• NSAID, including COX-2 inhibitors, should be reserved for symptoms and/or inflammatory conditions for which lower risk analgesics (e.g., acetaminophen) have either failed, or are not clinically indicated

**Exception:** Use of low dose aspirin (81–325 mg/day) as prophylactic treatment for cardiovascular events such as myocardial infarct or stroke may be appropriate

**Interactions**
• Aspirin may increase the adverse effects of COX-2 inhibitors on the gastrointestinal (GI) tract
• Some NSAIDS (e.g., ibuprofen) may reduce the cardioprotective effect of aspirin

**Monitoring**
• Monitor closely for bleeding when ASA > 325 mg/day is being used with another NSAID or when NSAIDS are used with other platelet inhibitors or anticoagulants (See See 42 CFR 483.60(c) F428 for Table of Common Medication-Medication Interactions in Long Term Care)

**Adverse Consequences**
• May cause gastrointestinal (GI) bleeding in anyone with a prior history of, or with increased risk for, GI bleeding. Compared to nonselective NSAIDs, COX-2 inhibitors may reduce—but do not eliminate—risk of gastrointestinal bleeding
• May cause bleeding in anyone who is receiving warfarin, heparin, other anticoagulants, or platelets inhibitors (e.g., ticlopidine, clopidogrel, and dipyridamole)
• Any NSAID may cause or worsen renal failure, increase blood pressure, or exacerbate heart failure
• Prolonged use of indomethacin, piroxicam, tolmetin, and meclofenamate should be avoided

**Medication Issues and Concerns**
because of central nervous system side effects, e.g., headache, dizziness, somnolence, confusion

**Opioid analgesics**

**Short-acting, e.g.,**
• codeine
• fentanyl
• hydrocodone
• hydromorphone
• meperidine
• morphine
• oxycodone

**Long-acting, e.g.,**
• fentanyl, transdermal
• methadone
• morphine sustained release
• oxycodone, sustained release

**Indications**
• The initiation of longer-acting opioid analgesics is not recommended unless shorter-acting opioids have been tried unsuccessfully, or titration of shorter-acting doses has established a clear daily dose of opioid analgesic that can be provided by using a long-acting form
• Meperidine is not an effective oral analgesic in doses commonly used in older individuals

**Adverse Consequences**
• May cause constipation, nausea, vomiting, sedation, lethargy, weakness confusion, dysphoria, physical and psychological dependency, hallucinations and unintended respiratory depression,
especially in individuals with compromised pulmonary function. These can lead to other adverse consequences such as falls.

- Meperidine use (oral or injectable) may cause confusion, respiratory depression even with therapeutic analgesic doses.
- Active metabolite of meperidine (normeperidine) accumulates with repeated use and has been associated with seizures.

**Pentazocine**

**Indications**
- Limited effectiveness because it is a partial opiate agonist-antagonist; is not recommended for use in older individuals.

**Adverse Consequences**
- This opioid analgesic causes central nervous system side effects (including confusion and hallucinations) more commonly than other opioid analgesics.
- May cause dizziness, lightheadedness, euphoria, sedation, hypotension, tachycardia, syncope.

**Medication Issues and Concerns**
- Propoxyphene and combination products with aspirin or acetaminophen.

**Indications**
- Offers few analgesic advantages over acetaminophen, yet has the adverse effects, including addiction risk, of other opioid medications; is not recommended for use in older individuals.

**Adverse Consequences**
- May cause hypotension and central nervous system effects (e.g., confusion, drowsiness, dizziness) that can lead to other adverse consequences such as falls.

**Antibiotics**

All antibiotics.

**Indications**
- Use of antibiotics should be limited to confirmed or suspected bacterial infection.

**Adverse Consequences**
- Any antibiotic may cause diarrhea, nausea, vomiting, anorexia, and hypersensitivity/allergic reactions.
- Antibiotics are non-selective and may result in the eradication of beneficial microorganisms and the emergence of undesired ones, causing secondary infections such as oral thrush, colitis, and vaginitis.

Parenteral vancomycin and aminoglycosides, e.g.,
- amikacin
- gentamycin/ gentamicin
- tobramycin

**Monitoring**
- Use must be accompanied by monitoring of renal function tests (which should be compared with the baseline) and by serum medication concentrations.
- Serious adverse consequences may occur insidiously if adequate monitoring does not occur.

**Exception:** Single dose administration prophylaxis.

**Adverse Consequences**
- May cause or worsen hearing loss and renal.

**Medication Issues and Concerns**
failure
nitrofurantoin

**Indications**
- It is not the anti-infective/antibiotic of choice for treatment of acute urinary tract infection or prophylaxis in individuals with impaired renal function (CrCl < 60 ml/min) because of ineffectiveness and the high risk of serious adverse consequences

**Adverse Consequences**
- May cause pulmonary fibrosis (e.g., symptoms including dyspnea, cough) and peripheral neuropathy
- Fluoroquinolones, e.g.,
  - ciprofloxacin
  - levofloxacin
  - moxifloxacin
  - ofloxacin

**Indications**
- Use should be avoided in individuals with prolonged QTc intervals or who are receiving antiarrhythmic agents in class Ia (e.g., procainamide), class Ic (e.g., flecainide) or class III (e.g., amiodarone)

**Adverse Consequences**
- May cause prolonged QTc interval
- May increase risk of hypo- or hyperglycemia in individuals age 65 or older, and in individuals with diabetes mellitus, renal insufficiency (CrCl < 60 ml/min), or those receiving other glucose-altering medications
- May increase risk of acute tendonitis

**Anticoagulants**
- warfarin

**Monitoring**
- Use must be monitored by Prothrombin Time (PT)/International Normalization Ratio (INR), with frequency determined by clinical circumstances, duration of use, and stability of monitoring results

**Adverse Consequences**
- Multiple medication interactions exist (See 42 CFR 483.60(c) F428 for Table of Common Medication-Medication Interactions in Long Term Care), which may:
  - Significantly increase PT/INR results to levels associated with life-threatening bleeding, or
  - Decrease PT/INR results to ineffective levels, or
  - Increase or decrease the serum concentration of the interacting medication

**Anticonvulsants**
- All anticonvulsants, e.g.,
  - carbamazepine
  - gabapentin
  - lamotrigine
  - levetiracetam
  - oxcarbazepine
• phenobarbital
• phenytoin
• primidone
• valproic acid

Indications
• In addition to seizures, may also be used to treat other disorders, such as bipolar disorder, schizoaffective disorder, chronic neuropathic pain, and for prophylaxis of migraine headaches
• Need for indefinite continuation should be based on confirmation of the condition (for example, distinguish epilepsy from isolated seizure due to medical cause or distinguish migraine from other causes of headaches) and its potential causes (medications, electrolyte imbalance, hypocalcemia, etc.)

Duration
• If used to manage behavior, stabilize mood, or treat a psychiatric disorder, refer to Section V – Tapering of a Medication Dose/Gradual Dose Reduction (GDR) in the guidance

Monitoring
• Serum medication concentration monitoring is not required or available for all anticonvulsants. Only the following anticonvulsants should be monitored with periodic serum concentrations: phenytoin, phenobarbital, primidone, divalproex sodium (as valproic acid), and carbamazepine
• Serum medication concentrations may help identify toxicity, but significant signs and symptoms of toxicity can occur even at normal or low serum concentrations.

Medication Issues and Concerns
• When anticonvulsants are used for conditions other than seizure disorders (e.g., as mood stabilizers), the same concerns exist regarding the need for monitoring for effectiveness and side effects; but evaluation of symptoms—not serum concentrations—should be used to adjust doses. High or toxic serum concentrations should, however, be evaluated and considered for dosage adjustments
• Symptom control for seizures or behavior can occur with subtherapeutic serum medication concentrations

Adverse Consequences
• May cause liver dysfunction, blood dyscrasias, and serious skin rashes requiring discontinuation of treatment
• May cause nausea/vomiting, dizziness, ataxia, somnolence/lethargy, incoordination, blurred or double vision, restlessness, toxic encephalopathy, anorexia, headaches. These effects can increase the risk for falls

Antidepressants
All antidepressants classes, e.g.,
• Alpha-adrenoceptor antagonist, e.g., mirtazapine
• Dopamine-reuptake blocking compounds, e.g., bupropion
• Monoamine oxidase inhibitors (MAOIs)
• Serotonin (5-HT 2) antagonists, e.g., nefazodone, trazodone
Selective serotonin-norepinephrine reuptake

**Indications**
- Agents usually classified as “antidepressants” are prescribed for conditions other than depression including anxiety disorders, post-traumatic stress disorder, obsessive compulsive disorder, insomnia, neuropathic pain (e.g., diabetic peripheral neuropathy), migraine headaches, urinary incontinence, and others

**Dosage**
- Use of two or more antidepressants simultaneously may increase risk of side effects; in such cases, there should be documentation of expected benefits that outweigh the associated risks and monitoring for any increase in side effects

**Medication Issues and Concerns**
- Inhibitors (SNRIs), e.g.,
  - duloxetine,
  - venlafaxine
- Selective serotonin reuptake inhibitors (SSRIs), e.g.,
  - citalopram
  - escitalopram
  - fluoxetine
  - fluvoxamine
  - paroxetine
  - sertraline
- Tricyclic (TCA) and related compounds

**Duration**
- Duration should be in accordance with pertinent literature, including clinical practice guidelines
- Prior to discontinuation, many antidepressants may need a gradual dose reduction or tapering to avoid a withdrawal syndrome (e.g., SSRIs, TCAs)
- If used to manage behavior, stabilize mood, or treat a psychiatric disorder, refer to Section V – Tapering of a Medication Dose/Gradual Dose Reduction (GDR) in the guidance

**Monitoring**
- All residents being treated for depression with any antidepressant should be monitored closely for worsening of depression and/or suicidal behavior or thinking, especially during initiation of therapy and during any change in dosage

**Interactions/Adverse Consequences**
- May cause dizziness, nausea, diarrhea, anxiety, nervousness, insomnia, somnolence, weight gain, anorexia, or increased appetite. Many of these effects can increase the risk for falls
- Bupropion may increase seizure risk and be associated with seizures in susceptible individuals
- SSRIs in combination with other medications affecting serotonin (e.g., tramadol, St. John’s Wort, linezolid, other SSRI’s) may increase the risk for serotonin syndrome and seizures
- Monoamine oxidase inhibitors (MAOIs), e.g.,
  - isocarboxazid
  - phenelzine
  - tranylcypromine

**Indications/Contraindications**
- Should not be administered to anyone with a confirmed or suspected cerebrovascular defect or to anyone with confirmed cardiovascular disease or hypertension
• Should not be used in the presence of pheochromocytoma
• MAO Inhibitors are rarely utilized due to their

**Medication**

**Issues and Concerns**

potential interactions with tyramine or tryptophan-containing foods, other medications, and their profound effect on blood pressure

**Adverse Consequences**

• May cause hypertensive crisis if combined with certain foods, cheese, wine

**Exception:** Monoamine oxidase inhibitors such as selegiline (MAO-B inhibitors) utilized for Parkinson’s Disease, unless used in doses greater than 10 mg per day

**Interactions**

• Should not be administered together or in rapid succession with other MAO inhibitors, tricyclic antidepressants, bupropion, SSRIs, buspirone, sympathomimetics, meperidine, triptans, and other medications that affect serotonin or norepinephrine

Tricyclic antidepressants (TCAs), e.g.,
• amitriptyline
• amoxapine
• doxepin
• combination products, e.g.,
  o amitriptyline and chlordiazepoxide
  o amitriptyline and perphenazine

**Indications**

• Because of strong anticholinergic and sedating properties, TCAs and combination products are rarely the medication of choice in older individuals

**Exception:** Use of TCAs may be appropriate if:
  o The resident is being treated for neurogenic pain (e.g., trigeminal neuralgia, peripheral neuropathy), based on documented evidence to support the diagnosis; and
  o The relative benefits outweigh the risks and other, safer agents including non-pharmacological interventions or alternative therapies are not indicated or have been considered, attempted, and failed

**Adverse Consequences**

• Compared to other categories of antidepressants, TCAs cause significant anticholinergic side effects

**Medication**

**Issues and Concerns**

and sedation (nortriptyline and desipramine are less problematic)

**Antidiabetic medications**

Insulin and oral hypoglycemics, e.g.,
• acarbose
• acetohexamide
• chlorpropamide
• glimepiride
• glipizide
• glyburide
• metformin
• repaglinide
- rosiglitazone
- tolazamide
- tolbutamide
Including combination products, e.g.,
- rosiglitazone/metformin
- glyburide/metformin
- glipizide/metformin
- pioglitazone/metformin

**Monitoring**
- Use of anti-diabetic medications should include monitoring (for example, periodic blood sugars) for effectiveness based on desired goals for that individual and to identify complications of treatment such as hypoglycemia, impaired renal function

