

Center for Medicaid and State Operations/Survey and Certification Group

Ref: S&C-09-22

DATE: January 23, 2009

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: **Nursing Homes** - Issuance of Revised Quality of Care Guidance at F309, including Pain Management as Part of Appendix PP, State Operations Manual, Additional Minor Changes Made to Appendices P and PP as Described Below

Memorandum Summary

- Revised guidance for long-term care surveyors at F309, Quality of Care, including a new general investigative protocol and new pain management guidance and investigative protocol will be effective March 31, 2009;
- The advance copy of this guidance and training materials are to be used to train all surveyors who survey nursing homes by the implementation date;
- Removed hospice and dialysis survey protocol language from Appendix P and inserted into F309;
- Removed weight loss investigative protocol from Appendix P due to the June 2008 issuance of F325 investigative protocol;
- Deleted guidance requiring paper copy storage of Minimum Data Set (MDS) in homes with electronic records at Tag F286, 483.20(d), Use; and
- Removed demand billing survey process at Appendix P, Part VII and inserted new procedure at Task 5C.

The Centers for Medicare & Medicaid Services (CMS) is revising the Guidance to Surveyors at F309, Quality of Care in Appendix PP of the State Operations Manual. We are:

- Completely revising the general quality of care guidance at this Tag;
- Adding a new general investigative protocol for quality of care;
- Adding major new guidance and an investigative protocol for pain management; and
- Moving the survey protocol language regarding review of residents receiving hospice care and dialysis services (currently under Appendix P, II.B. The Traditional Standard Survey, Sub-Task 5C Resident Review, parts K and L) into F309.

We are also making the following additional changes as part of this issuance:

- Deleting the investigative protocol for unintended weight loss (currently under Appendix P, II.B. The Traditional Standard Survey, Sub-Task 5C) due to the June 2008 issuance of the revised guidance at F325 Nutrition;
- Revising portions of the Appendix P Table of Contents to reflect the three deletions listed above;
- Removing a sentence under F286 Use [of the Resident Assessment] that had mandated the storage of paper copies of the MDS for homes that have all-electronic clinical records. The retention of paper copies is no longer required for these homes.
- Renumbering Part M of Sub-Task 5C, Review of Influenza and Pneumococcal Immunizations as section K due to removal of current K and L sections; and
- Removing the outdated demand bill survey procedure in Appendix P, Part VII and replacing it with new procedural language at Sub-Task 5C Resident Review, as new part L, Liability Notices and Beneficiary Appeal Rights.

This set of revisions and deletions to Appendices P and PP will become effective on March 1, 2009. At that time, a final copy of this new guidance will be available at <http://www.cms.hhs.gov/Transmittals/> and ultimately incorporated into Appendix PP of the State Operations Manual on the CMS Web site. An exception is the demand bill change which became effective with Survey and Certification Letter 09-20, published January 9, 2009.

The interpretive guidelines for F309 were revised to clarify areas such as assessment, care planning, and interventions. The investigative protocols explain objectives and procedures surveyors will need for their investigation. Deficiency categorization provides severity guidance for the determination of the correct level of severity of outcome to residents for deficiencies at Tag F309.

We are providing an advance copy of these changes to both Appendices, as well as a training package which is to be used to assure that all surveyors who survey nursing homes are trained in these revisions by the implementation date. These materials were presented and discussed in a teleconference with the CMS Regional Offices (ROs) on January 15, 2009. We encourage training of surveyors to be conducted in person with group discussions to enhance learning. However, if this is not feasible to meet the needs of your surveyors, it is acceptable to use other methods. The training material may also be used to communicate with providers groups and other stakeholders. RO training coordinators will document the completion of training on this new guidance for all RO and State nursing home surveyors within their region.

Enclosed with this memorandum are the following files:

- Training slides in MSWord (Powerpoint files will be emailed directly to ROs and SAs);
- Advance copy of surveyor guidance; and
- Transmittal Sheet listing all changes.

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For questions on this memorandum, please contact Beverly Cullen at 410-786-6784 or via email at beverly.cullen@cms.hhs.gov.

Effective Date: March 1, 2009.

Training: The materials should be distributed immediately to all State Agencies and training coordinators.

/s/
Thomas E. Hamilton

cc: Survey and Certification Regional Office Management

CMS Manual System

Pub. 100-07 State Operations Provider Certification

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

Transmittal

Date:

SUBJECT: Revision of Appendices P and PP

I. SUMMARY OF CHANGES: State Operations Manual, Appendix P deletions and revisions as specified below. Appendix PP, Revisions to Tags as specified below.

NEW/REVISED MATERIAL - EFFECTIVE DATE*: Upon Issuance

IMPLEMENTATION DATE: Upon Issuance

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

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

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

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	Appendix P, II. The Survey Process, B. The Traditional Standard Survey, Subtask 5C Resident Review: deleted current sections K (Review of a Resident Receiving Hospice Care) and L (Review of a Resident Receiving Dialysis Services), renumbered current section M (Review of Influenza and Pneumococcal Immunizations) as K and added new section L (Liability Notices and Beneficiary Appeal Rights)
D	Appendix P, VII. Additional Procedures for Medicare Participating Long Term Care Facilities
R	Appendix P, Table of Contents to accommodate changes listed above
R	Appendix PP, Tag F286, Use – deleted a sentence requiring storage of paper copies of assessments in facilities with electronic records
R	Appendix PP, Tag F309, Quality of Care

III. FUNDING: Medicare contractors shall implement these instructions within their current operating budgets.

IV. ATTACHMENTS:

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

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

State Operations Manual

Appendix P - Survey Protocol for Long Term Care Facilities - Part I

Advance Copy

Sub-Task 5C - Resident Review

(Rev.)

