

SLIDE #1

42 CFR 483.25 (F309)

QUALITY OF CARE

Changes to Interpretive Guidance

SLIDE #2

Training Objectives

- Review guidance for hospice and/or ESRD services, formerly in the SOM in Appendix P;
- Describe when to use F309 for Quality of Care issues;
- Identify when and how to use the investigative protocols:
 - The General Investigative Protocol; and
 - The Investigative Protocol for pain or the management of pain
- Identify compliance related to the provision of care;
- Describe the care process and examples of non-compliance and severity determinations related to pain management.

INSTRUCTOR'S NOTES:

Although the regulation does not specifically mention a particular condition, it does require that the necessary care and services be provided for each resident to attain or maintain his or her highest practicable level of well-being. Because different conditions have the potential to negatively affect a resident's well-being, the facility is expected to provide the necessary care and services necessary to improve, maintain, or prevent decline, to the extent possible.

We will be describing the care process as it relates to the facility's provision of care and services.

The General Investigative Protocol will be used to review the care of residents for whom a more specific regulation and investigative protocol do not apply.

The Pain Management Protocol will facilitate determining whether the facility is in compliance with the Quality of Care requirement as it relates to the provision of care and services to meet the needs of residents, including the recognition and management of pain.

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If the facility is not in compliance, it will be important to assign an appropriate level of severity to the deficiency based on guidance in appendix P and PP for a particular regulatory requirement.

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42 CFR 483.25 Quality of Care (F309) - 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.

INSTRUCTOR'S NOTES:

This regulation has not changed. The regulatory text which follows this introductory regulatory language at F309 includes some very specific requirements regarding a number of health conditions, but not every condition or care required by residents has its own regulatory language. This introductory language at F309 is applicable to those conditions and care not specifically addressed in the subsequent language of (a) through (m).

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42 CFR 483.25 Quality of Care (F309)

Note: Use guidance at F309 for review of quality of care not specifically covered by 483.25 (a) – (m). 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.

INSTRUCTOR'S NOTES:

Examples of conditions or care concerns that could be addressed by the regulatory text at F309 include end of life, pain, diabetes, bowel function, fractures, renal disease, and non-pressure-related skin ulcers. The introductory discussion and principles underlying the guidelines and quality of care procedures at F309 remain unchanged and applicable.

The guidance at F309 has been revised to add the guidance for surveying for a resident who receives either hospice or ESRD services which was formerly in appendix P, and addresses new guidance on the care related to recognizing and managing pain. It is important to remember that these are only a few aspects of care and services necessary to assist the resident to attain or maintain his or her highest practicable level of well-being.

SLIDE #5

General Investigative Protocol

Use the General Investigative Protocol (IP):

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- To investigate any Quality of Care concern not otherwise covered in the remaining tags of §483.25, Quality of Care;

Note: For investigating concerns related to pain or the management of pain, use the pain management investigative protocol.

INSTRUCTOR'S NOTES:

N/A

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General IP - Components

Components include the procedures for:

- Observations;
- Resident/Representative Interview; and
- Nursing Staff Interview;

INSTRUCTOR'S NOTES:

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/or potential negative outcomes.

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.

Interview nursing staff on various shifts to determine:

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

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- 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.

SLIDE #7

General IP - Components

- Assessment;
- Care Planning;
- Care Plan Revision;
- Interview with Health Care Practitioners and Professionals.

INSTRUCTOR'S NOTES:

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.

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.

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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.

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.

SLIDE #8

Determination of Compliance - F309

Criteria for Compliance with F309 - Quality of Care - that is not related to pain/pain management. 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.

INSTRUCTOR'S NOTES:

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.

SLIDE #9

DEFICIENCY CATEGORIZATION

Follow Part IV, Appendix P: The key elements for severity determination for F309 Quality of Care requirements:

1. Presence of harm/negative outcome (s) or potential for negative outcomes because of lack of appropriate treatment and care;
2. Degree of harm (actual or potential) related to the non-compliance.
 - The immediacy of correction required.

Follow the general guidance in Appendix P regarding Guidance on Severity and Scope Levels and Psychosocial Outcome Severity Guide.

INSTRUCTOR'S NOTES:

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.

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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.

The survey team must evaluate the harm or potential for harm for F309 based upon the levels of severity. Follow the general guidance in Appendix P for Guidance on Severity and Scope Levels and Psychosocial Outcome Severity Guide.

SLIDE #10

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

- 42 CFR 483.10(b)(11), F157, Notification of Changes;
- 42 CFR 483.(20)(b), F272, Comprehensive Assessments;
- 42 CFR 483.20(k), F279, Comprehensive Care planning;
- 42 CFR 483.20(k)(2)(iii), 483.10(d)(3), F280, Care Plan Revision;
- 42 CFR 483.20(k)3(i), F281, Services Provided Meets Professional Standards of Quality.

INSTRUCTOR'S NOTES:

During the investigation, the surveyor may have identified concerns with related outcome, process, and/or structure requirements. If an additional concern was identified, the surveyor should investigate the additional concern. The surveyor is cautioned to not cite any related or associated requirement before first conducting an investigation to determine compliance or non-compliance with that 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 of regarding significant changes in the resident's condition or a need to alter treatment significantly or notified the representative (if known) or an interested family member 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 Plans - 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.

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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 interventions, as indicated and obtained input from the resident or representative or interested family member 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.

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

- 42 CFR 483.20(k)(3)(ii), F282, Care Provided by Qualified Persons in Accordance with Plan of Care;
- 42 CFR 483.30(a)(1)&(2), F353, Sufficient Staff;
- 42 CFR 483.40(a)(1)&(2), F385, Physician Supervision;
- 42 CFR 483.75(f), F498, Proficiency of Nurse Aides;
- 42 CFR 483.75(i)(2), F501, Medical Director;
- 42 CFR 483.75(l), F514, Clinical Records.

INSTRUCTOR'S NOTES:

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)(1)&(2), 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 aides 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:

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- 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(1), 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.

SLIDE #12

Hospice Services

- Guidance formerly in Appendix P of the SOM, inserted at F309;
- Revised the note to refer hospice concerns as a complaint to the State Agency responsible for oversight of hospice survey activities identifying the specific resident(s) involved and the concerns identified.

INSTRUCTOR'S NOTES:

Previously in Appendix P, the guidance remains the same with the exception of revision of the note:

New 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.

SLIDE #13

ESRD Services

- Guidance formerly in Appendix P inserted at F309;
- Revised bulleted item on medication administration;

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- Revised the note to refer ESRD concerns as a complaint to the State Agency responsible for survey of dialysis providers, identifying the specific resident(s) involved and the concerns identified.

INSTRUCTOR'S NOTES:

Revised two items:

The bullet previously stated: "Whether medication is given at times for maximum effect."

This item was clarified to state:

"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;"

In addition, the note was revised:

New 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.

SLIDE #14

Interpretive Guidance – Related to Pain

Review of a Resident who:

- Has pain symptoms;
- Is being treated for pain; or
- Has the potential for pain symptoms related to conditions or treatments.