**NOTE:** Continued or long-term need for sliding scale insulin for non-emergency coverage may indicate inadequate blood sugar control
- Residents on rosiglitazone should be monitored for visual deterioration due to new onset and/or worsening of macular edema in diabetic patients

**Adverse Consequences**
- Metformin has been associated with the development of lactic acidosis (a potentially life threatening metabolic disorder), which is more likely to occur in individuals with:
  - serum creatinine $\geq 1.5$ mg/dL in males or $\geq 1.4$ mg/dL in females
  - abnormal creatinine clearance from any cause, including shock, acute myocardial infarction, or septicemia
  - age $\geq 80$ years unless measurement of creatinine clearance verifies normal renal function
  - radiologic studies in which intravascular iodinated contrast materials are given
  - congestive heart failure requiring pharmacological management
  - acute or chronic metabolic acidosis with or without coma (including diabetic ketoacidosis)

**Medication Issues and Concerns**
- Rosiglitazone and pioglitazone have been associated with edema and weight gain; therefore, their use should be avoided in residents with Stage III or Stage IV heart failure
- Sulfonylureas can cause the syndrome of inappropriate antidiuretic hormone (SIADH) and result in hyponatremia

**Indications**
- Chlorpropamide and glyburide are not considered hypoglycemic agents of choice in older individuals because of the long half-life and/or duration of action and increased risk of hypoglycemia

**Adverse Consequences**
- May cause prolonged and serious hypoglycemia (with symptoms including tachycardia, palpitations, irritability, headache, hypothermia, visual disturbances, lethargy, confusion, seizures, and/or coma)

**Antifungals**
- Imidazoles for systemic use, e.g.,
  - fluconazole
• itraconazole
• ketoconazole

**Indications**
• Should be used in lowest possible dose for shortest possible duration, especially in anyone receiving other medications known to interact with these medications

**Interactions/Adverse Consequences**
• Interaction with warfarin can cause markedly elevated PT/INR, increasing bleeding risk
• Multiple potentially significant medication interactions may occur, for example:
  o These medications when administered concurrently may increase the effect or toxicity of
    phenytoin, theophylline, sulfonylureas (hypoglycemics)
  o Other medications such as rifampin and

**Medication Issues and Concerns**
cimetidine may decrease the effect of these antifungals
• May cause hepatotoxicity, headaches, GI distress

**Monitoring**
• Enhanced monitoring may be required to identify and minimize adverse consequences when these antifungals are given with the following:
  o warfarin (PT/INR)
  o phenytoin (serum phenytoin levels)
  o theophylline (serum theophylline levels)
  o sulfonylureas (fasting blood glucose)

**Antimanic medications**
Lithium

**Indications**
• Should generally not be given to individuals with significant renal or cardiovascular disease, severe debilitation, dehydration, or sodium depletion

**Monitoring**
• Toxic levels are very close to therapeutic levels. Serum lithium concentration should be monitored periodically, and dosage adjusted accordingly

**Interactions/Adverse Consequences**
• May cause potentially dangerous sodium imbalance
• Adverse consequences may occur at relatively low serum concentrations (1–1.5 mEq/L)
• Serum lithium concentration levels can be affected by many other medications, e.g., thiazide diurectics, ACE inhibitors, NSAIDs

**Antiparkinson medications**
All classes, e.g.,
Catechol-O-Methyl Transferase (COMT) Inhibitors, e.g.,
• entacapone
Dopamine agonists, e.g.,
• bromocriptine
• ropinirole
• pramipexole
MAO inhibitors, e.g.,
• selegiline
Others, e.g.,
• amantadine
Various dopaminergic combinations, e.g.,
• carbidopa/levodopa
• carbidopa/levodopa/entacapone
delirium, dyskinesia, nausea, dizziness, hallucinations, agitation
• Increased risk of postural hypotension and falls, especially when given in conjunction with antihypertensive medications

**Antipsychotic medications**
All classes, e.g.,
First generation (conventional) agents, e.g.
• chlorpromazine
• fluphenazine
• haloperidol
• loxapine
• mesoridazine
• molindone
• perphenazine
• promazine
• thioridazine
• thiothixene
• trifluoperazine
• triflupromazine
Second generation (atypical) agents, e.g.
• aripiprazole
• clozapine
• olanzapine
• quetiapine
• risperidone
• ziprasidone

**Indications**
• An antipsychotic medication should 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):
  o Schizophrenia
  o Schizo-affective disorder
  o Delusional disorder
  o Mood disorders (e.g. mania, bipolar disorder, depression with psychotic features, and treatment refractory major depression)
  o Schizophreniform disorder
  o Psychosis NOS
  o Atypical psychosis
Medication
Issues and Concerns
- Brief psychotic disorder
- Dementing illnesses with associated behavioral symptoms
- Medical illnesses or delirium with manic or psychotic symptoms and/or treatment-related psychosis or mania (e.g., thyrotoxicosis, neoplasms, high dose steroids)
- In addition, the use of an antipsychotic must meet the criteria and applicable, additional requirements listed below:
  1. Criteria:
     - Since diagnoses alone do not warrant the use of antipsychotic medications, the clinical condition must also meet at least one of the following criteria (A or B or C):
       A. The symptoms are identified as being due to mania or psychosis (such as: auditory, visual, or other hallucinations; delusions (such as paranoia or grandiosity)); OR
       B. The behavioral symptoms present a danger to the resident or to others; OR
       C. The symptoms are significant enough that the resident is experiencing one or more of the following: inconsolable or persistent distress (e.g., fear, continuously yelling, screaming, distress associated with end-of-life, or crying); a significant decline in function; and/or substantial difficulty receiving needed care (e.g., not eating resulting in weight loss, fear and not bathing leading to skin breakdown or infection).
  2. Additional Requirements:
     - Acute Psychiatric Situations
     - Medication
Issues and Concerns
When an antipsychotic medication is being initiated or used to treat an acute psychiatric emergency (i.e., recent or abrupt onset or exacerbation of symptoms) related to one or more of the aforementioned conditions/diagnoses, that use must meet one of the above criteria and all of the following additional requirements:
A. The acute treatment period is limited to seven days or less; and
B. 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 psychiatric condition and verify the continuing need for antipsychotic medication; and
C. Pertinent non-pharmacological interventions must be attempted, unless contraindicated, and documented following the resolution of the acute psychiatric situation.
- Enduring Psychiatric 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 #1 above. In addition, before initiating or increasing an antipsychotic medication for enduring conditions, the target behavior must be clearly and specifically identified and monitored objectively and qualitatively, in order to ensure the behavioral symptoms are:
A. Not due to a medical condition or problem (e.g., headache or joint pain, fluid or electrolyte imbalance, pneumonia, hypoxia, unrecognized
Medication
Issues and Concerns
hearing or visual impairment) that can be expected to improve or resolve as the underlying condition is treated; and
B. Persistent or likely to reoccur without continued treatment; and
C. Not sufficiently relieved by non-pharmacological interventions; and
D. Not due to environmental stressors (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, physical barriers) that can be addressed to improve
the psychotic symptoms or maintain safety; and
E. Not due to psychological stressors (e.g., loneliness, taunting, abuse), or 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) that can
be expected to improve or resolve as the situation is addressed

• After initiating or increasing the dose of an antipsychotic medication, the behavioral symptoms
must be reevaluated periodically to determine the effectiveness of the antipsychotic and the
potential for reducing or discontinuing the dose

Exception: When antipsychotic medications are used for behavioral disturbances related to
Tourette’s disorder, or for non-psychiatric indications such as movement disorders associated
with Huntington’s disease, hiccups, nausea and vomiting associated with cancer or cancer
chemotherapy, or adjunctive therapy at end of life.

Inadequate Indications
Medication
Issues and Concerns
• In many situations, antipsychotic medications are not indicated. They should not be used if the
only indication is one or more of the following: 1) wandering; 2) poor self-care; 3) restlessness;
4) impaired memory; 5) mild anxiety; 6) insomnia; 7) unsociability; 8) inattention or indifference
to surroundings; 9) fidgeting; 10) nervousness; 11) uncooperativeness; or 12) verbal expressions
or behavior that are not due to the conditions listed under “Indications” and do not represent a
danger to the resident or others.

Dosage
• Doses for acute indications (for example, delirium) may differ from those used for long-term
treatment, but should be the lowest possible to achieve the desired therapeutic effects

Daily Dose Thresholds for Antipsychotic Medications Used to Manage Behavioral
Symptoms Related to Dementing Illnesses
Generic Medication
Dosage
First Generation
chlorpromazine
75 mg
fluphenazine
4 mg
haloperidol
2 mg
loxapine
10 mg
molindone
10 mg
perphenazine
8 mg
pimozide
prochlorperazine
* thioridazine
75 mg
thiothixene
7 mg
trifluoperazine
8 mg
Second Generation
aripiprazole
10 mg
clozapine
50 mg
olanzapine
7.5 mg
quetiapine
150 mg
risperidone
2 mg
ziprasidone
*

Medication
Issues and Concerns
* Not customarily used for the treatment of behavioral symptoms

References:

Duration
• If used to manage behavior, stabilize mood, or treat a psychiatric disorder, refer to Section V – Tapering of a Medication Dose/Gradual Dose Reduction (GDR) in the guidance

Monitoring/Adverse Consequences
• The facility assures that residents are being adequately monitored for adverse consequences such as:
  o anticholinergic effects (see Table II)
  o increase in total cholesterol and triglycerides
  o akathisia
  o parkinsonism
  o neuroleptic malignant syndrome (NMS)
  o blood sugar elevation (including diabetes mellitus)
- cardiac arrhythmias
- orthostatic hypotension
- death secondary to heart-related
cerebrovascular event (e.g., stroke, transient

**Medication**

**Issues and Concerns**
events (e.g., heart failure, sudden death)
- ischemic attack (TIA) in older individuals with dementia
  - falls
  - tardive dyskinesia
  - lethargy
  - excessive sedation
- When antipsychotics are used without monitoring they may be considered unnecessary
medications because of inadequate monitoring.

**Anxiolytics**

All Anxiolytics
Benzodiazepines, Short-acting, e.g.,
  - alprazolam
  - estazolam
  - lorazepam
  - oxazepam
  - temazepam
Benzodiazepines, Long acting, e.g.,
  - chlordiazepoxide
  - clonazepam
  - clorazepate
  - diazepam
  - flurazepam
  - quazepam
buspirone
Other antidepressants except bupropion

**Indications**

- Anxiolytic medications should only be used when:
  - Use is for one of the following indications as defined in the Diagnostic and Statistical Manual
    of Mental Disorders, Fourth Edition, Training Revision (DSM-IV TR) or subsequent editions:
    a. Generalized anxiety disorder
    b. Panic disorder
    c. Symptomatic anxiety that occurs in residents with another diagnosed psychiatric disorder
d. Sleep disorders (See Sedatives/Hypnotics)
e. Acute alcohol or benzodiazepine withdrawal
f. Significant anxiety in response to a situational trigger
g. Delirium, dementia, and other cognitive disorders with associated behaviors that:
   – Are quantitatively and objectively documented;
   – Are persistent;
   – Are not due to preventable or

**Medication**
**Issues and Concerns**
correctable reasons; and
– Constitute clinically significant distress or dysfunction to the resident or represent a danger to the resident or others
• Evidence exists that other possible reasons for the individual’s distress have been considered; and
• Use results in maintenance or improvement in the individual’s mental, physical or psychosocial well-being (e.g., as reflected on the MDS or other assessment tools); or
• There are clinical situations that warrant the use of these medications such as:
  – a long-acting benzodiazepine is being used to withdraw a resident from a short-acting benzodiazepine
  – used for neuromuscular syndromes (e.g., cerebral palsy, tardive dyskinesia, restless leg syndrome or seizure disorders)
  – symptom relief in end of life situations

**Dosage**
• Dosage is less than, or equal to, the following listed total daily doses unless higher doses (as evidenced by the resident’s response and/or the resident’s clinical record) are necessary to maintain or improve the resident’s function

**Total Daily Dose Thresholds for Anxiolytic Medications**

**Generic Medication**

**Dosage**
flurazepam
15 mg
chlordiazepoxide
20 mg
clorazepate
15 mg
diazepam
5 mg
clonazepam
1.5 mg
quazepam
7.5 mg

**Medication**

**Issues and Concerns**
estazolam
0.5 mg
alprazolam
0.75 mg
oxazepam
30 mg
lorazepam
2 mg

**Duration**
• If used to manage behavior, stabilize mood, or treat a psychiatric disorder, refer to Section V – Tapering of a Medication Dose/Gradual Dose Reduction (GDR) in the guidance
Adverse Consequences
• May increase risk of confusion, sedation, and falls
diphenhydramine and hydroxyzine