K. Review of Influenza and Pneumococcal Immunizations

Use the Investigative Protocol contained at Tag F334 to complete a review of the implementation of the facility's immunization policies and procedures.

(Rev.)

L. Liability Notices and Beneficiary Appeal Rights

Medicare-participating long term care facilities are obligated to inform Medicare Part A and B beneficiaries about specific rights related to billing, and to submit bills to the Fiscal Intermediary (FI) or Medicare Administrative Contractor (MAC) when requested by the beneficiary. In a Medicare-participating long term care facility, verify compliance with these requirements.

Listed below are the requirements of the Skilled Nursing Facility (SNF).

- 1. If a SNF provider believes on admission or during a resident's stay that Medicare will not pay for skilled nursing or specialized rehabilitative services and that an otherwise covered item or service may be denied as not reasonable and necessary, the facility must notify the resident or his/her legal representative in writing and explain:*
 - Why these specific services may not be covered;*
 - The beneficiary's potential liability for payment for the non-covered services;*
 - The beneficiary right to have a claim submitted to Medicare; and*
 - The beneficiary's standard claim appeal rights that apply if the claim is denied by Medicare.*

This notice requirement may be fulfilled by use of either the Skilled Nursing Facility Advanced Beneficiary Notice (SNFABN) (Form CMS-10055) or one of the five uniform

Denial Letters found in §358 of the SNF Manual. The SNFABN and the Denial Letters inform the beneficiary of his/her right to have a claim submitted to Medicare and advises them of the standard claim appeal rights that apply if the claim is denied by Medicare. These claims are often referred to as “demand bills” and are reviewed by the FI or MAC. (See Chapter 1, §60.3 of the Medicare Claims Processing Manual for detailed instructions on submitting institutional demand bills.). The SNF:

- *Must keep a copy of the SNFABN or Denial Notice on file;*
 - *Must file a claim when requested by the beneficiary; and*
 - *May not charge the resident for Medicare covered Part A services while a decision is pending.*
2. *The SNF must issue the Notice of Medicare Provider Non-coverage (Form CMS-10123) when there is a termination of all Medicare Part A services for coverage reasons. The Notice of Medicare Provider Non-coverage informs the beneficiary of his/her right to an expedited review of a service termination by the Quality Improvement Organization (QIO). The Notice to Medicare Provider Non-coverage is sometimes referred to as an “Expedited Appeal Notice” or a “Generic Notice.” The SNF should not issue this notice if the beneficiary exhausts the Medicare covered days as the number of SNF benefit days is set in law and the QIO cannot extend the benefit period. Thus, a service termination due to the exhaustion of benefits is not considered a termination for “coverage” reasons. The SNF:*
- *Must keep a copy of the Notice of Medicare Provider Non-coverage on file;*
 - *Must file a claim when requested by the beneficiary; and*
 - *May not charge the resident for Medicare covered Part A services while a decision is pending.*

Failure to provide written liability of payment and/or appeal notice(s), to submit the bill (if requested by a resident), or to charge the resident for Medicare covered Part A services while a decision is pending may constitute a violation of the facility’s provider agreement. Refer to S&C-09-20 or go to <http://www.cms.hhs.gov/bni/> for more details about liability notices and resident appeal rights.

Procedure to Determine Compliance

1. *During the entrance conference, obtain a list of Medicare beneficiaries who requested demand bills in the past six months. From the list, randomly select one resident’s file to determine if the facility submitted the bill to the FI or MAC. In general, Medicare claims must be filed within one full calendar year following the year in which the services were provided. (For more information, refer to 42 C.F.R. §424.44 and the Medicare Claims Processing Manual, Chapter 1 - General Billing Requirements, section 70.1.) If the facility failed to submit the bill to the FI or MAC within the required timeframe or charged the*

resident while the decision was pending, the facility is in violation of the provider agreement with respect to resident billing requirements. Cite Tag F492, 42 C.F.R. § 483.75(b), Compliance with Federal, State and local laws and professional standards, and refer to 42 C.F.R. §489.21, Specific limitations on charges.

Note: *If no Medicare beneficiaries requested a demand bill in the past six months, this portion of the review is complete, and the surveyor should continue with the closed record review.*

- 2. During closed record review, review three charts of discharged Medicare beneficiaries from the SNF. If the current closed record review sample does not include three Medicare beneficiaries discharged from the SNF, expand the sample. Look for a copy of appropriate liability and appeal notice(s). If the facility failed to provide the resident the appropriate liability and/or appeal notice(s), the facility is in violation of the notice requirements. Cite Tag F156, 42 C.F.R. 483.10, Resident rights.*

If the record indicates the resident requested the facility submit the bill for appeal, determine if the facility submitted the bill to the FI or MAC within the required timeframe. In general, Medicare claims must be filed within one full calendar year following the year in which the services were provided. (For more information refer to 42 C.F.R. § 424.44 and the Medicare Claims Processing Manual, Chapter 1 - General Billing Requirements, section 70.1.) If the facility failed to submit the bill to the FI or MAC within the required timeframe or charged the resident while the decision was pending, the facility is in violation of the provider agreement with respect to resident billing requirements. Cite Tag F492, 42 C.F.R. § 483.75(b), Compliance with Federal, State and local laws and professional standards and refer to 42 C.F.R. § 489.21, Specific limitations on charges.