INSTRUCTOR'S NOTES:

The interpretive guidance was developed to assist in the review of the care and services provide for a resident who has pain, is being treated for pain or who has the potential for pain due to treatments or conditions.

SLIDE #15

Training Objectives

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- Describe the relationship between the regulation and the pain guidance;
- Describe the care process related to pain management;
- Identify when and how to use the Investigative Protocol; and
- Evaluate compliance with F309 as it relates to pain, including severity determinations.

INSTRUCTOR'S NOTES:

N/A

SLIDE #16

Interpretive Guidance (IG) Related to Pain

Regarding Pain Recognition and Management:

- Introduction
- Definitions
- Overview
- Care Process for Pain Management
- Investigative Protocol
- Compliance Determination
- Deficiency Categorization

INSTRUCTOR'S NOTES:

We will discuss aspects of each of these components of the Guidance.

SLIDE #17

IG – Pain/Pain Management Introduction

Introduction: To help a resident attain or maintain his/her highest practicable level of well-being and to prevent or manage pain, to the extent possible, the facility:

- 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 resident's goals, the comprehensive assessment and plan of care, and current clinical standards of practice.

INSTRUCTOR'S NOTES:

Recognize, identify, evaluate, manage and prevent are all action words. In order to help the resident attain or maintain his or her highest practicable level of physical, mental, and psychosocial well-being, including the prevention and management of each resident's pain, the facility is expected to take action, including:

- Identifying when pain is present or can be expected;
- Evaluating the pain and, to the extent possible, identifying and treating the causes;
- Identifying the resident's goals for management of the pain; and
- Implementing interventions to prevent or manage the pain in accordance with the resident's goals, the comprehensive assessment and plan of care, and current standards of practice.

SLIDE #18

IG – Pain/Pain Management - Definitions

Definitions:

- Addiction
- Adjuvant Analgesics
- Adverse Consequence
- Complementary and Alternative Medicine (CAM)
- Non-pharmacological Interventions
- Pain
- Physical Dependence
- Standards of Practice
- Tolerance

INSTRUCTOR'S NOTES:

Definitions are provided to clarify terminology used in the description of pain, its treatment, and potential consequences of the treatment. These items are defined in the revised guidance.

Adverse consequence is described more fully in the Guidance regarding Unnecessary Medications, (refer to F329) but it is included in this Guidance regarding pain management because of the significant potential for adverse consequences involved with the pharmacological treatment of pain.

We will discuss the distinction between acute and chronic pain, what is meant by adjuvant analgesics, and the differences among addiction, physical dependence, and tolerance.

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The concepts regarding Standards of Practice are more fully discussed in the Guidance associated with F501 Medical Director and with F281 Services provided must meet professional standards of quality.

SLIDE #19

IG – Pain/Pain Management - Definitions

Pain:

An unpleasant sensory and emotional experience that can be acute, recurrent, or persistent.

INSTRUCTOR'S NOTES:

Unrelieved pain is not an inevitable consequence of aging, but it can lead to decreased function and diminished quality of life.

A resident's report of pain is the most reliable indicator of pain. Many residents, however, do not or cannot report pain, so the recognition of pain is an important aspect of resident care. As a surveyor, you would expect to see that the facility has evaluated any report or indication of pain.

SLIDE #20

IG – Pain/Pain Management - Definitions

Acute Pain:

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.

Persistent/Chronic Pain:

Pain that continues for a prolonged period of time or recurs more than intermittently for months or years.

INSTRUCTOR'S NOTES:

You'll notice that this definition of acute pain does not include any reference to the intensity of the pain, but rather speaks to the onset and duration of the pain. Often, acute pain is a normal, predicted physiological response to a known cause and there is an expected end-point to the pain. Many definitions indicate that acute pain usually does not extend beyond 2 to 3 months.

Persistent pain may be an unexplained continuation of pain that lingers long after the initial injury is healed or it may be due to an ongoing condition, such as arthritis or fibromyalgia. On the other hand, it may not be linked to a specific physiologic event, at all, and it may be very

difficult to find, remove or treat the cause. Persistent pain is often associated with long-standing functional and/or psychosocial impairment.

Both acute pain and persistent pain may fluctuate in intensity and character.

SLIDE #21

IG – Pain/Pain Management - Definitions

Adjuvant analgesics:

Medication with a primary indication other than pain management but with analgesic properties in some painful conditions.

INSTRUCTOR'S NOTES:

Medications that relieve pain by treating the underlying cause of the pain are not considered adjuvant medications. For example, antibiotics used to treat pneumonia that had resulted in pleurisy are not considered adjuvant analgesics despite the pain being relieved when the pneumonia was treated.

Because some medications are better at relieving one type of pain over another, the clinician may prescribe adjuvant analgesics that target pain from a specific source such as visceral, bone, or musculo-skeletal pain; or pain associated with nerve damage, for example herpetic neuralgia or diabetic neuropathy. Research has shown that many of these adjuvant medications can help relieve pain.

While analgesics, including adjuvant medications, may target the nature of the pain, they generally do not address the underlying cause. It is important that the adjuvant analgesics, like all other medications, are monitored for their effectiveness and for the emergence of adverse consequences.

Clinicians may be prescribing certain classes of antidepressants or anticonvulsants as adjuvant therapy for pain management. The use of anticonvulsants or antidepressants does not mean the pain is just in the resident's head or is the result of depression or convulsions.

Anticonvulsants such as gabapentin or pregabalin have been used to address the pain from nerve damage such as long term neuralgia from herpes. Pregabalin has recently been approved by the FDA for the treatment of fibromyalgia.

You may see a tricyclic antidepressant such as nortriptyline or desipramine being prescribed to cover a fairly broad array of pain sources, especially pain from nerve damage. You may recall from the guidance for Unnecessary Medications that amitriptyline (a tricyclic antidepressant) is not a medication of choice for geriatric persons because of anticholinergic properties.

Other examples of adjuvant analgesics include some of the following:

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- Corticosteroids such as prednisone or dexamethasone;
- Local anesthetics such as lidocaine; or
- Topical medications or applications such as capsaicin or lidocaine patches.

SLIDE #22

IG – Pain/Pain Management - Definitions

Addiction:

A primary, chronic, neurobiological disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations - characterized by an overwhelming craving for medication or behaviors including impaired control over drug use, compulsive use, continued use despite harm, and/or craving.

INSTRUCTOR'S NOTES:

A resident whose pain is not being adequately treated may exhibit drug seeking behavior and may be thought to be addicted until their pain is adequately treated and the drug seeking behavior stops. That is generally not considered a true addiction.

It is the responsibility of the clinician to differentiate between addiction and inadequate control of the resident's pain. Surveyors are to identify whether the care process has been followed and whether the resident's pain has been addressed or prevented in accordance with the assessment, care plan, and resident's goals for control of the pain.

It is important to know that many medications used to treat pain (such as ibuprofen, naproxen, or acetaminophen) do not result in addiction. It is also important to recognize that while opioid medications (such as morphine, hydrocodone, oxycodone, or fentanyl) can result in addiction, the opioids are a valuable and viable treatment option for pain that is not controlled by other means.