Indications
• Not appropriate for use as an anxiolytic
meprobamate

Indications
• Highly addictive and sedating medication; not indicated for use in older individuals

Dosage/Duration
• Those who have used meprobamate for prolonged periods may be physically and/or psychologically dependent and may need to be withdrawn slowly

Cardiovascular medications (including antihypertensives)
All antiarrhythmics

Adverse Consequences
• Cardiac antiarrhythmics can have serious adverse effects in older individuals, including impaired mental function, falls, appetite, behavior, and heart function
amiodarone

Indications
• Only approved indication for use is to treat documented life-threatening recurrent ventricular arrhythmias that do not respond to other

Medication

Issues and Concerns
antiarrhythmic agents or when alternative agents are not tolerated
• Common off-label use to treat atrial fibrillation; however, literature suggests that in many higher risk individuals, alternative approaches to managing atrial fibrillation (rate control and anticoagulation) are equally effective and less toxic*

Dosage/Monitoring
• It is critical to carefully consider risks and benefits, to use the lowest possible dose for the shortest possible duration, to closely monitor individuals receiving long-term amiodarone, and to seek and identify adverse consequences

Interactions/Adverse Consequences
• May cause potentially fatal toxicities, including pulmonary toxicity (hypersensitivity pneumonitis or interstitial/alveolar pneumonitis) and hepatic injury. May cause hypothyroidism, exacerbate existing arrhythmia, and worsen heart failure. Can also impair mental function and behavior
• May cause clinically significant medication interactions; for example, with digoxin and warfarin
• Toxicity increases with higher doses and longer duration of use
disopyramide

Adverse Consequences
• Disopyramide has potent negative inotropic effects

**Medication Issues and Concerns**
(decreased force of heart contraction), which may induce heart failure in older individuals, and is also strongly anticholinergic

All antihypertensives

**Dosage/Monitoring**
- Doses of individual antihypertensives may require modification in order to achieve desired effects while minimizing adverse consequences, especially when multiple antihypertensives are prescribed simultaneously
- When discontinuing some antihypertensives (e.g., clonidine, beta blockers), gradual tapering may be required to avoid adverse consequences caused by abrupt cessation

**Interactions/Adverse Consequences**
- May cause dizziness, postural hypotension, fatigue, and an increased risk for falls
- Many other medications may interact with antihypertensives to potentiate their effect (e.g., levodopa, nitrates)

Alpha blockers, e.g.,
- alfuzosin
- doxazosin
- prazosin
- tamsulosin
- terazosin

**Adverse Consequences**
- Doxazosin, prazosin, and terazosin can cause significant hypotension and syncope during the first few doses. Therefore, these medications should be initiated at bedtime with a slow titration of dose
- Prazosin can cause more CNS side effects and generally should be avoided in older individuals

Angiotensin converting enzyme (ACE) inhibitors, e.g.,
- benazepril
- captopril
- enalapril
- fosinopril
- lisinopril
- ramipril

**Monitoring**
- Monitoring of serum potassium is necessary especially in individuals receiving ACE inhibitors with potassium, or potassium sparing diuretics

**Adverse Consequences**
- May cause angioedema (signs and symptoms of immediate hypersensitivity), chronic persistent nonproductive cough, or may worsen renal failure

**Medication Issues and Concerns**
Angiotensin II receptor blockers, e.g.,
- candesartan
- eprosartan
- irbesartan
• losartan
• olmesartan
• valsartan
• Potential for life-threatening elevation of serum potassium concentrations when used in combination with potassium supplements, potassium-sparing diuretics including spironolactone

Beta adrenergic blockers, e.g.,

Nonselective, e.g.,
• propranolol
Cardioselective, e.g.,
• atenolol
• esmolol
• metoprolol
• nadolol
• timolol

**Adverse Consequences**

• May cause or exacerbate:
  o Bradycardia, especially in individuals receiving other medications that affect cardiac conduction (e.g., calcium channel blockers);
  o Dizziness, fatigue; depression, bronchospasm (especially, but not exclusively, propranolol); or
  o Cardiac decompensation that may require adjusting dose in residents with acute heart failure
• May mask tachycardia associated with symptomatic hypoglycemia
• May have increased effect or may accumulate in individuals with hepatic impairment

Calcium channel blockers, e.g.,
• nifedipine
• isradipine
• amlodipine
• nisoldipine
• diltiazem
• verapamil

**Adverse consequences**

• May cause clinically significant constipation
• May cause peripheral edema
• Some agents may cause generalized aching, headache, muscle pain
• Short acting/immediate release nifedipine increases the risk of cardiac complications and should not be used

methyldopa

Including combination

**Indications**

• Alternate treatments for hypertension are preferred

**Medication**

**Issues and Concerns**

products such as methyldopa/ hydrochlorothiazide

**Adverse Consequences**

• May cause bradycardia and excessive sedation; may exacerbate depression in older individuals
digoxin

**Indications**
• Digoxin is indicated only for the following diagnoses: congestive heart failure, atrial fibrillation, paroxysmal supraventricular tachycardia, or atrial flutter
• Should be used with caution in individuals with impaired renal function

**Dosage**
• Daily doses in older individuals should ordinarily not exceed 0.125 mg/day except when used to control atrial arrhythmia and ventricular rate

**Monitoring**
• Must be used cautiously in individuals with renal failure or fluid and electrolyte imbalance, with close monitoring for adverse consequences and monitoring, as indicated, of both renal function and serum medication concentration (“digoxin level”)
• Adverse consequences may occur even with therapeutic serum concentration, especially in older individuals

**Interactions/Adverse Consequences**
• May interact with many other medications, possibly resulting in digoxin toxicity or elevated serum concentrations of other medications
• May cause significant bradycardia, especially when used in individuals taking other medications affecting cardiac conduction
• Toxicity may cause fatigue, nausea, vomiting, anorexia, delirium, cardiac arrhythmia

**Diuretics, e.g.,**

**Adverse Consequences**

**Medication Issues and Concerns**
• bumetanide
• ethacrynic acid
• furosemide
• hydrochlorothiazide
• metolazone
• spironolactone
• torsemide
• triamterene
• May cause fluid and electrolyte imbalance (hypo/hypernatremia, hypo/hyperkalemia, dehydration, etc.), hypotension; may precipitate or exacerbate urinary incontinence, falls
• isosorbide mononitrate
• isosorbide dinitrate
• nitroglycerin

**Adverse Consequences**
• May cause headaches, dizziness, lightheadedness, faintness, or symptomatic orthostatic hypotension, especially when initially started or when taken in combination with antihypertensive medications

**Cholesterol lowering medications**
HMG-CoA Reductase Inhibitors (“statins”), e.g.,
• atorvastatin
• fluvastatin
• lovastatin
• pravastatin
• rosuvastatin
• simvastatin

**Monitoring**
• Liver function monitoring should be performed consistent with manufacturer’s recommendations, generally accepted as:
  • Prior to initiation of therapy, at 12 weeks following both initiation of therapy and any increase in dose, and periodically (e.g., semiannually) thereafter

**Adverse Consequences**
• May impair liver function; liver function tests should be monitored as indicated above
• May cause muscle pain, myopathy, and rhabdomyolysis (breakdown of skeletal muscle) that can precipitate kidney failure especially in combination with other cholesterol lowering medications.

**Interactions**
• May reduce the absorption of other medications being taken concurrently. Other medications, including diuretics, beta-blockers, corticosteroids, thyroid hormones, digoxin, valproic acid, NSAIDs, sulfonylureas, and warfarin should be administered

**Medication Issues and Concerns**
one hour before or four hours after cholestyramine administration to avoid this interaction

**Adverse Consequences**
• May cause constipation, dyspepsia, nausea or vomiting, abdominal pain
• fenofibrate
• clofibrate

**Monitoring**
• Fenofibrate and clofibrate require regular monitoring of liver tests as well as evaluating the complete blood count (CBC) prior to and after initiation

**niacin**

**Monitoring**
• Monitor glucose and liver function tests regularly

**Adverse Consequences**
• Interferes with glucose control and can aggravate diabetes
• Can exacerbate active gallbladder disease and gout
• Flushing is common

**Cognitive Enhancers**
Cholinesterase inhibitors, e.g.,
• donepezil
• galantamine
• rivastigmine

**Indications**
• As the underlying disorder progresses into advanced stages, the continued use of the medication should be reevaluated

**Adverse Consequences**
• May affect cardiac conduction, especially in individuals who already have a cardiac conduction disorder or who are taking other medications that affect heart rate
• May cause insomnia, dizziness, nausea, vomiting, diarrhea, anorexia, and weight loss
• Should be used with caution in individuals with severe asthma or obstructive pulmonary disease

Medication
Issues and Concerns
NMDA receptor antagonists, e.g.,
• memantine

Indications
• As the underlying disorder progresses into advanced stages, the continued use of the medication should be reevaluated

Adverse Consequences
• May cause restlessness, distress, dizziness, somnolence, hypertension, headache, hallucinations, or increased confusion

Cough, cold, and allergy medications

Indications/Duration
• Should be used only for a limited duration (less than 14 days) unless there is documented evidence of enduring symptoms that cannot otherwise be alleviated and for which a cause cannot be identified and corrected

Antihistamine H-1 blockers, e.g.,
• chlorpheniramine
• cyproheptadine
• diphenhydramine
• hydroxyzine
• meclizine
• promethazine

Indications
• H-1 blocker antihistamines have strong anticholinergic properties and are not considered medications of choice in older individuals
• If appropriate and effective, topical instead of oral diphenhydramine should be considered for allergic reactions involving the skin

Dosage/Duration
• Should be used in the smallest possible dosage for the shortest possible duration, especially in individuals who are susceptible to anticholinergic side effects or who are receiving other medications with anticholinergic properties (see Table II)

Adverse Consequences
• May cause excessive sedation, confusion, cognitive impairment, distress, dry mouth, constipation, urinary retention. These may lead to other adverse consequences such as falls

Medication
Issues and Concerns
Oral decongestants, e.g.,
• pseudoephedrine

Adverse Consequences
• May cause dizziness, nervousness, insomnia, palpitations, urinary retention, elevated blood pressure
• Should be used with caution in individuals who have insomnia or hypertension
**Gastrointestinal medications**
Phenothiazine-related antiemetics, e.g.,
• prochlorperazine
• promethazine

**Indications**
• Use with caution in individuals with Parkinson’s disease, narrow-angle glaucoma, BPH, seizure disorder

**Adverse Consequences**
• May cause sedation, dizziness, drowsiness, postural hypotension, and neuroleptic malignant syndrome
• May lower seizure threshold
• Promethazine and prochlorperazine may cause anticholinergic effects, such as constipation, dry mouth, blurred vision, urinary retention
• May cause extrapyramidal symptoms, including medication-induced parkinsonism, acute dystonic reactions, akathisia, and tardive dyskinesia
• May alter cardiac conduction or induce arrhythmias

trimethobenzamide

**Adverse Consequences**
• Relatively ineffective antiemetic that can cause significant extrapyramidal side effects in addition to lethargy, sedation, confusion

**Exception:** May be indicated in patients with Parkinson’s Disease taking apomorphine

metoclopramide

**Indications**
• High-risk medication with limited clinical indication and limited demonstrated effectiveness*
• Not recommended for first-line treatment of gastroesophageal reflux disease, especially in older individuals
• When used for diabetic gastroparesis, or other indications, relative benefits and risks should be assessed and documented


**Adverse Consequences**
• Especially in older individuals, metoclopramide may cause restlessness, drowsiness, insomnia, depression, distress, anorexia, and extrapyramidal symptoms, and may lower the seizure threshold
• May increase seizures in individuals with seizure disorders or exacerbate symptoms in individuals with Parkinson’s Disease

**Monitoring**
• It is essential to closely monitor at-risk individuals for adverse consequences

Proton pump inhibitors (PPI), e.g.,
• esomeprazole
• lansoprazole
• omeprazole
• rabeprazole
H-2 antagonists, e.g.,
• cimetidine
• famotidine
• ranitidine

**Indications**
• Indication for use should be based on clinical symptoms and/or endoscopic findings
• When used to treat or prevent NSAID-induced gastritis or esophagitis, documentation should exist that other, less GI-toxic analgesics have been tried or were not indicated

**Duration**
• If used for greater than 12 weeks, clinical rationale for continued need and/or documentation should support an underlying chronic disease (e.g., GERD) or risk factors (e.g., chronic NSAID use)

**Dosage**

**Medication**

**Issues and Concerns**
• Dosing of histamine-H2 antagonists should be based on renal function

**Interactions**
• Cimetidine has higher incidence of medication interactions and should be avoided in older individuals

**Adverse Consequences**
• May cause or exacerbate headache, nausea, vomiting, flatulence, dysphagia, abdominal pain, diarrhea, or other gastrointestinal symptoms
• H-2 antagonists may cause confusion
• PPIs may increase the risk of clostridium difficile colitis