(Rev.)

§483.25 Quality of Care

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

Intent: §483.25

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

Note: Use guidance at F309 for review of quality of care not specifically covered by 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.

Definitions: §483.25

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

Interpretive Guidelines §483.25

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

- An accurate and complete assessment (see §483.20);
- A care plan that is implemented consistently and based on information from the assessment; and
- Evaluation of the results of the interventions and revising the interventions as necessary.

Determine if the facility is providing the necessary care and services based on the findings of the *comprehensive assessment and plan of care*. If services and care are being provided, determine

if the facility is evaluating the *resident's* outcome and changing the interventions if needed. This should be done in accordance with the resident's customary daily routine.

Procedures §483.25

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

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

General Investigative Protocol for F309, Quality of Care

Use:

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

Procedure:

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

Observations:

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

Resident/Representative Interview

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

- *Awareness of the current condition(s) or history of the condition(s) or diagnosis/diagnoses;*

- *Involvement in the development of the care plan, goals, and if interventions reflect choices and preferences; and*
- *How effective the interventions have been and if not effective, whether alternate approaches have been tried by the facility.*

Nursing Staff Interview

Interview nursing staff on various shifts to determine:

- *Their knowledge of the specific interventions for the resident, including facility-specific guidelines/protocols;*
- *Whether nursing assistants know how, what, when, and to whom to report changes in condition; and*
- *How the charge nurse monitors for the implementation of the care plan, and changes in condition.*

Assessment

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

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

Care Planning

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

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

Care Plan Revision

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

- *Achieving the desired outcome;*
- *Resident failure or inability to comply with or participate in a program to attain or maintain the highest practicable level of well-being; and/or*
- *Change in resident condition, ability to make decisions, cognition, medications, behavioral symptoms or visual problems.*

Interview with Health Care Practitioners and Professionals

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

- *How it was determined that chosen interventions were appropriate;*
- *Risks identified for which there were no interventions;*
- *Changes in condition that may justify additional or different interventions; or*
- *How staff validated the effectiveness of current interventions.*

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

Synopsis of Regulation (Tag F309)

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

Criteria for Compliance:

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

- Recognized and assessed factors placing the resident at risk for specific conditions, causes and/or problems;*
- Defined and implemented interventions in accordance with resident needs, goals, and recognized standards of practice;*
- Monitored and evaluated the resident's response to preventive efforts and treatment; and*
- Revised the approaches as appropriate.*

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

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

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

Determine whether staff notified the resident and consulted the physician regarding significant changes in the resident's condition or a need to alter treatment significantly or notified the representative of a significant condition change.

- 42 CFR 483.(20)(b), F272, Comprehensive Assessments***

Determine whether the facility assessed the resident's condition, including existing status, and resident-specific risk factors (including potential causative factors) in relation to the identified concern under review.

- **42 CFR 483.20(k), F279, Comprehensive Care Plan**

Determine whether the facility established a care plan with timetables and resident specific goals and interventions to address the care needs and treatment related to the clinical diagnosis and/or the identified concern.

- **42 CFR 483.20(k)(2)(iii), 483.10(d)(3), F280, Care Plan Revision**

Determine whether the staff reviewed and revised the care plan as indicated based upon the resident's response to the care plan interventions, and obtained input from the resident or representative to the extent possible.

- **42 CFR 483.20(k)(3)(i), F281, Services Provided Meets Professional Standards of Quality**

Determine whether the facility, beginning from the time of admission, provided care and services related to the identified concern that meet professional standards of quality.

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

Determine whether care was provided by qualified staff and whether staff implemented the care plan correctly and adequately.

- **42 CFR 483.30(a), F353, Sufficient Staff**

Determine whether the facility had qualified nursing staff in sufficient numbers to assure the resident was provided necessary care and services 24 hours a day, based upon the comprehensive assessment and care plan.

- **42 CFR 483.40(a)(1)&(2), F385, Physician Supervision**

Determine whether the physician has assessed and developed a relevant treatment regimen and responded appropriately to the notice of changes in condition.

