

Summary of Revised and New Guidance at F309, Quality of Care

Previous Language	New Language and Additions
	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.
<p>Previous definition of “highest practicable”:</p> <p>Highest level of functioning and well-being possible, limited only by the individual’s <i>presenting functional status and potential for improvement or reduced rate of functional decline</i>. Highest practicable is determined through the comprehensive resident assessment by competently and thoroughly addressing the physical, mental or psychosocial needs of the individual.</p>	<p>Revised definition of “highest practicable physical, mental, and psychosocial well-being”:</p> <p>Highest possible level of functioning and well-being, limited by the individual’s <i>recognized pathology and normal aging process</i>. 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.</p>
<p>Interpretive Guidelines:</p> <p>Determine if the facility is providing the necessary care and services based on the findings of the RAI.</p>	<p>Interpretive Guidelines:</p> <p>Determine if the facility is providing the necessary care and services based on the findings of the comprehensive assessment and plan of care.</p>
	<p>Procedures:</p> <p>Addition of a section entitled “General Investigative Protocol for F309, Quality of Care,” to be used to investigate quality of care concerns that are not otherwise covered in the remaining tags of § 483.25 or for which specific investigative protocols have not been established.</p> <p>Surveyors should 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. Corroborate observations by interviews of residents or</p>

	<p>representatives, nursing staff on various shifts, health care practitioners and professionals, and record review.</p> <p>The facility is in compliance with this requirement if staff:</p> <ul style="list-style-type: none"> • 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.
	<p>There are a series of new sections that describe some specific issues or care needs that are not otherwise covered in the remaining tags of § 483.25. One is:</p> <p>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. See below.</p>

Summary of New Language in F309, Quality of Care

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.

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

- “Addiction”
- “Adjuvant Analgesics”
- “Adverse Consequences”
- “Complementary & Alternative Medicine”
- “Non-pharmacological interventions”
- “Pain” is an unpleasant sensory and emotional experience that can be acute, recurrent or persistent. Descriptions of several different types of pain include:
 - 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 or 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”
- “Standards of Practice”
- “Tolerance”

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 extent possible;
- Developing and implementing intervention/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
 - 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 including defining how and when to monitor the resident's symptoms and degree of pain relief; and
- Modifying the approaches as necessary.

Assessment

The facility must complete the RAI.

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, 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 goal 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 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. 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.

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.

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 may help manage pain effectively when used either independently or in conjunction with pharmacologic agents. The guidelines include examples of such approaches.

Pharmacological interventions

The interdisciplinary team 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.

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. The guidelines provide examples of different approaches.

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 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.

Investigative Protocol for Pain Management

Objective: 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: For a resident who has pain symptoms or who has the potential for pain symptoms related to conditions or treatments.

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.

More specifically, observe the resident during various activities, shifts, and interactions with staff, and determine:

- 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 to a report that a 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 consequences associated with treatment for pain; and
- How staff responded, if the interventions implemented did not reduce the pain consistent with the goals for pain management.

Interview the resident or representative; interview staff who provide direct care on various shifts.

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.

Review the care plan. Determine if pain management interventions include:

- 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.

Determine whether the pain has been reassessed and the care plan has been revised as necessary.

Interview health care practitioners and professionals:

- Interview a nurse who is knowledgeable about the needs and care of the resident.
- 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 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.
- 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.

For a resident with pain or the potential for pain, the facility is in compliance with F309 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 for F309 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.

Once the survey team has 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 regarding pain assessment and management are as follows:

- Presence of harm/negative outcomes or potential for negative outcomes because of lack of appropriate treatment and care. Actual or potential harm/negative outcome 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.
- 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 the harm has not yet occurred, determine the potential for serious injury, impairment, death, compromise, or discomfort to occur to the resident.
- 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 four levels of severity.

- Severity Level 4: Immediate jeopardy to resident health or safety for a resident with pain or potential for pain.
- Severity Level 3: Actual harm that is not immediate jeopardy for a resident with pain or potential for pain.

- Severity Level 2: 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 1: No actual harm with potential for no more than minimal harm for a resident with pain or potential for pain.