**Glucocorticoids**
All glucocorticoids (except topical or inhaled dosage forms), e.g.,
• dexamethasone
• hydrocortisone
• methylprednisolone
• prednisone

**Duration/Monitoring**
• Necessity for continued use should be documented, along with monitoring for and management of adverse consequences

**Adverse Consequences**
• Intermediate- or longer-term use may cause hyperglycemia, psychosis, edema, insomnia, hypertension, osteoporosis, mood lability, or depression

**Hematinics**
Erythropoiesis stimulants, e.g.,
• darbepoetin
• erythropoietin

**Indications**
• Assessment of causes and categories of anemia should precede or accompany the use of this medication

**Monitoring**
• Use must be monitored according to specific manufacturer’s instructions including blood pressure, baseline serum iron or ferritin level, and frequent complete blood count (CBCs) to permit

**Medication**

**Issues and Concerns**
tapering or discontinuation when hemoglobin/hematocrit reaches or exceeds target ranges

**Adverse Consequences**
• May cause or worsen hypertension
• Excessive dose or duration can lead to polycythemia, dangerous thrombotic events including myocardial infarction and stroke

**Iron**

**Indications**
• Iron therapy is not indicated in anemia of chronic disease when iron stores and transferrin levels are normal or elevated

**Dosage/Duration**
• Clinical rationale should be documented for long-term use (greater than two months) or administration more than once daily for greater than a week, because of side effects and the risk of iron accumulation in tissues

**Monitoring**
• Baseline serum iron or ferritin level and periodic CBC or hematocrit/ hemoglobin

**Adverse Consequences**
• May cause constipation, dyspepsia
• Can accumulate in tissues and cause multiple complications if given chronically despite normal or high iron stores

**Laxatives**
All categories including bulk producing laxatives, hyperosmolar agents, saline laxatives, stimulant laxatives, emollient laxatives

**Adverse Consequences**
• May cause flatulence, bloating, abdominal pain
• Bulk forming laxatives and stool softeners may cause accumulation of stool and possible bowel obstruction, if not used with adequate fluids or in individuals with other causes of impaired bowel

**Medication**

**Issues and Concerns**
motility

**Muscle relaxants**
All muscle relaxants, e.g.,
• baclofen
• carisoprodol
• chlorzoxazone
• cyclobenzaprine
• dantrolene
• metaxalone
• methocarbamol
• orphenadrine

**Indications/Adverse Consequences**
Most are poorly tolerated by older individuals due to anticholinergic side effects (see Table II), sedation, or weakness
Long-term use in individuals with complications due to multiple sclerosis, spinal cord injuries, cerebral palsy, and other select conditions may be indicated, although close monitoring is still warranted
Abrupt cessation of some muscle relaxants may cause or predispose individuals to seizures or hallucinations

**Exception:** Periodic use (once every three months) for a short duration (not more than seven days) may be appropriate, when other interventions or alternative medications are not effective or not indicated

**Orexigenics (appetite stimulants)**
All appetite stimulants, e.g.,
- megestrol acetate
- oxandrolone
- dronabinol

**Indications**
Use should be reserved for situations where assessment and management of underlying correctable causes of anorexia and weight loss is not feasible or successful, and after evaluating potential benefits/risks

**Monitoring**
Appetite and weight should be monitored at least monthly and agent should be discontinued if there is no improvement.

**Adverse Consequences**
- Megestrol acetate may cause fluid retention, adrenal suppression, and symptoms of adrenal insufficiency
- Oxandrolone may cause virilization of females and feminization of males, excessive sexual stimulation, and fluid retention
- Dronabinol may cause tachycardia, orthostatic hypotension, dizziness, dysphoria, and impaired cognition, which may lead to falls

**Medication Issues and Concerns**

**Osteoporosis medications**
Bisphosphonates, e.g.,
- alendronate
- ibandronate
- risedronate

**Dosage**
These medications must be taken according to very specific directions, including time of day, position, and timing relative to other medications and food

**Monitoring**
Individuals receiving these medications should be monitored closely for gastrointestinal complications, including esophageal or gastric erosion

**Adverse Consequences**
Potential to cause gastrointestinal symptoms including dysphagia, esophagitis, gastritis, or esophageal and gastric ulcers, especially when given to individuals who are also taking oral corticosteroids, aspirin or other nonsteroidal anti-inflammatory drugs (NSAIDs)
Platelet inhibitors
All platelet inhibitors, e.g.,
• dipyridamole
• dipyridamole extended-release and aspirin (as fixed-dose combination)
• aspirin
• clopidogrel

Interactions/Adverse Consequences
• May cause thrombocytopenia and increase risk of bleeding
• Common side effects include headache, dizziness, and vomiting
• See discussion at NSAIDs regarding aspirin
• Concurrent use with warfarin or NSAIDs may increase risk of bleeding

Indication
• Use may be appropriate in individuals who have

Medication

Issues and Concerns
had a previous stroke or have evidence of stroke precursors (i.e., transient ischemic attacks (TIAs)), and who cannot tolerate aspirin or another platelet inhibitor

Adverse Consequences
• Associated with more severe side effects and considerably more toxic than other platelet inhibitors; use should be avoided in older individuals
• Most serious side effects involve the hematologic system, including potentially life-threatening neutropenia
• May also cause nausea, vomiting, and diarrhea

Respiratory medications
theophylline

Interactions
• Potentially significant interactions with many other medications may occur, especially various antibiotics, seizure medications, and cardiac medications

Monitoring/Adverse Consequences
• There should be monitoring for signs and symptoms of toxicity, such as arrhythmia, seizure, GI upset, diarrhea, nausea/vomiting, abdominal pain, nervousness, headache, insomnia, distress, dizziness, muscle cramp, tremor
• Periodic monitoring of serum concentrations helps identify or verify toxicity

Inhalant medications classes, e.g.,
Anticholinergic, e.g.,
• ipratropium
• tiotropium
Beta 2 agonists, e.g.,
• albuterol
• formoterol

Adverse Consequences
• Inhaled anticholinergics can cause xerostomia (dry mouth)
• Inhaled beta agonists can cause restlessness, increased heart rate, and anxiety
• Inhaled steroids can cause throat irritation and oral candidiasis, especially if the mouth is not rinsed
Medication Issues and Concerns
• pirbuterol acetate
• salmeterol
Corticosteroids, e.g.,
• beclomethasone
• budesonide
• flunisolide
• fluticasone
• triamcinolone acetonide
Miscellaneous, e.g.,
• cromolyn
• nedocromil sodium
after administration
Sedatives/Hypnotics (sleep medications)
  All hypnotics
  Benzodiazepine hypnotics, e.g.,
• estazolam
• flurazepam
• quazepam
• temazepam
• triazolam
  Non-benzodiazepine hypnotics, e.g.,
• eszopiclone
• zaleplon
• zolpidem
  Melatonin receptor agonists, e.g.,
• ramelteon
  Other hypnotics, e.g.,
• chloral hydrate
Miscellaneous agents used for sleep, e.g.,
• sedating antidepressants (e.g., trazodone)
Indications
• Most cases of insomnia are associated with underlying conditions (secondary or co-morbid insomnia) such as psychiatric disorders (e.g., depression), cardiopulmonary disorders (e.g., COPD, CHF), urinary frequency, pain, obstructive sleep apnea, and restless leg syndrome. Insomnia may be further described by the duration of symptoms
• Before initiating medications to treat insomnia, other factors potentially causing insomnia should be evaluated, including, for example:
  o environment, such as excessive heat, cold, or noise; lighting
  o inadequate physical activity
  o facility routines that may not accommodate residents’ individual needs (e.g., time for sleep, awakening, toileting, medication treatments)
  o provision of care in a manner that disrupts sleep
  o caffeine or medications known to disrupt sleep
Medication
### Issues and Concerns

- sedating antihistamines (e.g., hydroxyzine)
  - pain and discomfort
  - underlying conditions (secondary or co-morbid insomnia) such as psychiatric disorders (e.g., depression), cardiopulmonary disorders (e.g., COPD, CHF), urinary frequency, pain, obstructive sleep apnea, and restless leg syndrome
- It is expected that interventions (such as sleep hygiene approaches, individualizing the sleep and wake times to accommodate the person’s wishes and prior customary routine, and maximizing treatment of any underlying conditions) are implemented to address the causative factor(s)
- These guidelines apply to any medication that is being used to treat insomnia. Initiation of medications to induce or maintain sleep should be preceded or accompanied by other interventions to try to improve sleep. All sleep medications should be used in accordance with approved product labeling; for example, timing and frequency of administration relative to anticipated waking time
- The use of sedating medications for individuals with diagnosed sleep apnea requires careful assessment, documented clinical rationale, and close monitoring

### Exceptions:

- Use of a single dose sedative for dental or medical procedures
- During initiation of treatment for depression, pain or other comorbid condition(s), short-term use of a sleep medication may be necessary until symptoms improve or the underlying aggravating factor can be identified and/or effectively treated

### Dosage

#### Daily Dose Thresholds For Sedative-Hypnotic Medications

<table>
<thead>
<tr>
<th>Medication</th>
<th>Oral Dosage</th>
</tr>
</thead>
<tbody>
<tr>
<td>chloral hydrate*</td>
<td>500 mg</td>
</tr>
<tr>
<td>diphenhydramine*</td>
<td>25 mg</td>
</tr>
<tr>
<td>estazolam</td>
<td>0.5 mg</td>
</tr>
<tr>
<td>eszopiclone</td>
<td>1 mg</td>
</tr>
<tr>
<td>flurazepam*</td>
<td>15 mg</td>
</tr>
<tr>
<td>hydroxyzine*</td>
<td>50 mg</td>
</tr>
<tr>
<td>lorazepam</td>
<td>1 mg</td>
</tr>
<tr>
<td>oxazepam</td>
<td>15 mg</td>
</tr>
<tr>
<td>quazepam*</td>
<td>7.5 mg</td>
</tr>
</tbody>
</table>
ramelteon
8 mg
temazepam
15 mg
triazolam*
0.125 mg
zaleplon
5 mg
zolpidem IR
5 mg
zolpidem CR
6.25 mg
* These medications are not considered medications of choice for the management of insomnia, especially in older individuals.

Reference:

**Duration**

- If used to induce sleep or treat a sleep disorder, refer to Section V – Tapering of a Medication Dose/Gradual Dose Reduction (GDR) in the guidance
- Barbiturates, e.g.,
  - amobarbital
  - butabarbital
  - pentobarbital
  - secobarbital
  - phenobarbital
  - amobarbital-secobarbital
  - barbiturates with other medications

**NOTE:** Refers to barbiturates used to induce sleep or treat anxiety disorder

**Indications**

- Barbiturates should not be initiated in any dose for any individuals to treat anxiety or insomnia; as they are highly addictive and cause numerous adverse effects, especially in older individuals

**Exception:** These guidelines do not apply to the use of phenobarbital to treat seizure disorders (see Anticonvulsant section)

**Medication Issues and Concerns**

**Interactions/Adverse Consequences**

- May increase the metabolism of many medications (e.g., anticonvulants, antipsychotics), which may lead to decreased effectiveness and subsequent worsening of symptoms or decreased control of underlying illness
- May cause hypotension, dizziness, lightheadedness, “hangover” effect, drowsiness, confusion, mental depression, unusual excitement, nervousness, headache, insomnia, nightmares, and hallucinations
- May increase the risk for falls

**Thyroid medications**

- All thyroid medications, e.g.,
  - levothyroxine
• triiodothyronine

**Interactions**
• Many clinically significant medication interactions have been identified; therefore, re-evaluation of medication doses is indicated

**Dosage**
• Initiation of thyroid supplementation should occur at low doses and be increased gradually to avoid precipitating cardiac failure or adrenal crisis

**Monitoring**
• Assessment of thyroid function (e.g., TSH, serum T4 or T3) should occur prior to initiation and periodically thereafter, including when new signs and symptoms of hypo- or hyperthyroidism are present

**Urinary incontinence medications**
Urinary Incontinence Types and Agents, e.g.,
Urge incontinence:
Anticholinergics, e.g.,
• darifenacin

**Indications**
• Before or soon after initiating medication(s) to manage urinary incontinence, assessment of underlying causes and identification of the type/category of urinary incontinence needs to be

**Medication Issues and Concerns**
• oxybutynin
• tolterodine
• trospium
Tricyclic antidepressants, e.g.,
• desipramine
• imipramine
Stress incontinence:
Alpha adrenergic agonists, e.g.,
• pseudoephedrine
Mixed incontinence, e.g.,
• estrogen replacement agents
• imipramine
Overflow incontinence, e.g.,
• alpha adrenergic antagonists (see antihypertensives)
• bethanechol chloride
documented
• These medications have specific, limited indications based on the cause and type/category of incontinence