- **42 CFR 483.75(f), F498, Proficiency of Nurse Aides**

Determine whether nurse 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:

- Assisted the facility in the development and implementation of policies and procedures and that these are based on current standards of practice; and*
- Interacts with the physician supervising the care of the resident if requested by the facility to intervene on behalf of the residents.*

- **42 CFR 483.75(l), F514, Clinical Records**

Determine whether the clinical records:

- Accurately and completely document the resident's status, the care and services provided in accordance with current professional standards and practices; and*
- Provide a basis for determining and managing the resident's progress including response to treatment, change in condition, and changes in treatment.*

DEFICIENCY CATEGORIZATION (Part IV, Appendix P)

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

- 1. Presence of harm/negative outcome(s) or potential for negative outcomes because of lack of appropriate treatment and care, such as decline in function or failure to achieve the highest possible level of well-being.*
- 2. Degree of harm (actual or potential) related to the non-compliance. Identify how the facility practices caused, resulted in, allowed or contributed to the actual or potential for harm:*
 - *If harm has occurred, determine if the harm is at the level of serious injury, impairment, death, compromise, or discomfort to the resident(s); and*
 - *If harm has not yet occurred, determine the potential for serious injury, impairment, death, compromise, or discomfort to occur to the resident(s).*
- 3. The immediacy of correction required. Determine whether the noncompliance requires immediate correction in order to prevent serious injury, harm, impairment, or death to one or more residents.*

The survey team must evaluate the harm or potential for harm for F309 based upon the four levels of severity. First, the team must rule out whether Severity Level 4, Immediate Jeopardy to a resident's health or safety, exists by evaluating the deficient practice in relation to immediacy,

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

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

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

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

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

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

An arterial ulcer is ulceration that occurs as the result of arterial occlusive disease when non-pressure related disruption or blockage of the arterial blood flow to an area causes tissue necrosis. Inadequate blood supply to the extremity may initially present as intermittent claudication. Arterial/Ischemic ulcers may be present in individuals with moderate to severe peripheral vascular disease, generalized arteriosclerosis, inflammatory or autoimmune disorders (such as arteritis), or significant vascular disease elsewhere (e.g., stroke or heart attack). The arterial ulcer is characteristically painful, usually occurs in the distal portion of the lower extremity and may be over the ankle or bony areas of the foot (e.g., top of the foot or toe, outside edge of the foot). The wound bed is frequently dry and pale with minimal or no exudate. The affected foot may exhibit: diminished or absent pedal pulse, coolness to touch, decreased pain when hanging down (dependent) or increased pain when elevated, blanching upon elevation, delayed capillary fill time, hair loss on top of the foot and toes, toenail thickening.

A venous ulcer (previously known as a stasis ulcer) is an open lesion of the skin and subcutaneous tissue of the lower leg, often occurring in the lower leg around the medial ankle. Venous ulcers are reported to be the most common vascular ulceration and may be difficult to heal, may occur off and on for several years, and may occur after relatively minor trauma. The ulcer may have a moist, granulating wound bed, may be superficial, and may have minimal to copious serous drainage unless the wound is infected. The resident may experience pain that may increase when the foot is in a dependent position, such as when a resident is seated with her or his feet on the floor.

Recent literature implicates venous hypertension as a causative factor. Venous hypertension may be caused by one (or a combination of) factor(s) including: loss of (or compromised) valve

function in the vein, partial or complete obstruction of the vein (e.g., deep vein thrombosis, obesity, malignancy), and/or failure of the calf muscle to pump the blood (e.g., paralysis, decreased activity). Venous insufficiency may result in edema and induration, dilated superficial veins, *dry scaly crusts, dark pigmented skin in the lower third of the leg, or dermatitis*. The pigmentation may appear as darkening skin, tan or purple areas in light skinned residents and dark purple, black or dark brown in dark skinned residents. *Cellulitis may be present if the tissue is infected*.

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

Review of a Resident Receiving Hospice Services.

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

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

For a resident receiving hospice benefit care, evaluate if:

- The plan of care reflects the participation of the hospice, the facility, and the resident or representative to the extent possible;*
- The plan of care includes directives for managing pain and other uncomfortable symptoms and is revised and updated as necessary to reflect the resident's current status;*
- Medications and medical supplies are provided by the hospice as needed for the palliation and management of the terminal illness and related conditions;*
- The hospice and the facility communicate with each other when any changes are indicated to the plan of care;*
- The hospice and the facility are aware of the other's responsibilities in implementing the plan of care;*

- *The facility's services are consistent with the plan of care developed in coordination with the hospice, (the hospice patient residing in a SNF/NF should not experience any lack of SNF/NF services or personal care because of his/her status as a hospice patient); and*
- *The SNF/NF offers the same services to its residents who have elected the hospice benefit as it furnishes to its residents who have not elected the hospice benefit. The resident has the right to refuse services in conjunction with the provisions of 42 CFR 483.10(b)(4), F155.*

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

Review of a Resident Receiving Dialysis Services.

When dialysis is provided in the facility by an outside entity, or the resident leaves the facility to obtain dialysis, the nursing home must have an agreement or arrangement with the entity in accordance with 42 CFR 483.75 (h), F500. This agreement/arrangement should include all aspects of how the resident's care is to be managed, including:

- *Medical and non-medical emergencies;*
- *Development and implementation of the resident's care plan;*
- *Interchange of information useful/necessary for the care of the resident; and*
- *Responsibility for waste handling, sterilization, and disinfection of equipment.*

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

- *Review to assure that medications are administered before and after dialysis as ordered by the physician. This should account for the optimal timing to maximize effectiveness and avoid adverse effects of the medications;*
- *Whether staff know how to manage emergencies and complications, including equipment failure and alarm systems (if any), bleeding/hemorrhaging, and infection/bacteremia/septic shock;*
- *Whether facility staff are aware of the care of shunts/fistulas, infection control, waste handling, nature and management of end stage renal disease (including nutritional needs, emotional and social well-being, and aspects to monitor); and*