SLIDE #23

IG – Pain/Pain Management - Definitions

Physical Dependence:

Physiological state of neuro-adaptation that is characterized by a withdrawal syndrome if medication is stopped or decreased abruptly, or if an antagonist is administered.

INSTRUCTOR'S NOTES:

If a resident has developed a physical dependence on a medication and the medication is being discontinued, you may expect to see the dose being incrementally decreased or tapered and not stopped abruptly in order to avoid potential withdrawal symptoms.

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IG – Pain/Pain Management - Definitions

Tolerance:

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.

INSTRUCTOR’S NOTES:

Both physical dependence and tolerance may be anticipated natural results of long term or regular use of pain medications. If the resident has developed a tolerance for the medication, you may see that the clinician changes the treatment in order to achieve the previous or desired level of pain control. For example, the clinician may increase the dose or the frequency of the medication or potentially may change the medication being used.

SLIDE #25

IG – Pain/Pain Management - Overview

Resident, family or staff misconceptions regarding:

- Recognition;
- Assessment; and
- Management of Pain.

INSTRUCTOR’S NOTES:

There are many misconceptions that can negatively affect the ability to adequately recognize, assess, prevent, or manage a resident’s pain.

Let’s discuss some misconceptions about pain. That pain is:

- A normal part of aging; or
- Sign of weakness;
- An attention getting mechanism; or that
- Elderly and cognitively impaired have higher tolerance.

Although many think of persistent pain as being part of growing older, pain is not normal or healthy. While it may be more challenging for the clinicians and staff to identify, assess and address the pain of the cognitively impaired and elderly residents, studies have not demonstrated that these residents have a higher tolerance for pain.

Some residents do not report pain or acknowledge that they need something to help manage their pain, because they are stoic or they believe:

- It is a sign of weakness;
- That it may be a problem for busy staff;
- That they will be seen as seeking attention; or
- That it will subject them to costly or invasive testing.

Failure to report pain must not be interpreted as absence of pain in elderly or cognitively impaired residents.

A resident with cognitive impairment may be able to accurately report whether he or she is experiencing pain at that moment and, if so, the intensity of the pain. The resident, however, frequently will be unable recall when he or she has had pain previously, the characteristics of that pain, and the circumstances at the time.

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IG – Pain/Pain Management - Overview

Potential outcomes with unresolved persistent pain may involve:

- Function and/or mobility;
- Mood;
- Sleep;
- Participation in usual activities.

INSTRUCTOR'S NOTES:

Studies have shown that up to 80% of the residents may experience substantial persistent or long term pain. Persistent pain frequently results in long term negative consequences.

Which of these aspects of a resident's well-being could be affected by unresolved pain?

Note to the Instructor - elicit the participants' responses before proceeding with the rest of the message.

Long term pain may affect a number of domains, including these four (4). For example, pain from immobility or arthritis may result in a decreased ability to feed, dress, or bathe oneself or to transfer or ambulate. Pain may also result in gait disturbance, generalized de-conditioning and falls.

It may contribute to anorexia, anxiety, depression, decreased participation in usual activities, inability to fall asleep or stay asleep, or a generally diminished quality of life.

SLIDE #27

IG – Pain/Pain Management - Overview
Acute Pain – The onset potentially signals

- New injury or illness;
- Possible life-threatening condition.

INSTRUCTOR'S NOTES:

When we're speaking of acute pain in these guidelines, we are not speaking of the transient pain, such as that associated with the administration of an injection, such as the flu or pneumonia vaccines.

The onset of acute pain may indicate the resident is experiencing a change of condition or a potentially life threatening condition such as a heart attack or an impaction and potential for ruptured bowel. It could indicate a potential fracture or other trauma, or pain which may be an indication of an infectious or other pathogenic process.

SLIDE #28

IG – Pain/Pain Management – Overview

Factors affecting pain management:

- Language and cultural barriers;

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- Non-specific symptoms;
- Co-morbidities;
- Staff and practitioner knowledge, skill, training;
- Misunderstanding about analgesics, including opioids.

INSTRUCTOR'S NOTES:

Barriers posed by the problems with communication such as cultural diversity, use of a language other than the dominant language of the nursing home, cognitive impairment, inability to speak, or stoicism may make it difficult recognize, evaluate, and manage a resident's pain.

In addition, many of the non-verbal behaviors or symptoms that could indicate that a resident is experiencing pain, may also be indicators of other conditions. These non-verbal indicators, therefore, need to be recognized and evaluated within that resident's entire clinical context.

If a resident has multiple co-existing conditions or the resident is receiving many medications, the resident's response to pain and the ability to interpret or report pain may be diminished. This, too, may make it more difficult for staff and clinicians to recognize and appropriately evaluate a resident's pain.

Residents, staff, and practitioners may misunderstand the indications for use of opioids or other analgesics or may not understand the benefits and risks of those medications. Because of the potential for addiction, they may not use the opioids, even though opioids may be the best choice for managing the resident's pain when other medications and non-pharmacological approaches have been unsuccessful at controlling the pain.

The actual risk of becoming addicted to opioids may depend upon a number of variables, including, for example, a history of prior use, genetic predisposition, prolonged or increasing use. A resident being treated with opioid medications may develop tolerance or physical dependence on the opioids. As you know, tolerance and dependence are not the same as addiction.

Other variables affecting how and whether a resident's pain is addressed may include, for example:

- High staff turnover;
- Lack of familiarity with the resident's usual and customary behavior and routines; and
- Lack of education about pain symptoms, the evaluation of the symptoms, and the treatment options available.

SLIDE #29

IG – Pain/Pain Management – Care Process

Care processes for pain management:

- Assessment;
- Address/treat underlying cause(s);
- Develop and implement approaches;
- Monitor;
- Modify approaches.

INSTRUCTOR’S NOTES:

The surveyor should be able to identify how the care process has been implemented by the facility through record review, observations and interviews. The facility must provide care and services that are determined through the care process. This includes, but is not limited to:

Assessment:

- Assess potential for pain;
- Recognize onset or presence of pain;
- Assess the pain;
- Assessing the resident’s needs.

Addressing/treating underlying cause(s) by determining a diagnosis and identifying and treating causative factors to the extent possible;

Developing and implementing approaches to manage pain including:

- Identifying resident centered goals; and
- Implementing approaches determined to be the most appropriate to facilitate reaching those goals.

Monitoring the outcome of interventions and monitoring for effectiveness and onset of adverse consequences; and

Depending upon the effectiveness of the interventions or onset of adverse consequences, modifying the approaches, as necessary.

It is the ongoing care process that provides the foundation for the clinicians and the facility to help each resident attain or maintain his or her highest practicable level of well-being, including preventing or managing pain to the extent possible. Throughout this guidance and other Interpretive Guidelines, the care process has been based upon an interdisciplinary approach to identifying and meeting the resident's needs.

SLIDE #30

IG – Pain/Pain Management – Care Process

Pain Recognition/Identification:

- Admission
- Ongoing observation
- Evaluation

INSTRUCTOR'S NOTES:

The facility is responsible for providing care and services, beginning with the resident's admission, to assist the resident to attain or maintain his or her highest practicable level of well-being including the management or prevention of pain. In order to provide the necessary care, it is important that the staff and clinician recognize when pain may be anticipated and/or recognizing and evaluating indicators that may indicate the resident is having pain.