**Monitoring**
• Ongoing assessments of the effects of the medication on the individual’s urinary incontinence as well as lower urinary tract symptoms should be done periodically

**Adverse Consequences**
• Anticholinergics and TCAs may cause anticholinergic effects (see Table II)
• Estrogen Replacement Agents: oral agents may cause systemic side effects and increased risks (e.g., deep venous thrombosis, breast cancer); therefore, topical agents may be preferred
• Bethanechol may cause hypotension, increased sweating and salivation, headache, cramps, diarrhea, nausea and vomiting, and worsening of asthma

**TABLE II**
**MEDICATIONS WITH SIGNIFICANT ANTICHOLINERGIC PROPERTIES**
Table II lists common medications with significant anticholinergic properties and potential adverse consequences, but is not all-inclusive. Any of the following signs and symptoms may be caused by any of the medications in the lists below, alone or in combination, as well as by other medications not listed here that have anticholinergic properties. This table is provided because: 1) Medications in many categories have anticholinergic properties; 2) The use of multiple medications with such properties may be particularly problematic because of the cumulative effects; and 3) Anticholinergic side effects are particularly common and problematic, especially in the older individual.61, 62

**Examples of Medications with Anticholinergic Properties**

**ANTIHISTAMINES (H-1 BLOCKERS)**
clorpheniramine cyproheptadine
diphenhydramine hydroxyzine

**CARDIOVASCULAR MEDICATIONS**
furosemide digoxin
nifedipine disopyramide

**ANTIDEPRESSANTS**
amoxapine amitriptyline
clo mipramine des ipramine
doxepin imipramine
nortriptyline protriptyline
paroxetine

**GASTROINTESTINAL MEDICATIONS**
Antidiarrheal Medications
diphenoxylate atropine
Antispasmodic Medications
belladonna clidinium chlordiazepoxide dicyclomine
hyoscymine propantheline
Antiulcer Medications
cimetidine ranitidine

**ANTIPARKINSON MEDICATIONS**
amantadine benztropine
biperiden trihexyphenidyl

**ANTIPSYCHOTIC MEDICATIONS**
chlorpromazine clozapine
olanzapine thioridazine

**MUSCLE RELAXANTS**
cyclobenzaprine dantrolene
orphenadrine

**URINARY INCONTINENCE**
oxycodone probantheline
solifenacin tolterodine
trospium
ANTIVERTIGO MEDICATIONS
meclizine scopolamine

PHENOTHIAZINE ANTIEMETICS
prochlorperazine promethazine

Potential Adverse Consequences of Medications with Anticholinergic Properties
Blood pressure, increased
Breathing difficulty, changes
Clumsiness or unsteadiness
Convulsions
Digestive system changes, e.g.,
Bloating
Bowel motility, decreased
Constipation
Ileus, paralytic/adynamic
Nausea or vomiting
Swallowing difficulty with dry mouth
Mental status/behavior changes, e.g.,
Distress, excitement, nervousness
Attention, impaired
Cognitive decline
Confusion/disorientation
Hallucinations
Memory loss
Restlessness or irritability
Delirium
Dizziness
Drowsiness
Fever
Headache
Heart rate, increased
Lethargy, fatigue
Mucous membrane dryness: mouth, nose
Muscle weakness, severe
Speech, slurring
Skin, changes
Dryness Sweating, decreased
Flushing Warmth, excessive
Vision impairment, changes in acuity
Blurring Glaucoma, worsening
Eye pain Light sensitivity
Urinary retention or difficulty

ENDNOTES
INVESTIGATIVE PROTOCOL
UNNECESSARY MEDICATIONS - MEDICATION REGIMEN REVIEW
Because they are closely related, the investigations of the requirements for medication regimen review and the review for unnecessary medications have been merged.

Objectives
• To determine whether each resident receives or is provided:
  o Only those medications that are clinically indicated in the dose and for the duration to meet his or her assessed needs;
  o Non-pharmacological approaches when clinically indicated, in an effort to reduce the need for or the dose of a medication; and
  o Gradual dose reduction attempts for antipsychotics (unless clinically contraindicated) and tapering of other medications, when clinically indicated, in an effort to discontinue the use or reduce the dose of the medication.
• To determine if the facility in collaboration with the prescriber:
  o Identifies the parameters for monitoring medication(s) or medication combinations (including antipsychotics) that pose a risk for adverse consequences; and for monitoring the effectiveness of medications (including a comparison with therapeutic goals); and
  o Recognizes and evaluates the onset or worsening of signs or symptoms, or a change in condition to determine whether these potentially may be related to the medication regimen; and follows-up as necessary upon identifying adverse consequences.
• To determine if the pharmacist:
  o Performed the monthly medication regimen review, and identified any existing irregularities regarding indications for use, dose, duration, and the potential for, or the existence of adverse consequences or other irregularities; and
  o Reported any identified irregularities to the attending physician and director of nursing.
• To determine whether the facility and/or practitioner acted on the report of any irregularity.

Use
Use this protocol during every initial and standard survey. In addition, this protocol may be used on revisits or abbreviated survey (complaint investigation) as necessary.

NOTE: This review is not intended to direct medication therapy. However, surveyors are expected to review factors related to the implementation, use, and monitoring of medications. The surveyor is not expected to prove that an adverse consequence was directly caused by a medication or combination of medications, but rather that there was a failure in the care process related to considering and acting upon such possibilities.

If during the course of this review, the surveyor needs to contact the attending physician regarding questions related to the medication regimen, it is recommended that the facility’s staff have the opportunity to provide the necessary information about the resident and the concerns to the physician for his/her review prior to responding to the surveyor’s inquiries.

Procedures
Review the medications (prescription, over-the-counter medications, and nutritional supplements such as herbal products) currently ordered and/or discontinued by the prescriber at least back to the most recent signed recapitulation/reorder of all medications. Obtain a copy of the current orders if necessary. Gather information regarding the resident’s mental, physical, functional, and
psychosocial status and the medication-related therapeutic goals identified in the care plan as the basis for further review.

1. Observation and Record Review
Use the table below to guide observations, record review, and interviews with the resident or representative and relevant staff. Observe whether the medication-related interventions are consistently implemented over time and across various shifts. Note deviations from the care plan as well as potential medication-related adverse consequences. Verify observations by gathering additional information; for example, additional record reviews and/or interviews with the resident or representative, relevant staff, and practitioners.

### SYMPTOMS, SIGNS, AND CONDITIONS THAT MAY BE ASSOCIATED WITH MEDICATIONS

### REVIEW FOR HOW FACILITY MANAGED MEDICATIONS FOR THE RESIDENT
Determine if the resident has been transferred to acute care since the last survey and/or has recently (e.g., the previous 3 months) experienced a change in condition or currently has signs and symptoms, such as:
- Anorexia and/or unplanned weight loss, or
- Behavioral changes, unusual behavior patterns (including increased distressed behavior)
- Bleeding or bruising, spontaneous or unexplained
- Bowel dysfunction including diarrhea, constipation and impaction
- Dehydration, fluid/electrolyte imbalance
- Depression, mood disturbance
- Dysphagia, swallowing difficulty
- Falls, dizziness, or evidence of impaired coordination
- Gastrointestinal bleeding
- Headaches, muscle pain, generalized or nonspecific aching or pain
- Mental status changes, (e.g., new or worsening confusion, new cognitive decline, worsening of dementia (including delirium))
- Rash, pruritus
- Respiratory difficulty or changes
- Sedation (excessive), insomnia, or sleep disturbance
- Seizure activity
- Urinary retention or incontinence

If observations or record review indicate symptoms or changes in condition that may be related to medications (refer to Tables I and II, supplemented with current medication references), determine whether the facility considered medications as a potential cause of the change or symptom.
- Clinical indications for use of the medication
- Consideration of non-pharmacological interventions
- Dose, including excessive dose and duplicate therapy
• Duration, including excessive duration
• Consideration of potential for tapering/GDR or rationale for clinical contraindication
• Monitoring for and reporting of:
  o Response to medications and progress toward therapeutic goals
  o Emergence of medication-related adverse consequences
• Adverse consequences, if present and potentially medication-related, note if there was:
  o Recognition, evaluation, reporting, and management by the facility
  o Physician action regarding potential medication-related adverse consequences

2. Interview
Interview the resident and or family/responsible party, to the extent possible, to determine:
• His/her participation in care planning and decision making, including discussions of the goals related to the use of medications;
• Whether approaches other than medications (as indicated) were discussed; and
• His/her evaluation of the results of the medication therapy and other approaches (such as decreasing symptoms of pain, improving functional ability).

If during the review, you identify concerns about the lack of indication for use; the dose or duration of a medication; lack of monitoring; failure to implement the care plan; or condition changes or functional decline that may be related to the medication regimen, interview knowledgeable staff to determine:
• Whether the resident has experienced any changes in the functioning or amount of activity that he/she is able to do;
• The clinical rationale for the use of the medication, dose or duration and how the interdisciplinary team is monitoring the resident’s response to the medication;
• What process is in place to assure the care plan interventions for medication use are being implemented;
• Whether they were aware that the signs and symptoms may be adverse consequences related to the medication regimen;
• Whether the staff had contacted the attending physician to discuss the signs and symptoms and the current medication regimen;
• Whether and how the physician responded when informed of suspected adverse medication consequences; and
• Whether the pharmacist performed a medication regimen review and identified related signs and symptoms, or the staff informed the pharmacist of them if they occurred after the last pharmacist visit.

Interview the physician, as appropriate, to determine:
• Whether staff notified him/her of potential medication-related issues and concerns;
• His/her assessment of the significance of medication-related issues and concerns; and
• Rationale for his/her management of the resident’s medications and/or medication-related issues or concerns.

3. Medication Regimen Review (MRR)
Review for compliance with the MRR requirements at F428. Determine:
• If the pharmacist had identified and reported to the director of nursing and attending physician any irregularities with the medication regimen such as:
  o The emergence or existence of clinically significant adverse consequences;
Excess dose or duration, lack of monitoring, lack of indication for use, lack of GDR (as indicated) or behavioral interventions for residents receiving antipsychotics, medication interactions potentially affecting the medication’s effectiveness; and

- Whether the attending physician and the director of nursing acted on any irregularities identified in the report. The responses from the attending physician could include the following:
  - Changed the medication regimen in response to the concern raised in the report (or after additional review of the situation);
  - Provided a clinically pertinent rationale that is relevant to that specific resident’s signs and symptoms, prognosis, test results, etc., documenting or indicating why the benefit of the medication(s) or dose(s) outweighed the risks of the adverse consequence;
  - Provided a clinically pertinent rationale for why any gradual dose reduction (for antipsychotic medications) and/or tapering (for other medications) is contraindicated, even for a trial period; or
  - Provided a clinically pertinent rationale for why a particular medication, dose, or duration is appropriate for a resident despite its risks (for example, the resident has had recurrent seizures unless he/she receives anticonvulsant dosing that exceeds the usual recommended serum medication concentration level or therapeutic range, and the attending physician and facility have been monitoring for and addressing adverse consequences).

If the pharmacist identified a suspected adverse consequence, and the attending physician did not respond, determine if staff followed up with the attending physician.

**NOTE:** If the staff and pharmacist identify a medication that they believe may be causing a serious adverse consequence or a risk of clinically significant adverse consequences for the resident, and the attending physician did not address the risks or harm to the resident, determine what steps staff took; e.g., contacting the medical director to review the situation and address the issue with the attending physician, as necessary. See guidance at 42 CFR 483.75(i) Medical Director (F501) for additional guidance.

If problems are identified with the MRR, interview the pharmacist, as indicated, to determine:

- How he/she conducts the MRR, including the frequency and extent of the medication review and under what circumstances a review might be conducted more often than monthly;
- How the facility communicates with him/her regarding medication-related issues in specific residents; and
- How he/she approaches the MRR process for short stay residents.