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

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

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

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

- *Recognizes when the resident is experiencing pain and identifies circumstances when pain can be anticipated;*
- *Evaluates the existing pain and the cause(s), and*
- *Manages or prevents pain, consistent with the comprehensive assessment and plan of care, current clinical standards of practice, and the resident's goals and preferences.*

Definitions Related to Recognition and Management of Pain

- *“Addiction” is a primary, chronic, neurobiological disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by an overwhelming craving for medication or behaviors that include one or more of the following: impaired control over drug use, compulsive use, continued use despite harm, and craving¹*
- *"Adjuvant Analgesics" describes any medication with a primary indication other than pain management but with analgesic properties in some painful conditions.²*
- *“Adverse Consequence” is an unpleasant symptom or event that is due to or associated with a medication, such as impairment or decline in a resident’s mental or physical condition or functional or psychosocial status. It may include various types of adverse drug reactions and interactions (e.g., medication-medication, medication-food, and medication-disease).*

Note: *Adverse drug reaction (ADR) is a form of adverse consequences. It may be either a secondary effect of a medication that is usually undesirable and different from the therapeutic effect of the medication or any response to a medication that is noxious and unintended and occurs in doses for prophylaxis, diagnosis, or treatment. The term “side effect” is often used interchangeably with ADR; however, side effects are but one of five ADR categories, the others being hypersensitivity, idiosyncratic response, toxic*

reactions, and adverse medication interactions. A side effect is an expected, well-known reaction that occurs with a predictable frequency and may or may not constitute an adverse consequence.

- *“Complementary and Alternative Medicine” (CAM) is a group of diverse medical and health care systems, practices, and products that are not presently considered to be a part of conventional medicine.³*
- *“Non-pharmacological interventions” refers to approaches to care that do not involve medications, generally directed towards stabilizing or improving a resident’s mental, physical or psychosocial well-being.*
- *“Pain” is an unpleasant sensory and emotional experience that can be acute, recurrent or persistent.⁴ Following are descriptions of several different types of pain:*
 - *“Acute Pain” is generally pain of abrupt onset and limited duration, often associated with an adverse chemical, thermal or mechanical stimulus such as surgery, trauma and acute illness;*
 - *“Breakthrough Pain” refers to an episodic increase in (flare-up) pain in someone whose pain is generally being managed by his/her current medication regimen;*
 - *“Incident Pain” refers to pain that is typically predictable and is related to a precipitating event such as movement (e.g., walking, transferring, or dressing) or certain actions (e.g., disimpaction or wound care); and*
 - *“Persistent Pain” or “Chronic Pain” refers to a pain state that continues for a prolonged period of time or recurs more than intermittently for months or years.*
- *“Physical Dependence” is a physiologic state of neuroadaptation that is characterized by a withdrawal syndrome if a medication or drug is stopped or decreased abruptly, or if an antagonist is administered.*
- *“Standards of Practice” refers to approaches to care, procedures, techniques, treatments, etc., that are based on research and/or expert consensus and that are contained in current manuals, textbooks, or publications, or that are accepted, adopted or promulgated by recognized professional organizations or national accrediting bodies.*
- *“Tolerance” is a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce the same effect or a reduced effect is observed with a constant dose.⁵*

Overview of Pain Recognition and Management

Effective pain recognition and management requires an ongoing facility-wide commitment to resident comfort, to identifying and addressing barriers to managing pain, and to addressing any misconceptions that residents, families, and staff may have about managing pain. Nursing home

residents are at high risk for having pain that may affect function, impair mobility, impair mood, or disturb sleep, and diminish quality of life.⁶ The onset of acute pain may indicate a new injury or a potentially life-threatening condition or illness. It is important, therefore, that a resident's reports of pain, or nonverbal signs suggesting pain, be evaluated.

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

Certain factors may affect the recognition, assessment, and management of pain. For example, residents, staff, or practitioners may misunderstand the indications for, and benefits and risks of, opioids and other analgesics; or they may mistakenly believe that older individuals have a higher tolerance for pain than younger individuals, or that pain is an inevitable part of aging, a sign of weakness, or a way just to get attention. Other challenges to successfully evaluating and managing pain may include communication difficulties due to illness or language and cultural barriers, stoicism about pain, and cognitive impairment.^{7,8,9}

It is a challenge to assess and manage pain in individuals who have cognitive impairment or communications difficulties.^{10,11} Some individuals with advanced cognitive impairment can accurately report pain and/or respond to questions regarding pain.^{12,13} One study noted that 83 percent of nursing home residents could respond to questions about pain intensity.¹⁴

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

Resources Related to Pain Management

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

- American Geriatrics Society Clinical Practice Guideline at: http://www.americangeriatrics.org/education/cp_index.shtml;
- American Medical Directors Association (AMDA) Clinical Practice Guideline "Pain Management in the Long-Term Care Setting" (2003) at: www.amda.com/tools/guidelines.cfm;
- American Academy of Hospice and Palliative Medicine at www.aahpm.org;