Residents may experience pain from several different causes simultaneously. Clues that could indicate to the facility and to the surveyor that the resident may be experiencing pain can become evident during interaction with and observation of the resident, for example, while the resident is resting, eating, engaging in activity, or during prescribed treatments. The act of walking or even moving about in bed may cause pain for a resident with arthritis or multiple sclerosis.

Throughout the resident's stay, the RAI process including the quarterly MDS is a mechanism that helps to identify actual pain as well as the potential for pain. In addition to the specific pain item, several other items such as insomnia or changes in sleep patterns, withdrawal from activities of interest, verbal or physical abuse, mood changes, a decline in function, weight loss or an unstable clinical condition may indicate that the resident has been experiencing pain and needs additional evaluation.

The facility, in accordance with the RAI Utilization Guidelines will be evaluating changes in the resident to determine if the change constitutes a change of condition that requires a comprehensive assessment. During the process of making that determination, the facility and physician will be evaluating the resident and identifying whether the circumstances including the presence of pain are transient and whether treatment is necessary.

SLIDE #31

IG – Pain/Pain Management – Care Process

Assessment/Recognition of Pain:

- Change in condition/function;
- Diagnoses, care, treatments associated with pain;
- Verbal expressions.

INSTRUCTOR’S NOTES:

Pain is commonly associated with many diagnoses, disease processes, or conditions, such as: diabetic neuropathy, immobility, amputation, post stroke, oral health conditions, urinary tract infections, pressure ulcers or venous and arterial ulcers. Many treatments or procedures are also associated with pain such as dressing changes, ambulation, exercises and range of motion.

The resident may verbally express pain or discomfort using terms such as hurting or aching but not think of those feelings as being pain. It is important to recognize that terms used to describe pain may differ based on severity, culture, cognitive ability, language and region of the country. Some pain characteristics are closely associated with musculo-skeletal pain and others are more closely associated with neurogenic or other sources of pain. The terms that the resident uses to describe the pain may help the practitioner determine the source.

SLIDE #32

IG – Pain/Pain Management – Care Process

Assessment/Identification of Pain:

- Symptoms associated with pain;
- Non-verbal indicators;
- Cognitive Impairment;
- Resident, representative or staff reports.

INSTRUCTOR’S NOTES:

There are also many nonverbal symptoms that may indicate the resident is experiencing pain. While these non-verbal indicators may be clues that a resident is having pain, the symptoms must be evaluated within the context of the resident’s clinical condition because they may represent something other than or in addition to pain. Examples of these non-verbal indicators include:

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- Facial expressions such as grimacing or clenching of the jaw;
- Physical changes such as perspiration or changes in gait;
- Behavior or changes in behavior such as irritability, resisting care, or decreased
- Participation in social activities;
- Loss of function or inability to carry out ADLs; or
- Difficulty eating or sleeping.

Non-verbal symptoms or behaviors may be the first indications of potential pain in residents who have moderate to advanced cognitive impairment. Because these triggers frequently are not specific for pain, the symptoms need to be further assessed in relation to the whole resident not just the pain. This evaluation may include for example looking for physical causes for pain, such as: inflammation, acute illness, trauma, infections. The assessment also may look for a history of physical problems that are associated with pain such as arthritis, old fracture site pain, falls, or neuropathies. Many residents with cognitive impairment can reliably answer simple yes or no questions regarding pain. In addition, there are some assessment tools available for use in the clinical setting.

Family members, nursing assistants, and ancillary staff such as housekeeping, activities staff, dietary, or therapy staff may also identify and report that the resident may be experiencing pain. Nurse aides who have had an opportunity to become acquainted with their residents and who have had some training in the changes that may accompany pain should more readily recognize and report that a resident may be experiencing pain.

SLIDE #33

IG – Pain/Pain Management – Care Process

Assessment of Pain:

- History of pain;
- Prior treatment;
- Effectiveness of prior treatment.

INSTRUCTOR’S NOTES:

The regulation at 483.20 requires, at a minimum, that the facility conduct a comprehensive assessment using the state mandated RAI. Remember that 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)

Current standards of practice indicate that, based on the resident's condition, it may be appropriate to include a variety of factors in the assessment of the resident's pain and the circumstances when pain may be anticipated, when there is a change in the characteristics of pain that has been previously assessed, or when there is a change in status that potentially may be associated with the onset of or increase in pain.

If a newly admitted resident is already receiving pain medication, it is important that both the pain and the effectiveness of the interventions be evaluated.

Efforts to manage or prevent pain may benefit from a review, if possible, of the history of the pain and previous treatments attempted, such as when the pain started, whether it has been getting worse, whether pharmacological or non-pharmacological approaches have been attempted and how successful they have been.

SLIDE #34

IG – Pain/Pain Management – Care Process

Assessment of pain characteristics:

- Intensity;
- Descriptors;
- Pattern;
- Location and radiation;
- Frequency, timing and duration.

INSTRUCTOR'S NOTES:

Ascertaining the intensity of the pain may help determine the most appropriate interventions. As a surveyor, you should expect to see that the intensity of the pain has been assessed and monitored using the same measures consistently. If, for example, the intensity is rated initially on a scale of 1-5 or using a specific tool, using that same scale or tool throughout should help the reliability of determining the effectiveness of an intervention. Using a 10 point scale one time and a five point scale another or using one assessment tool one time and a different tool later does not facilitate an accurate evaluation from one time to the next.

How the resident describes the pain, for example, gnawing, burning, or stabbing and whether the pain is intermittent or constant, how frequently it occurs and how long it lasts, where the pain is

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located and whether it radiates to another site, may help the clinician determine the source, type and cause of the resident's pain.

SLIDE #35

IG – Pain/Pain Management – Care Process

Assessment of impact of pain:

- Factors that may precipitate/aggravate pain;
- Factors that may lessen pain.

INSTRUCTOR'S NOTES:

Assessing the socio-cultural variables that may influence the resident's perception of pain and the goals for treatment as well as the impact and type and severity of pain will be helpful when developing an effective intervention plan to meet the resident's needs. The continuum of pain may range from being a nuisance to being debilitating and having a significant effect upon the resident's function and activities, as well as psychosocial, mental and physical well-being.

When attempting to ascertain what seems to trigger the onset of pain or aggravate or relieve the pain, several factors may be implicated and warrant consideration, including for example:

- What has been happening to the resident in terms of changes in the resident's social and environmental framework;
- Whether the pain is affected by heat, cold, resting, light, sound, or by a specific motion or food;
- Whether the therapeutic end-point of pain medication has been reached;
- Whether there is an infectious process starting; and
- Whether the resident has been experiencing any other symptoms that may be associated with pain, such as: sweating profusely, weakness, nausea or vomiting, or confusion.

Determining the precipitating factors that may cause pain, may be as simple as recognizing and addressing treatments such as dressing changes, range of motion exercises.