**DETERMINATION OF COMPLIANCE (Task 6, Appendix P)**

**Synopsis of Regulation (F329)**

The unnecessary medication requirement has six aspects in order to assure that medication therapy is appropriate for the individual resident. The facility must assure that medication therapy (including antipsychotic agents) is based upon:

- An adequate indication for use;
- Use of the appropriate dose;
- Provision of behavioral interventions and gradual dose reduction for individuals receiving antipsychotics (unless clinically contraindicated) in an effort to reduce or discontinue the medication;
- Use for the appropriate duration;
- Adequate monitoring to determine whether therapeutic goals are being met and to detect the emergence or presence of adverse consequences; and
- Reduction of dose or discontinuation of the medication in the presence of adverse consequences, as indicated.
Criteria for Compliance
Compliance with 42 CFR 483.25(l), F329, Unnecessary Medications
For a resident who has been, or is, receiving medication(s), the facility is in compliance if they, in collaboration with the prescriber:
• Assessed the resident to ascertain, to the extent possible, the causes of the condition or symptoms requiring treatment, including recognizing, evaluating, and determining whether the condition or symptoms may have reflected an adverse medication consequence;
• Based on the assessment, determined that medication therapy was indicated and identified the therapeutic goals for the medication;
• Utilized only those medications in appropriate doses for the appropriate duration, which are clinically necessary to treat the resident’s assessed condition(s);
• Implemented a gradual dose reduction and behavioral interventions for each resident receiving antipsychotic medications unless clinically contraindicated;
• Monitored the resident for progress towards the therapeutic goal(s) and for the emergence or presence of adverse consequences, as indicated by the resident’s condition and the medication(s); and
• Adjusted or discontinued the dose of a medication in response to adverse consequences, unless clinically contraindicated.
If not, cite F329.
Noncompliance for F329
After completing the investigation, determine whether or not compliance with the regulation exists. Noncompliance for F329 may include:
• Inadequate Indications for Use – Examples of noncompliance related to a medication being used without adequate indications include, but are not limited to:
  o Failure to document a clinical reason or demonstrate a clinically pertinent rationale, verbally or in writing, for using medication(s) for a specific resident.
  o Prescribing or administering a medication despite an allergy to that medication, or without clarifying whether a true allergy existed as opposed to other reactions (e.g., idiosyncratic reaction or other side effect).
  o Failure to provide a clear clinical rationale for continuing a medication that may be causing an adverse consequence.
  o Initiation of an antipsychotic medication to manage distressed behavior without considering a possible underlying medical cause (e.g., UTI, congestive heart failure) or environmental or psychosocial stressor.
  o Initiation of a medication presenting clinically significant risks without considering relative risks and benefits or potentially lower risk medications.
  o Concomitant use of two or more medications in the same pharmacological class without a clinically pertinent explanation.
• Inadequate Monitoring – Examples of noncompliance related to inadequate monitoring include, but are not limited to:
  o Failure to monitor the responses to or effects of a medication and failure to respond when monitoring indicates a lack of progress toward the therapeutic goal (e.g., relief of pain or normalization of thyroid function) or the emergence of an adverse consequence.
  o Failure to monitor a medication consistent with the current standard of practice or manufacturer’s guidelines.
Failure to carry out the monitoring that was ordered or failure to monitor for potential clinically significant adverse consequences. For example, use of warfarin in conjunction with:
– Inadequate or absent monitoring of PT/INR during treatment; and/or
– Failure to recognize and monitor the increased risk of adverse consequences when the resident is receiving other medications that are known to increase the risk of bleeding or to interact with warfarin and increase PT/INR.

**Excessive Dose (including duplicate therapy)** – Examples of noncompliance related to excessive dose include, but are not limited to:

- Giving a total amount of any medication at one time or over a period of time that exceeds the amount recommended by the manufacturer’s recommendations, clinical practice guidelines, evidence-based studies from medical/pharmacy journals, or standards of practice for a resident’s age and condition, without a documented clinically pertinent rationale.
- Failure to consider periodically the continued necessity of the dose or the possibility of tapering a medication.
- Failure to provide and/or document a clinical rationale for using multiple medications from the same pharmacological class.

**Excessive Duration** – Examples of noncompliance related to excessive duration include, but are not limited to:

- Continuation beyond the manufacturer’s recommended time frames, the stop date or duration indicated on the medication order, facility-established stop order policies, or clinical practice guidelines, evidence-based studies from medical/pharmacy journals, or current standards of practice, without documented clinical justification.
- Continuation of a medication after the desired therapeutic goal has been achieved without evaluating whether the medication can offer any additional benefit, for example:
  – Use of an antibiotic beyond the recommended clinical guidelines or the facility policy without adequate reassessment of the resident and determination of continuing need.
  – Failure to re-evaluate the rationale for continuing antipsychotic medication initiated in an emergency after the acute phase has stabilized.

**Adverse Consequences** – Examples of noncompliance related to adverse consequences include, but are not limited to:

- Failure to act upon (i.e., discontinue a medication or reduce the dose or provide clinical justification for why the benefit outweighs the adverse consequences) a report of the risk for or presence of clinically significant adverse consequence(s);
- Failure to respond to actual or potentially clinically significant adverse consequences related to the use of warfarin when the PT/INR exceeds the target goal.

**Antipsychotic Medications without Gradual Dose Reduction and Behavioral Interventions unless Clinically Contraindicated** – Examples of noncompliance related to this requirement include, but are not limited to:

- Failure to attempt GDR in the absence of identified and documented clinical contraindications.
- Prolonged or indefinite antipsychotic use without attempting gradual dose reductions.
- Failure to implement behavioral interventions to enable attempts to reduce or discontinue an antipsychotic medication.

**Potential Tags for Additional Investigation**

If noncompliance with 483.25(l) 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 may 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 if the resident has not responded to medication therapy as anticipated and/or indicated.

- **42 CFR 483.10 (b)(3) and (4), F154, F155, Notice of Rights and Services and (d)(2) Free Choice**
  - Determine whether the resident was advised of her/his medical condition and therapy and was informed about her/his treatment including medications and the right to refuse treatments.

- **42 CFR 483.20(b), F272, Comprehensive Assessments**
  - Review whether the facility’s initial and periodic comprehensive assessments include an assessment of the resident’s medication regimen.

- **42 CFR 483.20(k)(1) and (2), F279, F280, Comprehensive Care Plans**
  - Review whether the resident’s comprehensive care plan: a) was based on the assessment of the resident’s conditions, risks, needs, and behavior; b) was consistent with the resident’s therapeutic goals; c) considered the need to monitor for effectiveness based on those therapeutic goals and for the emergence or presence of adverse consequences; and (d) was revised as needed to address medication-related issues.

- **42 CFR 483.25(a)(1), F310, Decline in ADL**
  - Review whether the facility had identified, evaluated, and responded to a new or rapidly progressive decline in function, development or worsening of movement disorders, increased fatigue and activity intolerance that affected the resident’s ADL ability in relation to potential medication adverse consequences.

- **42 CFR 483.25(d), F315, Urinary Incontinence**
  - Review whether the facility had identified, evaluated, and responded to a change in urinary function or continence status in relation to potential medication adverse consequences.

- **42 CFR 483.25(f)(1)&(2), F319, F320, Mental and Psychosocial Functioning**
  - Review whether the facility had identified, evaluated, and responded to a change in behavior and/or psychosocial changes, including depression or other mood disturbance, distress, restlessness, increasing confusion, or delirium in relation to potential medication adverse consequences.

- **42 CFR 483.25(i)(1), F325, Nutritional Parameters**
  - Review if the facility had identified, evaluated, and responded to a change in nutritional parameters, anorexia or unplanned weight loss, dysphagia, and/or swallowing disorders in relation to potential medication adverse consequences.

- **42 CFR 483.25(j), F327, Hydration**
  - Review if the facility had identified, evaluated, and responded to a change in hydration or fluid or electrolyte balance (for example, high or low sodium or potassium) in relation to potential medication adverse consequences.

- **42 CFR 483.40(a), F385, Physician Supervision**
  - Review if the attending physician supervised the resident’s medical treatment, including assessing the resident’s condition and medications, identifying the clinical rationale, and monitoring for and addressing adverse consequences.
42 CFR 483.40(b), F386, Physician Visits
  o Review if the attending physician or designee reviewed the resident’s total program of care and wrote, signed, and dated progress notes covering pertinent aspects of the medication regimen and related issues.

42 CFR 483.60(c), F428, Medication Regimen Review
  o Review whether the licensed pharmacist has provided consultation regarding the integrity of medication-related records (e.g., MAR, physician order sheets, telephone orders), and potential or actual medication irregularities.

42 CFR 483.75(i), F501, Medical Director
  o Review whether the medical director, when requested by the facility, interacted with the attending physician regarding a failure to respond or an inadequate response to identified or reported potential medication irregularities and adverse consequences; and whether the medical director collaborated with the facility to help develop, implement, and evaluate policies and procedures for the safe and effective use of medications in the care of residents.

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.

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**F332 and F333**

§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)**

Medication Error -- The observed preparation or administration of drugs or biologicals which is not in accordance with:

1. Physician’s orders;
2. Manufacturer’s specifications (not recommendations) regarding the preparation and administration of the drug 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 unequilved by an ordered laxative that results in a drug 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 errors. The numerator in the ratio is the total number of errors that the survey team observes, both significant and nonsignificant. The denominator is called “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:

\[
\text{Medication Error Rate} = \frac{\text{Number of Errors Observed}}{\text{Opportunities for Errors}} \times 100.
\]

“**Medication error rate**” -- A medication error rate of 5% or greater includes both significant and nonsignificant medication errors. It indicates that the facility may have systemic problems with its drug distribution system and a deficiency should be written. The error rate must be 5% or greater. Rounding of a lower rate (e.g., 4.6%) to a 5% rate is not permitted.

**Significant and Nonsignificant 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 drug 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 drug that has a Narrow Therapeutic Index (NTI) (i.e., a drug in which the therapeutic dose is very close to the toxic dose). Examples of drugs 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 drug 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 drug category.

“**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 nonsignificant have also been designated primarily on the basis of the nature of the drug. Resident status and frequency of error could classify these errors as significant.

**Examples of Medication Errors Detected**

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

<table>
<thead>
<tr>
<th>Drug Order</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Haldol 1mg BID</td>
<td>NS</td>
</tr>
<tr>
<td>Motrin 400mg TID</td>
<td>NS</td>
</tr>
<tr>
<td>Quinidine 200mg TID</td>
<td>S**</td>
</tr>
<tr>
<td>Tearisol Drops 2 both eyes TID</td>
<td>NS</td>
</tr>
<tr>
<td>Metamucil one packet BID</td>
<td>NS</td>
</tr>
<tr>
<td>Multivitamin one daily</td>
<td>NS</td>
</tr>
<tr>
<td>Mylanta Susp. one oz., TID AC</td>
<td>NS</td>
</tr>
<tr>
<td>Nitrol Oint. one inch</td>
<td>S</td>
</tr>
</tbody>
</table>
* Not Significant
**Significant

**Unauthorized Drug Examples (Drugs administered without a physician’s order):**

<table>
<thead>
<tr>
<th>Drug Order</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feosol</td>
<td>NS</td>
</tr>
<tr>
<td>Coumadin 4mg</td>
<td>S</td>
</tr>
<tr>
<td>Zyploprim 100mg</td>
<td>NS</td>
</tr>
<tr>
<td>Tylenol 5 gr</td>
<td>NS</td>
</tr>
<tr>
<td>Motrin 400mg</td>
<td>NS</td>
</tr>
</tbody>
</table>

**Wrong Dose Examples:**

<table>
<thead>
<tr>
<th>Drug Order</th>
<th>Administered</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Timoptic 0.25% one drop in the left eye TID</td>
<td>Three drops in each eye</td>
<td>NS</td>
</tr>
</tbody>
</table>
Digoxin 0.125mg everyday
0.25mg
S
Amphojel 30ml QID
15ml
NS
Dilantin 125 SUSP 12ml
2ml
S
Wrong Route of Administration Examples:
Drug Order
Administered
Significance
Cortisporin Ear Drops 4 to 5 left ear QID
Left Eye
S
Wrong Dosage Form Examples:
Drug Order
Administered
Significance
Colace Liquid 100mg BID
Capsule
NS
Mellaril Tab 10mg
Liquid Concentrate
NS*
Drug Order
Administered
Significance
Dilantin Kapseals 100 mg three Kapseals p.o. HS
Prompt Phenytoin 100 mg three capsules p.o. HS
S
* If correct dose was given.
** Parke Davis Kapseals have an extended rate of absorption. Prompt phenytoin capsules do not.
Wrong Drug Examples:
Wrong Time Examples:
Drug Order
Administered
Significance
Digoxin 0.25mg daily at 8 a.m.
At 9:30 am
NS
Percocet 2 Tabs 20 min. before painful treatment
2 Tabs given 3 after treatment
S
**Medication Errors Due to Failure to Follow Manufacturers Specifications or Accepted Professional Standards**

The following situations in drug administration may be considered medication errors:

- **Failure to “Shake Well”:** The failure to “shake” a drug product that is labeled “shake well.” This may lead to an under dose or over dose depending on the drug 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 drugs, for example dilantin, 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.

- **Crushing Medications that should not be Crushed:** Crushing tablets or capsules that the manufacturer states “do not crush.”

  **Exceptions to the “Do Not Crush” rule:**

  - If the prescriber orders a drug 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.

**Drug Order Administered Significance**

<table>
<thead>
<tr>
<th>Tums</th>
<th>Oscal</th>
<th>NS</th>
<th>Vibramycin</th>
<th>Vancomycin</th>
</tr>
</thead>
</table>

- If the facility can provide literature from the drug manufacturer or from a reviewed health journal to justify why modification of the dosage form will not compromise resident care.