- *American Academy of Pain Medicine at <http://www.painmed.org>;*
- *American Pain Society at www.ampainsoc.org;*
- *Brown University's Pain and Physical Symptoms Toolkit at <http://www.chcr.brown.edu/pcoc/physical.htm>;*
- *Hospice and Palliative Nurses Association at <http://www.hpna.org>;*
- *John A Hartford Institute for Geriatric Nursing "Try This" series at http://www.hartfordign.org/Resources/Try_This_Series;*
- *National Initiative on Pain Control at www.painedu.org;*
- *Partners Against Pain[®] at <http://www.partnersagainstpain.com>;*
- *Quality Improvement Organizations at www.medqic.org; and*
- *Resource Center for Pain Medicine and Palliative Care at Beth Israel Medical Center (2000) at http://www.stoppain.org/education_research/index.html.*

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

Care Process for Pain Management

Processes for the prevention and management of pain include:

- *Assessing the potential for pain, recognizing the onset or presence of pain, and assessing the pain;*
- *Addressing/treating the underlying causes of the pain, to the extent possible;*
- *Developing and implementing interventions/approaches to pain management, depending on factors such as whether the pain is episodic, continuous, or both;*
- *Identifying and using specific strategies for different levels or sources of pain or pain-related symptoms, including:*
 - *Identifying interventions to address the pain based on the resident-specific assessment, a pertinent clinical rationale, and the resident's goals;*
 - + *Trying to prevent or minimize anticipated pain;¹⁶*

- + *Considering non-pharmacological and CAM interventions;*
- *Using pain medications judiciously to balance the resident's desired level of pain relief with the avoidance of unacceptable adverse consequences;*
- *Monitoring appropriately for effectiveness and/or adverse consequences (e.g., constipation, sedation) including defining how and when to monitor the resident's symptoms and degree of pain relief; and*
- *Modifying the approaches, as necessary.*

Pain Recognition

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

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

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

- *Difficulty eating or loss of appetite; and*
- *Difficulty sleeping (insomnia).*

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

Many residents have more than one active medical condition and may experience pain from several different causes simultaneously. Many medical conditions may be painful such as pressure ulcers, diabetes with neuropathic pain, immobility, amputation, post- CVA, venous and arterial ulcers, multiple sclerosis, oral health conditions, and infections. In addition, common procedures, such as moving a resident or performing physical or occupational therapies or changing a wound dressing may be painful. Understanding the underlying causes of pain is an important step in determining optimal approaches to prevent, minimize, or manage pain.

Observations at rest and during movement, particularly during activities that may increase pain (such as dressing changes, exercises, turning and positioning, bathing, rising from a chair, walking) can help to identify whether the resident is having pain. Observations during eating or during the provision of oral hygiene may also indicate dental, mouth and/or facial pain.

Recognizing the presence of pain and identifying those situations where pain may be anticipated involves the participation of health care professionals and direct care and ancillary staff who have contact with the resident. Information may be obtained by talking with the resident, directly examining the resident, and observing the resident's behavior.²⁰ Staffing consistency and the nursing staff's level of familiarity with the residents was reported in one study to have a significant effect on the staff member's ability to identify and differentiate pain-related behavior from other behavior of cognitively impaired residents.²¹

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

Assessment

Observing the resident during care, activities, and treatments helps not only to detect whether pain is present, but also to potentially identify its location and the limitations it places on the resident. The facility must complete the Resident Assessment Instrument (RAI) (See 483.20 F272). According to the CMS Revised Long-Term Care Facility Resident Assessment Instrument User's Manual, Version 2.0, Manual Chapter 1.14 CMS Clarification Regarding Documentation Requirements, "Completion of the MDS does not remove the facility's responsibility to document a more detailed assessment of particular issues of relevance for the resident....Clinical documentation that contributes to identification and communication of residents' problems,

needs and strengths, that monitors their condition on an on-going basis, and that records treatment and response to treatment is a matter of good clinical practice and is an expectation of trained and licensed health care professionals.” An assessment or an evaluation of pain based on clinical standards of practice may necessitate gathering the following information, as applicable to the resident:

- *History of pain and its treatment (including non-pharmacological and pharmacological treatment);*
- *Characteristics of pain, such as:*
 - *Intensity of pain (e.g., as measured on a standardized pain scale);*
 - *Descriptors of pain (e.g., burning, stabbing, tingling, aching);*
 - *Pattern of pain (e.g., constant or intermittent);*
 - *Location and radiation of pain;*
 - *Frequency, timing and duration of pain;*
- *Impact of pain on quality of life (e.g., sleeping, functioning, appetite, and mood);*
- *Factors such as activities, care, or treatment that precipitate or exacerbate pain;*
- *Strategies and factors that reduce pain;*
- *Additional symptoms associated with pain (e.g., nausea, anxiety);*
- *Physical examination (may include the pain site, the nervous system, mobility and function, and physical, psychological and cognitive status);*
- *Current medical conditions and medications; or*
- *The resident’s goals for pain management and his or her satisfaction with the current level of pain control.*

Management of Pain

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

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

The basis for effective interventions includes several considerations, such as the resident's needs and goals; the source(s), type and severity of pain (recognizing that the resident may experience pain from one or more sources either simultaneously or at different times) and awareness of the available treatment options. Often, sequential trials of various treatment options are needed to develop the most effective approach.