SLIDE #36

IG – Pain/Pain Management – Care Process

Assessment of present condition:

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- Current medical condition and medications;
- Resident's goal for pain management;
- Satisfaction with current level of pain control.

INSTRUCTOR'S NOTES:

A clinician's hands-on evaluation of the major physiologic systems is integral to an initial assessment for pain. A review of the neuro and musculo-skeletal systems may include for example a search for impairment such as weakness, numbness, tenderness, inflammations, deformity, decreased range of motion, and so forth. Because some residents may experience pain from multiple causes and many residents cannot or do not report pain, a physical examination is key to identifying and evaluating:

- The presence or absence of pain;
- Circumstances surrounding when pain may be anticipated;
- The nature and location of pain; and
- The cause of the pain.

Other important considerations include evaluating what other medical conditions the resident is experiencing and what medications the resident is taking. A review of the current medication regimen may help determine whether the medications are causing or alleviating the resident's pain.

An assessment also involves attempting to determine the resident's goals for managing his or her pain. It is also important to determine if the resident is satisfied with the current level of pain control. One resident may wish to be as pain free as possible, while another resident may wish to just have the edge taken off.

The resident may be able to participate in determining the level of pain relief desired, if he or she understands, to the extent possible, the risks and benefits of a particular intervention and what effect the pain management intervention may have on him or her.

SLIDE #37

IG – Management of Pain

Care Plan:

- Care plan;
- Clinical Standards of Practice;

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- Responsibility.

Interventions

- Resident's needs/goals;
- Source, type and severity of pain;
- Available treatment options.

Approaches

- Address underlying cause, when possible;
- Target strategies to source, intensity, nature of symptoms;
- Prevent/minimize anticipated pain.

INSTRUCTOR'S NOTES:

It is important to remember that there is no requirement that there be a separate care plan established for pain management. The interventions for managing the pain, for example, may be incorporated into the plan for dressing changes or treatments or may be incorporated as an entirely separate problem or need. The interventions and treatment approaches should be preceded by an appropriate evaluation of the pain.

It is important that the pain management approaches selected follow pertinent clinical standards of practice. Because managing a resident's pain involves a facility-wide effort, it is important that the approaches identify who is responsible for managing the pain and for implementing the individual approaches or supplying the services. This may include, for example, the CNA, the RN, a certified hospice, the attending physician or therapist.

We know that the cause of the pain may not always be identified. Following the pertinent clinical standards of practice may provide recommended approaches to managing the pain, even when the cause cannot be or has not been identified.

The resident, the resident's representative and the interdisciplinary team develop pertinent interventions and realistic, measurable goals that are based on the assessment or evaluation of the pain and the resident's condition. In order to help the resident participate in defining his or her treatment goals and interventions, the resident should be informed about the:

- Disease process;
- Nature of the pain;

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- Approaches available to manage the pain;
- Need to report pain when it occurs; and
- The need to evaluate the effectiveness of the interventions employed.

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.

When an intervention is selected, it should be implemented in a timely, respectful, compassionate, and consistent manner. You would expect to see, for example, that when the intervention includes pre-medication before a dressing change or treatment or exercises, that the medication is given enough in advance to allow it to become effective before the treatment is started.

Addressing and treating the underlying cause of pain, where possible:

- May eliminate the pain;
- May shorten the duration and lessen the amount of pharmacological intervention needed to manage the pain; and
- May reduce the risks of complications or adverse complications.

Since the resident may experience pain from more than one cause, the management of pain may require a variety of approaches depending upon the cause and the nature of the pain the resident is experiencing at that time. Finding the most effective approaches may require sequential trials of various approaches.

You may see that the care team is still in the process of identifying the most effective approaches. This, of course, is predicated upon an evaluation of the effectiveness of the various approaches having been used.

SLIDE #38

IG - Management of Pain

Certified hospice and pain management:

- SNF/NF – primary care giver;
- Hospice – professional management;

- Coordination of care.

INSTRUCTOR'S NOTES:

If the resident is receiving hospice services for end-of-life care, it is important that the care of the resident be appropriately coordinated among all providers. The nursing home remains the resident's primary care giver and the SNF/NF requirements for participation in Medicare or Medicaid still apply for that resident. The hospice assumes full responsibility for professional management of the resident's hospice care in accordance with the hospice Conditions of Participation, including the requirement to assess, plan, monitor, and evaluate the resident's pain management program and other symptoms related to the terminal illness.

Hospice and facility staff need to work together to be sure that whatever is needed to implement the interventions to manage the pain is available and that staff are trained on the resident's pain management regimen.

SLIDE #39

Interpretive Guidelines- Management of Pain

True or False

Non-Pharmacological Approaches are rarely effective, unless they are used with one or more pain medications.

INSTRUCTOR'S NOTES:

Allow the participants a brief period to offer thoughts.

Message

While this may seem like a trick question, it really is not. Non-pharmacological approaches frequently enhance the effectiveness of medications, but they do not always require the use of a medication to be effective.

Take for example, a resident suffering from back pain that seems to be getting worse. The evaluation looking for the cause of the pain may find that the pain started after the resident was moved from one room to another and had been placed in a different bed. When the resident was given a new mattress, the pain was alleviated.

Sometimes merely repositioning or changing a resident's position and emphasizing normal or providing support to maintain neutral body alignment helps decrease a resident's pain.

On the other hand, a resident suffering from bursitis or tendonitis may be helped most by the use of an NSAID in combination with ultrasound and ice packs.

SLIDE #40

IG - Management of Pain

Use of Non-Pharmacological Interventions, such as

- Physical modalities;
- Cognitive interventions; and
- CAM

INSTRUCTOR'S NOTES:

Many Complementary and Alternative medicine (CAM) approaches, including physical and cognitive modalities are effective especially when used in conjunction with medication. As with any approaches, non-pharmacological interventions need to be individualized based on the need and effectiveness for that specific resident and the expertise available within the facility. Sometimes, modifying the approach to care may relieve some of the discomfort, such as delaying the bath or shower until later in the day, if movement for the resident is painful early in the day.

Physical modalities may include, for example, ice packs to reduce inflammation or swelling, mild heat to decrease joint stiffness and increase blood flow, massage, ultrasound, soothing or supportive touch, and so forth. Physical therapy aimed at muscle strengthening or stretching may relieve muscle spasm. Stretching, on the other hand, by someone not skilled in that modality increases the risk of injury to the resident. However, it is important to note that non-pharmacological interventions are not necessarily risk free. For example, ice packs and heat need to be applied and monitored in accordance with standards of practice to avoid tissue damage. The use of ice in some cases, such as Reynaud's or peripheral vascular disease, may exacerbate the pain.

Cognitive interventions including approaches such as soothing, distracting verbal communication, music therapy that uses music preferred by the resident, reading to the resident, activities or recreation may help distract the resident's focus on pain. While inactivity and immobility may contribute to depression and worsening of pain, the stress from constant activity or sensory stimulating experiences may exceed the resident's pain threshold.