- **Adequate Fluids with Medications:** The administration of medications without adequate fluid when the manufacturer specifies that adequate fluids be taken with the medication. For example:

  - **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. 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). 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; 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.
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 drugs 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

**Generic Name**

**Brand Name**

Etodolac
Lodine
Fenoprofen
Nalfon
Ibuprofen
Motrin, Advil
Indomethacin
Indocin
Ketoprofen
Orudis, Oruvail
Mefenamic Acid
Ponstel
Nabumetone
Relafen
Naproxen
Naprosyn, Aleve
Piroxicam
Feldene
Sulindac
Cloniril
Tolmetin
Tolectin

• Medications Administered with Enteral Nutritional Formulas: Administering medications immediately before, immediately after, or during the administration of enteral nutritional formulas (ENFs) without achieving the following minimum objectives:

  o Check the placement of the naso-gastric or gastrostomy tube in accordance with the facility’s policy on this subject. **NOTE:** If the placement of the tube is not checked, this is not a
medication error; it is a failure to follow accepted professional practice and should be evaluated under Tag F281 requiring the facility to meet professional standards of quality.

- Flush the enteral feeding tube with at least 30 ml of preferably warm water before and after medications are administered. While it is noted that some facility policies ideally adopt flushing the tube after each individual medication is given, as opposed to after the group of multiple medications is given, unless there are known compatibility problems between medicines being mixed together, a minimum of one flushing before and after giving the medications is all the surveyor need review. There may be cases where flushing with 30 ml after each single medication is given may overload an individual with fluid, raising the risk of discomfort or stress on body functions. Failure to flush, before and after, would be counted as one medication error and would be included in the calculation for medication errors exceeding 5 percent.

- The administration of enteral nutrition formula and administration of 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 dilantin, then the surveyor should consider simultaneous administration a medication error.

- Medications Instilled into the Eye: The administration of eye drops without achieving the following critical objectives:
  - **Eye Contact**: The eye drop, but not the dropper, must make full contact with the conjunctival sac and then be washed over the eye when the resident closes the eyelid; and
  - **Sufficient Contact Time**: 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 can 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.)

- Allowing Resident to Swallow Sublingual Tablets: 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 drug.

- Medication Administered Via Metered Dose Inhalers (MDI): The use of MDI in other than the following ways (this includes use of MDI by the resident). This is an error if the person administering the drug did not do all the following:
  - Shake the container well;
  - Position the inhaler in front of or in the resident’s mouth. Alternatively a spacer may be used;
  - For cognitively impaired residents, many clinicians believe that the closed mouth technique is easier for the resident and more likely to be successful. However, the open mouth technique often results in better and deeper penetration of the medication into the lungs, when this method can be used; and
  - If more than one puff is required, (whether the same medication or a different medication) wait approximately a minute between puffs.

**NOTE:** If the person administering the drug 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 called 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 drug is ordered before meals (AC) and administered after meals (PC), always count this as a medication error. Likewise, if a drug is ordered PC and is given AC, count as a medication error. Count a wrong time error if the drug 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 drug with a long half-life (e.g., digoxin) as a wrong time error when it is 15 minutes late is improper because this drug 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 drug 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 drug.

**Procedures §483.25(m)**

**Medication Error Detection Methodology** -- Use an observation technique to determine medication errors. The survey team should observe the administration of drugs, on several different drug “passes,” when necessary. Record what is observed; and reconcile the record of observation with the prescriber’s drug 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 drugs, in what strength, and dosage forms, are being administered. This is accomplished prior to drug administration and may be done in a number of ways depending on the drug distribution system used (e.g. unit dose, vial system, punch card).

1. Identify the drug product. There are two principal ways to do this. In most cases, they are used in combination:
   - Identify the product by its size, shape, and color. Many drug products are identifiable by their distinctive size, shape, or color. This technique is problematic because not all drugs have distinctive sizes, shapes, or color.
   - Identify the product 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 drug product. 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 drugs (“pass”). Follow the person administering drugs and observe residents receiving drugs (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 drug “passes,” if possible, so the survey team will have an assessment of the entire facility rather than one staff member on one drug 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.

3. Reconcile the surveyor’s record of observation with physician’s orders. Compare the record of observation with the most current orders for drugs. This comparison involves two distinct activities:
• For each drug 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 drug? Was the drug the correct one?
• For drugs not on the surveyor’s list: Are there orders for drugs that should have been administered, but were not? Examine the record for drug orders that were not administered and should have been. Such circumstances may represent omitted doses, one of the most frequent types of errors.
• Ask the person administering drugs, if possible, to describe the system for administering the drugs 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 drugs, 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 drugs are not available, ask their supervisor for clarification.

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 drugs 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 drug 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 drugs with the number of days the drug has been in use and the directions for use. For example, if a drug were
in use for 5 days with direction to administer the drug 4 times a day, then 20 doses should have been used. If a count of the supply of that drug 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 drugs received, and the date and the specific “pass” when that particular drug 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.

F334
§483.25(n) Influenza and pneumococcal immunizations---
(1) Influenza. The facility must develop policies and procedures that ensure that--
i. Before offering the influenza immunization, each resident or the resident’s legal representative receives education regarding the benefits and potential side effects of the immunization;
ii. Each resident is offered an influenza immunization October 1 through March 31 annually, unless the immunization is medically contraindicated or the resident has already been immunized during this time period;
iii. The resident or the resident’s legal representative has the opportunity to refuse immunization; and
iv. The resident’s medical record includes documentation that indicates, at a minimum, the following:
   (A) That the resident or resident’s legal representative was provided education regarding the benefits and potential side effects of influenza immunization; and
   (B) That the resident either received the influenza immunization or did not receive the influenza immunization due to medical contraindications or refusal.

(2) Pneumococcal disease. The facility must develop policies and procedures that ensure that—
i. Before offering the pneumococcal immunization, each resident or the resident’s legal representative receives education regarding the benefits and potential side effects of the immunization;
ii. Each resident is offered an pneumococcal immunization, unless the immunization is medically contraindicate or the resident has already been immunized;
iii. The resident or the resident’s legal representative has the opportunity to refuse immunization; and
iv. The resident’s medical record includes documentation that indicates, at a minimum, the following:
   (A) That the resident or resident’s legal representative was provided education regarding the benefits and potential side effects of pneumococcal immunization; and
   (B) That the resident either received the pneumococcal immunization or did not receive the pneumococcal immunization due to medical contraindication or refusal.

v. Exception. As an alternative, based on an assessment and practitioner recommendation, a second pneumococcal immunization may be given after 5 years following the first pneumococcal immunization, unless medically contraindicated or the resident or the resident’s legal representative refuses the second immunization.

Intent:
The intent of this requirement is to:

- Minimize the risk of residents acquiring, transmitting, or experiencing complications from influenza and pneumococcal pneumonia by assuring that each resident:
  - Is informed about the benefits and risks of immunizations; and
  - Has the opportunity to receive, unless medically contraindicated or refused or already immunized, the influenza and pneumococcal vaccine; and

- Assure documentation in the resident’s medical record of the information/education provided regarding the benefits and risks of immunization and the administration or the refusal of or medical contraindications to the vaccine(s).

**Definitions**

Medical contraindication – A condition or risk that precludes the administration of a treatment or intervention because of the substantial probability that harm to the individual may occur.

Precaution - A condition in a potential recipient that might increase the risk for a serious adverse reaction or that might compromise the vaccine’s induction of immunity. However, the risk for this happening is less than expected with a contraindication. For example, as a result of the resident’s condition, complications could result, or a person might experience a more severe reaction to the vaccine than would have otherwise been expected; however, the risk for this happening is less than expected with medical contraindications.

**Overview**

Receipt of vaccinations is essential to the health and well-being of long-term care residents. Establishing an immunization program facilitates achievement of this objective. Flu outbreaks place both the residents and the nursing facility staff at risk of infection. Pneumococcal pneumonia, a type of bacterial pneumonia, is a common cause of hospitalization and death in older people. People 65 years or older are two to three times more likely than the younger population to get pneumococcal infections.

According to the Centers for Disease Control and Prevention (CDC), (see http://www.cdc.gov/mmwr/preview/mmwrhtml/rr54e713a1.htm) “the primary option for reducing the effect of influenza is immuno-prophylaxis with vaccine. Inactivated (i.e., killed virus) influenza vaccine and live, attenuated influenza vaccine are available for use in the United States. Vaccinating persons at high risk for complications and their contacts each year before seasonal increases in influenza virus circulation is the most effective means of reducing the effect of influenza. When vaccine and epidemic strains are well-matched, achieving increased vaccination rates among persons living in closed settings (e.g., nursing homes and other chronic-care facilities) and among staff can reduce the risk for outbreaks by inducing herd immunity. Vaccination of health-care workers and other persons in close contact with persons at increased risk for severe influenza illness can also reduce transmission of influenza and subsequent influenza-related complications. Antiviral drugs used for chemoprophylaxis or treatment of influenza are a key adjunct to vaccine …However, antiviral medications are not a substitute for vaccination.”

Because of the clinically complex conditions of most nursing home residents, it is especially important for the facility to have a program in place for the prevention of disease. The Long Term Care regulations at 42 CFR 483.65 (Tag F441) Infection Control, requires that each “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.” The regulation for immunization complements this existing infection control regulation in the areas of prevention of the development and transmission of disease. (For
more information on immunizations programs, see http://www.cdc.gov/nip/publications/long-term-care.pdf.)
An effective immunization program involves collaborating with the medical director to develop resident care policies for immunization(s) that reflect current standards of practice and that include:
• Physician approved policies for orders for influenza and pneumococcal polysaccharide vaccines (administration must be based on an assessment of each resident for possible medical contraindications – See Tag F386 for physician orders for vaccinations);
• Identification, of each resident’s immunization status, including assessment for potential medical contraindications and record of vaccination;
• The vaccination schedule including mechanisms for recording and monitoring for administration of both influenza and pneumococcal pneumonia vaccines; and
• How pertinent information will be provided to residents. The facility may wish to use educational resources such as those provided by the U. S. Centers for Disease Control (CDC):
  o For trivalent inactivated vaccine (TIV): http://www.cdc.gov/nip/publications/VIS/vis-flu.pdf;
  o For live attenuated vaccine (LAIV) LAIV: http://www.cdc.gov/nip/publications/VIS/vis-flulive.pdf; and
For information on the influenza vaccines, the following site contains information on the background, types of vaccines, medical contraindications and other information: http://www.cdc.gov/mmwr/preview/mmwrhtml/rr54e713a1.htm.

PROVISION OF IMMUNIZATIONS
In order for a resident to exercise his or her right to make informed choices, it is important for the facility to provide the resident with education regarding the benefits and potential side effects of immunizations. Facilities are required by 42 CFR 483.25(n)(1)(iv) and 42 CFR 483.25(n)(2)(iv) to document the provision of this education and the administration or refusal of the immunization or the medical contraindication of the immunization. There may be clinical indications or other reasons that a resident may not have received immunizations. Examples may include, but are not limited to the following:
• A decision may have been made to delay vaccination for a resident because a precaution is present. According to the CDC, “under normal circumstances, vaccinations should be deferred when a precaution is present. However, a vaccination might be indicated in the presence of a precaution because the benefit of protection from the vaccine outweighs the risk for an adverse reaction. The presence of a moderate or severe acute illness with or without a fever is a precaution to administration of all vaccines;”
• A resident may be in the end stages of a terminal illness and receiving care that is limited to comfort or palliative measures only. Vaccination decisions for residents in the end stages of a terminal illness should be made jointly by the physician and resident;
• A resident may have medical contraindications for live attenuated influenza vaccine (LAIV) that, according to the Centers for Disease Control and Prevention (www.cdc.gov/flu/professionals/vaccination/shouldnotlaiv.htm) include, but are not limited to:
  o Persons who are 50 years of age or older, have asthma, reactive airway disease, or other chronic disorders of the pulmonary or cardiovascular systems;
  o Persons with underlying medical conditions, including such metabolic diseases such as diabetes, renal dysfunction, and hemoglobinopathies;
- Persons with known or suspected immunodeficiency diseases or who are receiving immunosuppressive therapies; and
- Persons with a history of hypersensitivity, including anaphylaxis, to any of the components of LAIV or to eggs;
  - A resident may have already received the influenza vaccine for this season; and the pneumococcal immunization status is current; and
  - The resident refused the immunization.

**NOTE:** Inactivated influenza vaccine contains noninfectious killed viruses and cannot cause influenza. Since there is a delay in developing antibodies after vaccination, the resident may develop influenza if there was exposure prior to receiving the vaccine. Coincidental respiratory disease unrelated to influenza vaccination can occur at any time after vaccination.

Following vaccination with inactivated vaccine a person may experience local reaction and/or systemic reactions. Local reactions typically include soreness at the vaccination site and body aches. Systemic reactions include fever, malaise and myalgia and persons who have had no previous exposure to the influenza virus antigens in the vaccine are most often affected.