It is important for pain management approaches to follow pertinent clinical standards of practice and to identify who is to be involved in managing the pain and implementing the care or supplying the services (e.g., facility staff, such as RN, LPN, CNA; attending physician or other practitioner; certified hospice; or other contractors such as therapists). Pertinent current standards of practice may provide recommended approaches to pain management even when the cause cannot be or has not been determined.

If a resident or the resident's representative elects the Medicare hospice benefit for end-of-life care, the facility remains the resident's primary care giver and the SNF/NF requirements for participation in Medicare or Medicaid still apply for that resident. According to the Medicare Hospice Conditions of Participation at CFR 418.112(b) Standard: Professional Management, "The hospice must assume responsibility for professional management of the resident's hospice services provided, in accordance with the hospice plan of care and the hospice conditions of participation, and make any arrangements necessary for hospice-related inpatient care in a participating Medicare/Medicaid facility according to §418.100 and §418.112(b)." The care of the resident, including pain management, must be appropriately coordinated among all providers.

In order to provide effective pain management, it is important that staff be educated and guided regarding the proper evaluation and management of pain as reflected in or consistent with the protocols, policies, and procedures employed by the facility.

Non-pharmacological interventions

Non-pharmacologic interventions may help manage pain effectively when used either independently or in conjunction with pharmacologic agents.²² Examples of non-pharmacologic approaches may include, but are not limited to:

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

- *Physical modalities, such as ice packs or cold compresses (to reduce swelling and lessen sensation), mild heat (to decrease joint stiffness and increase blood flow to an area), neutral body alignment and repositioning, baths, transcutaneous electrical nerve stimulation (TENS), massage, acupuncture/acupressure, chiropractic, or rehabilitation therapy;*
- *Exercises to address stiffness and prevent contractures; and*
- *Cognitive/Behavioral interventions (e.g., relaxation techniques, reminiscing, diversions, activities, music therapy, coping techniques and education about pain).*

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

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

- *National Center for Complementary and Alternative Medicine at www.nccam.nih.gov;*
and
- *Food and Drug Administration (FDA) at www.fda.gov.*

Because CAM can include herbal supplements, some of which potentially can interact with prescribed medications, it is important that any such agents are recorded in the resident's chart for evaluation by the physician and consultant pharmacist.

Pharmacological interventions

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

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

Factors influencing the selection and doses of medications include the resident's medical condition, current medication regimen, nature, severity, and cause of the pain and the course of the illness. Analgesics may help manage pain; however, they often do not address the underlying cause of pain. Examples of different approaches may include, but are not limited to:

administering lower doses of medication initially and titrating the dose slowly upward, administering medications “around the clock” rather than “on demand” (PRN); or combining longer acting medications with PRN medications for breakthrough pain. Recurrent use of or repeated requests for PRN medications may indicate the need to reevaluate the situation, including the current medication regimen. Some clinical conditions or situations may require using several analgesics and/or adjuvant medications (e.g., antidepressants or anticonvulsants) together. Documentation helps to clarify the rationale for a treatment regimen and to acknowledge associated risks.

Opioids or other potent analgesics have been used for residents who are actively dying, those with complex pain syndromes, and those with more severe acute or chronic pain that has not responded to non-opioid analgesics or other measures. Opioids should be selected and dosed in accordance with current standards of practice and manufacturers’ guidelines in order to optimize their effectiveness and minimize their adverse consequences. Adverse consequences may be especially problematic when the resident is receiving other medications with significant effects on the cardiovascular and central nervous systems. Therefore, careful titration of dosages based on monitoring/evaluating the effectiveness of the medication and the occurrence of adverse consequences is necessary. The clinical record should reflect the ongoing communication between the prescriber and the staff is necessary for the optimal and judicious use of pain medications.

Other interventions have been used for some residents with more advanced, complex, or poorly controlled pain. Examples include, but are not limited to: radiation therapy, neurostimulation, spinal delivery of analgesics (implanted catheters and pump systems), and neurolytic procedures (chemical or surgical)²⁵ that are administered under the close supervision of expert practitioners.

Monitoring, Reassessment, and Care Plan Revision

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

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

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

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

Endnotes for Pain Management

¹*Definitions Related to the Use of Opioids for the Treatment of Pain: Consensus document from the American Academy of Pain Medicine, the American Pain Society, and the American Society of Addiction Medicine, 2001. Document available at www.painmed.org, www.ampainsoc.org and www.asam.org.*

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Investigative Protocol for Pain Management

Quality of Care Related to the Recognition and Management of Pain

Objective

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

Use

Use this protocol for a resident who has pain symptoms or who has the potential for pain symptoms related to conditions or treatments. This includes a resident:

- Who states he/she has pain or discomfort;*
- Who displays possible indicators of pain that cannot be readily attributed to another cause;*
- Who has a disease or condition or who receives treatments that cause or can reasonably be anticipated to cause pain;*
- Whose assessment indicates that he/she experiences pain;*
- Who receives or has orders for treatment for pain; and/or*
- Who has elected a hospice benefit for pain management.*

Procedures

Briefly review the care plan and orders to identify any current pain management interventions and to focus observations. Corroborate observations by interview and record review.