Complementary and alternative medicine may include such techniques as acupuncture, reflexology, chiropractic or osteopathic manipulation, massage, dietary supplements (including herbal products), meditation, biofeedback, topical application of herbal products (such as aloe vera), and so forth. The use of herbal products and other dietary supplements should be recorded for review by the pharmacist and physician to avoid any adverse medication interactions.

SLIDE #41

IG - Management of Pain

Judicious use of pharmacological interventions:

- Factors influencing selection of medications and doses include, but are not limited to:
 - Resident condition;
 - Source/nature/location of pain;
 - Risk/benefit/resident choice considerations;
 - Use of Analgesics/Adjuvants;
 - PRN (on-demand) vs. scheduled (by the clock).

INSTRUCTOR'S NOTES:

The interdisciplinary team, including the practitioner, determines the appropriate interventions for the prevention and/or treatment of pain, to the extent possible. This may include the use of pharmacological interventions. The judicious use of pain medications is important to balance the resident's desired level of pain relief with the avoidance of unacceptable adverse consequences;

The three main categories of pharmacological interventions are:

- Non-opioids, such as acetaminophen or NSAIDS;
- Opioids; and
- Adjuvants.

Not all types of pain are appropriately treated with analgesics and not all residents will respond in the same way to the same medication in the same dose. Long term use of medication frequently increases the risk of adverse consequences, such as gastrointestinal, respiratory, or other internal organ problems, or trouble with alertness, balance, coordination, memory, agitation, and cognition.

Considerations that influence the selection, dose, and route of medication include the risk profile of the medication and the resident's medical condition and course of the illness; the cause, source, location and character of the pain; the resident's desired level of pain control and tolerance for adverse consequences.

It is important to anticipate and prevent or address any adverse consequences that may occur. Initiating a program early to counteract the most common side effects may help reduce the severity of an adverse consequence. For example, starting a bowel regimen that may include increased activity and fluids and the use of stool softeners and lubricants soon after opioids have been prescribed may reduce constipation and the potential for bowel impaction.

Some clinical situations may require the use of a combination of pharmacological interventions or the use of medication prescribed around the clock rather than on a prn basis, but the regimen chosen to prevent or minimize the resident's pain should follow pertinent clinical guidelines and be monitored regularly for effectiveness and the emergence of adverse consequences.

SLIDE #42

IG - Monitoring and Reassessment

- Why
- What
- How
- When
- By whom

INSTRUCTOR'S NOTES:

Monitoring the resident's response to the interventions used to control pain helps determine whether the pain is controlled in accordance with the resident's goals, whether the interventions need to be modified and whether the resident is experiencing any adverse consequences. Monitoring also provides evidence of when the pain, and potentially its cause has resolved and the need for interventions no longer exists.

Monitoring is needed to determine the effectiveness of approaches to prevent adverse complications and the nature and extent of adverse consequences, if they occur.

The process of monitoring involves defining how the effectiveness of pain control will be determined, for example, identifying which symptoms indicate the resident is in pain and the intensity of the pain. In addition, the facility determines whether the monitoring will include the use of a standardized pain assessment tool as well as how frequently this more formal evaluation should occur and who should be responsible for evaluating and communicating the information from the monitoring and reassessment.

Monitoring also involves an ongoing awareness by the care team of the resident's condition, functional status, and presence or absence of pain and whether there has been a change.

SLIDE #43

IG - EFFECTIVE PAIN MANAGEMENT

INVOLVES:

- Facility - wide commitment to resident comfort;
- Addressing misconceptions and/or barriers to pain management;
- Identifying residents with pain or at risk for pain;
- Assessing the pain;
- Understanding resident's goals;
- Identifying and treating underlying causes, to the extent possible;
- Developing/Implementing approaches to manage or prevent pain;
- Monitoring the effectiveness of interventions;
- Revising interventions as necessary.

INSTRUCTOR'S NOTES:

In summary, the effective care of a resident having pain, or at risk for pain, involves following these principles.

SLIDE #44

Investigative Protocol (IP) For Pain Management

IP: Quality of care related to the recognition and management of pain

- Objectives;
- Use;
- Procedures.

INSTRUCTOR'S NOTES:

The investigative protocol defines the objective for the investigation, identifies the type of resident for whom the protocol will be applied, and describes the procedures for surveyors to follow.

SLIDE #45

IP - Objectives

To determine whether:

- The facility provided and the resident received care and services to address and manage the resident's pain, and
- The resident's highest practicable level of physical, mental, and psychosocial well-being were supported, in accordance with the comprehensive assessment and plan of care.

INSTRUCTOR'S NOTES:

The investigation will help the surveyors determine whether the facility recognized that the resident was having or was subject to experiencing pain, assessed the pain and surrounding circumstances, and, based on the assessment and care plan, provided the necessary care and services to prevent or manage the pain to the extent possible in order to promote the resident's highest practicable level of physical, mental and psychosocial well-being.

SLIDE #46

IP - Use

Use this protocol for a sampled 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.

INSTRUCTOR'S NOTES:

Follow this protocol whenever there is a likelihood or evidence that a resident in the sample currently has or recently has had pain. Indicators of pain could include, for example:

- The resident has asked for a pain medication;

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- The resident or his/her representative says he or she is having pain;
- The resident's behavior or vocalizations may suggest the resident is having pain;
- The resident receives therapy to regain function after a hip replacement; or the resident has a diagnosis which is frequently associated with pain, such as arthritis, multiple sclerosis, cancer; or
- The record indicates orders for pain medications, adjuvant medications, or non-pharmacological interventions.

Pain management is usually one of the major end-of-life goals for a resident who has elected the hospice benefit.

SLIDE #47

IP - Procedures

- Observation;
- Interview;
- Record Review.

INSTRUCTOR'S NOTES:

The investigative steps include observation of the delivery of care and services to the resident, interviews with the resident and/or his or her representative, staff and others involved in the delivery of care and services as appropriate, and a review of the clinical record.

To initially determine whether this protocol should be followed for this resident and to establish the basis for the review, briefly gather information regarding the resident's mental, physical, functional, and psychosocial status and whether the resident has been experiencing, or is being treated for, pain.

Review the care plan and orders to identify any current pain management interventions and to focus observation. Corroborate observations with interviews and record review.

Determine who is responsible for providing and implementing pain management interventions, for example, level of staff or other entities such as therapists, certified hospice, or anesthesiology consultants.

SLIDE #48

IP - Observation

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Observe the resident during various activities and over various shifts to determine:

- If the plan of care for the management of pain (if any) is implemented as written;
- Whether the resident has pain and the impact of the pain; and
- If staff recognized potential or actual pain and their response.

INSTRUCTOR'S NOTES:

During the observation, note whether:

- The resident exhibits signs or symptoms of pain or verbalizes the presence of pain;
- The resident requests or has received treatment for pain, and
- If the pain or treatment appears to affect the resident's function or ability to participate in routine care or activities.

If there is currently evidence of pain, observe whether staff have had an opportunity to recognize that the resident is having pain and whether staff have assessed the resident's status and surrounding circumstances.

If the pain occurs as a result of a treatment regimen such as exercises post operatively or pressure ulcer care, or as a result of activity when the resident has a diagnosis frequently associated with pain, note whether staff recognized the pain and how they responded.