Other reactions as identified by the CDC, which may occur immediately, presumably allergic reactions (e.g., hives, angioedema, allergic asthma, and systemic anaphylaxis) rarely are due to the influenza component of the vaccination, but probably result from hypersensitivity to other vaccine components; the majority of reactions probably are caused by residual egg protein.

Persons who have had hives or swelling of the lips or tongue, or who have experienced acute respiratory distress or collapse after eating eggs should consult a physician for appropriate evaluation to help determine if vaccine should be administered. Persons who have documented immunoglobulin E (IgE)-mediated hypersensitivity to eggs, including those who have had occupational asthma or other allergic responses to egg protein, might also be at increased risk for allergic reactions to influenza vaccine, and consultation with a physician should be considered.

The following resource contains information on side effects of influenza vaccines: [http://www.cdc.gov/mmwr/preview/mmwrhtml/rr54e713a1.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/rr54e713a1.htm)

The resident’s record should show vaccination administration to the resident unless the record contains documentation as to why vaccine was not administered, including but not limited to:
- Precautions necessitating delay in administering the vaccination;
- Medical contraindications to the use of the vaccines;
- The eligible resident refused the vaccine; or
- The resident has already been immunized.

**NOTE:** The influenza vaccine is given seasonally. Although the vaccines usually are representative of the influenza viruses likely to circulate during the flu season, occasionally the vaccine may not be as closely representative. The CDC indicates that administering the vaccine during October or November is generally most effective. However, residents admitted late in the influenza season, February or March, should be offered the influenza vaccine as late season outbreaks do occur. If a resident was admitted outside the influenza season (which is October 1 through March 31), the facility is not expected to offer the influenza vaccine to the resident, but they may, at their discretion.

There should be documentation in the medical record if there is reason to believe that the pneumococcal vaccine was given previously but the date cannot be verified and this had an impact upon the decision regarding administration of the vaccine.

According to the CDC, “Pneumococcal polysaccharide vaccine generally is considered safe based on clinical experience since 1977, when the pneumococcal polysaccharide vaccine was
licensed in the United States. Approximately half of persons who receive pneumococcal vaccine develop mild, local side effects (e.g., pain at the injection site, erythema, and swelling). These reactions usually persist for less than 48 hours. Moderate systemic reactions (e.g., fever and myalgia) and more severe local reactions (e.g., local induration) are rare. Intradermal administration may cause severe local reactions and is inappropriate. Severe systemic adverse effects (e.g., anaphylactic reactions) rarely have been reported after administration of pneumococcal vaccine. For more information for the pneumococcal vaccine, see http://www.cdc.gov/mmwr/preview/mmwrhtml/00047135.htm

The pneumococcal vaccine does not prevent or lessen the impact of other types of pneumonia, such as aspiration, fungal, or viral.

INVESTIGATIVE PROTOCOL

Immunizations for Influenza and Pneumococcal Pneumonia

Objectives:
• To determine if the facility’s immunization program has been implemented and assures that residents are offered vaccines, and that residents or legal representatives receive related education;
• To determine if education regarding the benefits and potential side effects of immunization(s) was provided to the resident or legal representative each time a vaccine was offered; and
• To determine if each resident received the influenza and/or pneumococcal immunization(s) unless medically contraindicated, refused, or already immunized, or because of circumstances outside of the facility’s control, such as vaccine production delays.

Sampling:
For surveys during influenza season (October 1-March 31), follow the Procedure below for all residents who are selected for Comprehensive Reviews in Task 5C – Resident Review. If this number is below 5 residents, select additional residents from the Phase 1 Focused Review sample residents to meet the minimum number of 5 residents.

For surveys conducted outside influenza season, select 5 residents from the list the facility provided (see Task 2 – Entrance Conference) of all current residents who were in the facility during the previous influenza season. Give precedence in selection to those residents whom the survey team has selected as Phase 1 sample residents.

Procedure
For all residents selected for this review, determine the following:

For the provision of Pneumococcal Pneumonia Vaccine, review all selected residents for:
• The provision of education related to the vaccine; and
• Either documentation of the administration of the vaccine; or
• If not provided, documentation as to why the vaccine was not provided, such as medical contraindications, refusal, or vaccine was already given prior to admission.

For the provision of Influenza Vaccine:
• For surveys occurring outside of influenza season, review selected residents for the provision of influenza education and immunization during the previous influenza season.
• For surveys occurring during influenza season, review all selected residents for the provision of influenza education and immunization during the current influenza season.

Review residents for:
• The provision of education for the vaccine; and
The administration of the vaccine, or if the vaccine was not provided, the reason why the vaccine was not provided, such as medical contraindications, refusal, unavailability of the vaccine, or vaccine was already given prior to admission.

NOTE: (For surveys occurring during influenza season) - Unavailability of the influenza vaccine can be a valid reason why a facility has not implemented the influenza vaccine program, especially during the early weeks of the influenza season. It is also likely that a facility surveyed during October may not have administered the vaccine, yet. In these instances, ask the facility to demonstrate that:

- The vaccine has been ordered and the facility received either the vaccine or a confirmation of the order indicating that the vaccine has been shipped or that the product is not available but will be shipped when the supply is available;
- Plans are developed on how and when the vaccines are to be administered;
- Residents have been screened to determine how many and which residents are eligible and wish to receive the vaccine; and
- Education regarding immunizations has been implemented.

For surveys occurring during influenza season, review the facility’s immunization program if:

- There has been no shortage or lack of availability of the vaccines and residents have not refused the vaccine, but the residents have not yet been vaccinated;
- The resident(s), have not been evaluated for vaccination status, or
- The resident(s) has not received information/education about the benefits and potential risks of the immunizations.

For all facilities, determine if the facility developed influenza and pneumococcal vaccine policies and procedures including, but not limited to the following:

- The type of information/education provided to the resident prior to administration of the immunization(s);
- How the influenza vaccine program is implemented during the influenza season (October through March), including physician orders and standing orders (if standing orders are used);
- How the pneumococcal vaccine will be provided (i.e., throughout the calendar year);
- How residents and families are educated about the benefits and risks of the vaccines;
- Processes to address issues that are out of the facility’s control such as non-availability of vaccines due to production delay or distribution problems, or the presence of a precaution in a resident that may warrant a delay in vaccine;
- The identification and tracking/monitoring of a resident’s vaccination status (including medical contraindications or delayed administrations); and
- The location of documentation of education and administration of the vaccines.

If there are significant discrepancies between the facility's policies and procedures and the follow through for the vaccine program, ask the person responsible for implementing the procedures to explain the discrepancies.

Determination of Compliance (Task 6, Appendix P)

Synopsis of Regulation (F334)

The influenza and pneumococcal vaccination requirement has five aspects:

1. The resident is provided education regarding the benefits and potential side effects of the vaccinations;
2. The facility must offer each resident influenza and pneumococcal immunizations unless the immunization is medically contraindicated, or the resident’s immunization status is current;
3. The resident, or the resident’s legal representative, has the right to refuse the vaccinations;
4. Each eligible resident is administered the influenza and pneumococcal vaccine (unless refused or contraindicated or the resident has already been immunized); and
5. The facility must document that education was provided and that the resident either received the vaccine(s) or, if not received, that the vaccines(s) was (were) refused or medically contraindicated or the resident had already been immunized.

Criteria for Compliance

- Compliance with 42 CFR 483.25 (n), F334, Influenza and Pneumococcal Immunizations
  - The facility is in compliance with this requirement:
    - If each resident receives education regarding the benefits and potential side effects of the vaccine(s);
    - If each resident has been evaluated for eligibility to receive the vaccine(s);
    - If each resident is offered, unless medically contraindicated or already vaccinated, an influenza vaccine October 1 through March 31 annually, and a pneumococcal vaccine;
    - If the resident has the opportunity to refuse; and
    - If the record includes documentation that indicates, at a minimum:
      - The resident was provided education regarding the benefits and potential side effects; and
      - That the resident received the immunizations, refused the vaccination(s), or did not receive the vaccine(s) because of already being immunized, or as a result of a medical contraindication (including the nature of the resident’s medical contraindications), unavailability, or a precaution that delayed the administration and a later date for administration has been planned.

If the facility is not in compliance with each of these aspects of the requirement, cite F334.

Non-compliance for F334

After completing the investigative protocol, determine whether noncompliance with the regulation exists. Noncompliance for F334 may include, but is not limited to, one or more of the following:

- An eligible resident did not receive either the influenza and/or the pneumococcal vaccines without a valid reason;
- The facility did not evaluate to identify potential medical contraindications to the vaccines;
- The facility administered either of the vaccines to a resident who had refused them;
- The facility administered the influenza vaccine to a resident with medical contraindications, without physician involvement and/or approval;
- The facility administered the vaccine(s) to a resident who had an identified precaution, such as moderate or severe acute illness with or without fever, without physician involvement and/or approval;
- The facility administered the live attenuated influenza vaccine without physician approval to a resident who has a medical contraindication for live attenuated influenza vaccine;
- The facility failed to provide the pertinent information regarding the immunizations to the resident;
- The facility failed to document that the resident or resident's legal representative was provided education regarding the benefits and potential side effects of the influenza and, as applicable, the pneumococcal immunization; and
• The facility failed to document that the resident either received the vaccine(s) or did not receive the vaccine(s) due to medical contraindications or refusal.

Potential Tags for Additional Investigation
During the investigation of F334, the surveyor may have identified concerns with additional requirements related to outcome, process, and/or structure requirements. The surveyor is cautioned to investigate these related requirements before determining whether non-compliance may be present. Examples of some of the related requirements that may be considered when non-compliance F334 has been identified include the following:
• 42 CFR 483.20(b), F272, Comprehensive Assessments
  o Review whether the resident’s comprehensive assessment documented whether the influenza and/or pneumococcal vaccines were administered in the facility, including the reason(s) why a vaccine may not have been received in the facility.
• 42 CFR 483.65, F441, Infection Control Program
  o Review whether the facility’s program for infection control includes the prevention of the development and transmission of disease and infections including influenza and pneumococcal pneumonia.
• 42 CFR 483.75(i)(2), F501, Medical Director
  o Determine whether the medical director has collaborated with the facility to develop policies and procedures based on current standards of practice for an immunization program, including the assessment of the resident, identification of medical contraindications/precautions and emergency medical interventions in the case of allergic reactions to the vaccines.

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 non-compliance with the regulation at F334 exists, the team must determine the severity of the deficient practice(s) and the resultant harm or potential for harm to the resident. The key elements for severity determination for F334 are as follows:
1. Presence of harm/negative outcome(s) or potential for negative outcomes because of lack of appropriate treatment and care.
Non-compliance related to an actual or potential harm/negative outcome for F334 may include, but is not limited to:
• A resident who is not eligible to receive the vaccines is administered the vaccine and has a reaction;
• A resident who is eligible for the vaccine refuses the immunization, however, the resident is administered the vaccine; or
• The facility fails to implement the immunization program and the residents experience an outbreak of influenza.

2. Degree of harm (actual or potential) related to the non-compliance.
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, or compromise or discomfort to occur to the resident.

3. The immediacy of correction required.
Determine whether the non-compliance 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 F334. 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 non-compliance does not remove a finding of immediate jeopardy. The facility is required to implement specific actions to correct the non-compliance 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 non-compliance with one or more requirements of participation:

• Has allowed/caused/resulted in, or is likely to cause/allow/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 of the facility’s non-compliance that may cause or contribute to negative outcomes at severity level 4 include:

• A resident who is not eligible to receive the vaccine due to medical contraindications is administered the vaccine and experiences a life threatening reaction, such as anaphylactic shock; or
• Residents who were eligible to receive vaccines did not receive them as a result of the facility’s failure to have any program for vaccinating residents.

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 non-compliance that results in actual harm, and can include, but may not be limited to clinical compromise, decline, or the resident’s ability to maintain and/or reach his/her highest practicable well-being. Examples of negative outcomes may include, but are not limited to:

• A resident who was not eligible to receive the vaccine due to medical contraindications receives the vaccine and experiences a reaction that is not life threatening, but requires treatment; or

• Because of an unwarranted delay (e.g., several weeks after it is available to the facility) in administering the influenza vaccine despite its availability, an eligible resident who has agreed to receive the influenza vaccine develops influenza.

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 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 non-compliance 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 of outcomes may include, but are not limited to:
• An eligible resident did not receive the vaccine, but did not develop symptoms of influenza;
• An eligible resident received two doses of the pneumococcal vaccine, due to a failure to document the receipt of the first dose, but did not experience any untoward reactions; or
• The staff did not assess for medical contraindications prior to providing the vaccines, but there were no reactions to the vaccine.

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

The facility failed to document that information/education was provided to the resident prior to administering the immunizations.