If there are pain management interventions for the resident, note whether staff implemented interventions, including non-pharmacological approaches, to try to prevent or address the resident's pain.

Note whether staff have evaluated the status of the resident's pain after interventions. Follow up on:

- Deviations from the planned interventions;
- Pain management interventions that may be inconsistent with current standards of practice; and
- Potential adverse consequence(s) associated with treatment for pain (e.g., medications).

Also follow up on how staff responded:

- If there were no pain management approaches defined or prescribed, or

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- If the interventions implemented did not reduce the pain consistent with the goals for pain management.

Observations should be corroborated with additional information from interviews, additional observations, or record reviews.

SLIDE #49

IP - Resident Interview

Interview the resident or responsible party to determine:

- If the resident has or has had pain and its characteristics;
- Care-planning participation and goals; and
- Implementation and results/effectiveness of approaches

INSTRUCTOR'S NOTES:

Interview the resident, family or representative to the degree possible.

If the resident is experiencing pain presently or has periodically had pain, determine:

- The characteristics of the pain, such as: when it occurs, its location, how the resident would describe the pain, what relieves it or makes it worse;
- What approaches have been used to address the pain in the past and how the resident typically has responded to the various interventions;
- Whether staff was informed (which staff) about the pain/discomfort, how the staff responded, and whether the pain has or had been relieved.

Also determine:

- How the resident and/or his/her representative have been involved in developing pain management strategies and establishing goals regarding the level of pain control desired;
- What treatment options or approaches were discussed, including whether non-pharmacological approaches were considered; and
- How effectively the approaches being used have managed the pain and whether the resident or representative has been involved in modifying the approaches, if they are not effective.

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If the resident has turned down one or more of the interventions that was available or was discussed, determine whether there was a discussion of the potential impact on the resident and whether alternatives or other approaches were offered.

SLIDE #50

IP - Nurse Aide Interview

Interview direct care staff on various shifts to determine:

- Whether they are aware of a resident's pain; and
- How they respond to the resident's pain.

INSTRUCTOR'S NOTES:

Determine:

- If staff are aware of whether there are signs or symptoms that characteristically indicate the resident is having pain or whether the resident has voiced complaints of pain;
- To whom they report the resident's complaints or signs and symptoms and how they respond to the resident's pain; 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).

SLIDE #51

IP - Record Review

Assessment:

- Review information sources, e.g., orders, MAR, progress notes, assessments including RAI/MDS; and
- Determine if information accurately, and comprehensively reflects resident's condition

INSTRUCTOR'S NOTES:

Review information such as orders, medication administration records, multidisciplinary progress notes, the RAI/MDS, and any specific assessments regarding pain that may have been

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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; and
- Identifies the resident's response to interventions including efficacy and adverse consequences, and any modification of interventions as indicated.

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).

SLIDE #52

IP: Care Plan

Review:

- Pain management goals;
- Interventions;
- Monitoring;
- Facility specific pain management protocol, if being used.
- Revised as necessary.

INSTRUCTOR'S NOTES:

The care plan interventions may be identified as part of another problem or as a specific pain management plan. Review the care plan to determine whether the plan includes as appropriate:

- Measurable pain management goals, reflecting resident needs and preferences;
- Pertinent non-pharmacological and/or pharmacological interventions;
- Specifics for monitoring the status of the resident's pain, including who is responsible, time frames, and the approaches used to evaluate the effectiveness of the interventions;

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- Identification of clinically significant medication-related adverse consequences associated with the use of the prescribed medication, such as falling, constipation, anorexia, or drowsiness, and a plan to try to minimize those adverse consequences; and
- Whether the pain has been reassessed and the care plan revised as necessary with input from the resident or representative, to the extent possible, if the current interventions are not effective or the resident has experienced a change of condition or status.

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, determine whether the care plan reflects coordination by all providers regarding 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.

SLIDE #53

Coordination of Care

Note: Refer hospice concerns as a complaint to the State Agency responsible for oversight of hospice survey activities identifying the specific resident(s) involved and the concerns identified.

INSTRUCTOR'S NOTES:

The previous note in the Appendix P related to the coordination of services between a nursing home and a Medicare certified hospice has been revised. The intent of the revision is to assure that if there are concerns regarding the care not being coordinated between the two entities, the services should be reviewed (by the appropriate agency) in order to review for compliance.

The new language states:

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.

SLIDE #54

IP - Nurse Interview.

Interview a nurse who is knowledgeable about the resident's pain management to determine how staff:

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- Identify, assess, develop interventions, monitor the response, communicate with the prescriber and revise the plan as appropriate; and
- For a resident receiving the hospice benefit, coordinate approaches, communicate and monitor the outcomes (both effectiveness and adverse consequences) with the hospice.

INSTRUCTOR'S NOTES:

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).

SLIDE #55

IP - Interview

Interview other knowledgeable health care professionals about the evaluation and management of the resident's pain/symptoms if:

- Interventions or care appear inconsistent with current standards of practice; and/or

- Resident's pain appears to persist or recur.

INSTRUCTOR'S NOTES:

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.

SLIDE #56

Determination of Compliance-Synopsis of Regulation (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.

INSTRUCTOR'S NOTES:

The language of this regulation makes it clear that the facility must do more than merely make services and care available. The resident is to receive the care and services that will facilitate the attainment or maintenance of the resident's highest practicable overall well-being. The regulatory language does not specifically mention the care provided for the resident with pain. Pain is only one condition or one type of resident need and care that falls under the umbrella regulation regarding quality of care. Recognizing and managing a resident's pain is integral to promoting a resident's overall well-being.

SLIDE #57

Determination of Compliance- Criteria for Compliance

The facility is in compliance with 42 CFR §483.25 (F309), Quality of Care regarding care for the resident with pain, if the facility:

- Recognized and evaluated the resident who experienced pain;
- Developed and implemented interventions to prevent or manage the resident's pain;
- Recognized and provided measures to minimize or prevent pain for situations where pain could be anticipated;
- Monitored the response to the interventions;
- Communicated with the health care practitioner when the resident's pain was not adequately managed or the resident had a suspected or confirmed adverse consequence related to the treatment; and
- Modified the approaches as indicated.

INSTRUCTOR'S NOTES:

The facility is in compliance with the Quality of Care regulation as it relates to the recognition and management of pain for a resident, 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.

The care and services necessary for care of the resident with pain include (refer to slide):

- Recognizing that the resident is or has been experiencing pain and assessing the resident to determine (to the extent possible) causes and characteristics of the pain, as well as factors influencing the pain;
- Developing and implementing interventions to manage the resident's pain, consistent with the resident's goals, risks, and current standards of practice or providing a clinically pertinent rationale about why they did not do so;
- Recognizing and providing approaches to minimize or prevent pain for situations where pain could be anticipated,
- Monitoring the effects of the interventions;

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- Communicating with the practitioner when a resident has experienced pain that is not adequately managed or the resident was having a suspected or confirmed adverse consequence; and
- Modifying the approaches as indicated.

SLIDE #58

Noncompliance with Quality of Care for Resident with Pain-F309

Examples of noncompliance for F309 with regard to pain management, may include failure to:

- Recognize and evaluate the resident who is experiencing pain in enough detail to permit pertinent individualized pain management;
- Develop interventions for a resident who is experiencing pain;
- Provide pain management interventions in situations where pain can be anticipated;
- Implement interventions to address pain to the greatest extent possible consistent with the resident's goals and current standards of practice and failed to provide a clinically pertinent rationale why this was not done;
- Monitor the effectiveness of intervention to manage pain; or
- Coordinate pain management with an involved hospice as needed.

INSTRUCTOR'S NOTES:

After completing the Investigative Protocol, analyze the data in order to determine whether or not noncompliance with the regulation exists.

These are only a few examples of what may constitute noncompliance with regard to care for a resident having pain or who is receiving treatments or procedures that may be expected to cause episodic pain.

Other examples of noncompliance may include failure to define or implement interventions to manage pain that the resident has regularly experienced when the effectiveness of prescribed pain medication wears off or the failure to attempt to determine or address the causes of the pain or failure to attempt non-pharmacological interventions that have become part of recognized standards of practice.

SLIDE #59

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

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- 42 CFR 483.10(b)(4) F155, The Right to Refuse Treatment;
- 42 CFR 483.10(b)(11), F157, Notification of Changes;
- 42 CFR 483.15(b), F242, Self-determination and Participation;
- 42 CFR 483.15(e)(1), F246, Accommodation of Needs.

INSTRUCTOR'S NOTES:

During the investigation, the surveyor may have identified concerns with related outcome, process, and/or structure requirements. If an additional concern was identified, the surveyor should investigate the additional concern. The surveyor is cautioned to not cite any related or associated requirement before first conducting an investigation to determine compliance or non-compliance with that 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.

SLIDE #60

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

- 42 CFR 483.20(b), F272, Comprehensive Assessments;
- 42 CFR 483.20(g) F278, Accuracy of Assessments;
- 42 CFR 483.20(k), F279, Comprehensive Care Plans;
- 42 CFR 483.20(k)(2)(iii), 483.10(d)(3), F280, Comprehensive Care Plan Revision;
- 42 CFR 483.20(k)(3)(i), F281, Services provided meet professional standards of quality;
- 42 CFR 483.20(k)(3)(ii), F282, Care provided.

INSTRUCTOR'S NOTES:

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

42 CFR 483.20(b), 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.

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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 or interested family member, 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.

SLIDE #61

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

- 42 CFR 483.25(l), F329, Unnecessary Drugs;
- 42 CFR 483.40(a), F385, Physician Supervision;
- 42 CFR 483.60, F425, Pharmacy Services;
- 42 CFR 483.75(i)(2), F501, Medical Director;
- 42 CFR 483.75(l) F514, Clinical Records.

INSTRUCTOR'S NOTES:

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

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.

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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 CFR 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.

SLIDE #62

Deficiency Categorization

Pain Recognition and Management

Severity Determination Considerations Levels 4 through 1. The key elements for severity determination are:

- Presence of harm or potential for negative outcomes;
- Degree of harm or potential harm related to noncompliance;
- Immediacy of correction required.

INSTRUCTOR'S NOTES:

We will briefly review the bases for determining the severity of a deficiency and will discuss examples at the various severity levels. The bases for determining which level of Severity applies are:

1. Presence of potential or actual harm or negative outcome(s) related to lack of pain recognition or appropriate treatment and care. Examples of actual or potential harm for F309 related to Pain Assessment and Management may include:
 - Persisting or recurring pain and discomfort related to substantial 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 4 levels.

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. Appendix Q provides additional guidance for determining immediate jeopardy.

SLIDE #63

Severity Level 4

Level 4: Immediate Jeopardy to resident health or safety. Noncompliance with one or more requirements of participation:

- Has allowed, caused, or resulted in (or is likely to allow, cause, result in) serious injury, harm, impairment, or death to a resident; and
- Requires immediate correction.

INSTRUCTOR'S NOTES:

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 may be anticipated 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.

Some examples of Level 4 Severity may include:

- 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
- A 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.

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.

SLIDE #64

Severity Level 3

Level 3: Actual Harm, not Immediate Jeopardy

- Noncompliance resulted in harm;
- May include clinical compromise, decline, inability to maintain/reach highest practicable well-being.

INSTRUCTOR'S NOTES:

Level 3 indicates noncompliance that results in expressions (verbal and non-verbal) of persistent 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).

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Some examples of Level 3 severity may include:

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.

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.

SLIDE #65

Severity Level 2

Level 2: No actual harm with potential for more than minimal harm that is not immediate jeopardy. Noncompliance resulted in:

- No more than minimal discomfort;
- The potential to compromise the resident's ability to maintain or reach his or her highest practicable level of well-being; and/or
- The potential for greater harm if interventions are not provided.

INSTRUCTOR'S NOTES:

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.

Some examples of Severity Level 2 include:

The resident experienced daily or less than daily discomfort with no compromise in physical or psychosocial functioning as a result of the facility's failure to adequately 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

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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.

SLIDE #66

Severity Level 1

Level 1: No actual harm with potential for minimal harm

- Noncompliance with F309 with regard to quality of care for a resident with pain places the resident at risk for more than minimal harm;
- Severity Level 1 does not apply for F309 Quality of Care related to Recognition and Management of Pain.

INSTRUCTOR'S NOTES:

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 Quality of Care related to pain recognition and management.

SLIDE #67

Other Changes

At the same time F309 changes are issued, we are issuing the following other changes:
Appendix P: deletion of Unintended Weight Loss Investigative Protocol (use protocol at F325)
Appendix P: deletion of Task 5C, parts K (Review of a Resident Receiving Hospice Care) and L (Review of a Resident Receiving Dialysis Services). These were moved to F309

INSTRUCTOR'S NOTES:

For weight loss, surveyors should use the protocol at F325.

As discussed previously in this training package, the hospice and dialysis information is now at F309.

Also, as a minor change, the section currently noted as M (Review of Influenza and Pneumococcal Immunizations) will become part K. There was no change to the text of this section.

SLIDE #68

Other Changes

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Appendix P: deletion of part VII (demand billing procedure) and insertion of new procedure into Task 5C Resident Review, new part L: Liability Notices and Beneficiary Appeal Rights
This new procedure went into effect via a recent Survey and Certification letter.

These changes were necessary due to a change in demand billing requirements. See this letter for additional information

INSTRUCTOR'S NOTES:

None

SLIDE #69

Other Changes

Appendix PP

Deletion of sentence at F286 (MDS Use) requiring storage of paper copy of MDS for homes using all electronic records. This is no longer required for these homes.

INSTRUCTOR'S NOTES:

The following sentence is being deleted: "Whether or not the facility's clinical record system is entirely electronic, a hard copy of all MDS forms, including the signatures of the facility staff attesting to the accuracy and completion of the records, must be maintained in the residents' clinical record."

Maintaining 15 months of MDS data is still required. This deletion simply removes the "hard copy" language for homes using electronic records. The MDS records must still be accessible to clinical staff, the State, and CMS, as stated by current language that remains at this Tag.