Note: *Determine who is involved in the pain management process (for example, the staff and practitioner, and/or another entity such as a licensed/certified hospice).*

1. Observation

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

- *If the resident exhibits signs or symptoms of pain, verbalizes the presence of pain, or requests interventions for pain, or whether the pain appears to affect the resident's function or ability to participate in routine care or activities;*
- *If there is evidence of pain, whether staff have assessed the situation, identified, and implemented interventions to try to prevent or address the pain and have evaluated the status of the resident's pain after interventions;*
- *If care and services are being provided that reasonably could be anticipated to cause pain, whether staff have identified and addressed these issues, to the extent possible;*
- *Staff response, if there is a report from the resident, family, or staff that the resident is experiencing pain;*
- *If there are pain management interventions for the resident, whether the staff implements them. Follow up on:*
 - *Deviations from the care plan;*
 - *Whether pain management interventions have a documented rationale and if it is consistent with current standards of practice; and*
 - *Potential adverse consequence(s) associated with treatment for pain (e.g., medications); and*
- *How staff responded, if the interventions implemented did not reduce the pain consistent with the goals for pain management.*

2. Resident/Representative Interviews

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

- *Characteristics of the pain, including the intensity, type (e.g., burning, stabbing, tingling, aching), pattern of pain (e.g., constant or intermittent), location and radiation of pain and frequency, timing and duration of pain;*
- *Factors that may precipitate or alleviate the pain;*
- *How the resident typically has expressed pain and responded to various interventions in the past;*

- *Who the resident and/or representative has told about the pain/discomfort, and how the staff responded;*
- *What treatment options (e.g., pharmacological and/or non-pharmacological) were discussed;*
- *How effective the interventions have been; and*
- *If interventions have been refused, whether there was a discussion of the potential impact on the resident, and whether alternatives or other approaches were offered.*

3. Nurse Aide(s) Interview. *Interview staff who provide direct care on various shifts to determine:*

- *If they are aware of a resident's pain complaints or of signs and symptoms that could indicate the presence of pain;*
- *To whom they report the resident's complaints and signs, or symptoms; and*
- *If they are aware of, and implement, interventions for pain/discomfort management for the resident consistent with the resident's plan of care, (for example, allowing a period of time for a pain medication to take effect before bathing and/or dressing).*

4. Record review

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

- *Identifies the pain indicators and the characteristics, causes, and contributing factors related to pain;*
- *Identifies a history of pain and related interventions, including the effectiveness and any adverse consequences of such interventions;*
- *Identifies the impact of pain on the resident's function and quality of life; 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)*

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

- Measurable pain management goals, reflecting resident needs and preferences;
- Pertinent non-pharmacological and/or pharmacological interventions;
- Time frames and approaches for monitoring the status of the resident's pain, including the effectiveness of the interventions; and
- Identification of clinically significant medication-related adverse consequences such as falling, constipation, anorexia, or drowsiness, and a plan to try to minimize those adverse consequences.

If the care plan refers to a specific facility pain management protocol, determine whether interventions are consistent with that protocol. If a resident's care plan deviates from the protocol, determine through staff interview or record review the reason for the deviation.

If the resident has elected a hospice benefit, all providers must coordinate their care of the resident. This care includes aspects of pain management, such as choice of palliative interventions, responsibility for assessing pain and providing interventions, and responsibility for monitoring symptoms and adverse consequences of interventions and for modifying interventions as needed.

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

Care Plan Revisions

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

5. Interviews with health care practitioners and professionals:

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

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

- *How the interventions for pain management have been developed and the basis for selecting them;*
- *If the resident receives pain medication (including PRN and adjuvant medications), how, when, and by whom the results of medications are evaluated (including the dose, frequency of PRN use, schedule of routine medications, and effectiveness);*
- *How staff monitor for the emergence or presence of adverse consequences of interventions;*
- *What is done if pain persists or recurs despite treatment, and the basis for decisions to maintain or modify approaches;*
- *How staff communicate with the prescriber/practitioner about the resident's pain status, current measures to manage pain, and the possible need to modify the current pain management interventions; and*
- *For a resident who is receiving care under a hospice benefit, how the hospice and the facility coordinate their approaches and communicate about the resident's needs and monitor the outcomes (both effectiveness and adverse consequences).*

Interviews with Other Health Care Professionals. *If the interventions or care provided do not appear to be consistent with current standards of practice and/or the resident's pain appears to persist or recur, interview one or more health care professionals as necessary (e.g., attending physician, medical director, consultant pharmacist, director of nursing or hospice nurse) who, by virtue of training and knowledge of the resident, should be able to provide information about the evaluation and management of the resident's pain/symptoms. Depending on the issue, ask about:*

- *How chosen interventions were determined to be appropriate;*
- *How they guide and oversee the selection of pain management interventions;*
- *The rationale for not intervening, if pain was identified and no intervention was selected and implemented;*
- *Changes in pain characteristics that may warrant review or revision of interventions; or*
- *When and with whom the professional discussed the effectiveness, ineffectiveness and possible adverse consequences of pain management interventions.*

If during the course of this review, the surveyor needs to contact the attending physician regarding questions related to the treatment regimen, it is recommended that the facility's staff have the opportunity to provide the necessary information about the resident and the concerns to the physician for his/her review prior to responding to the surveyor's inquiries. If the attending physician is unavailable, interview the medical director as appropriate.

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

Synopsis of Regulation (Tag F309)

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

Criteria for Compliance with F309 for a Resident with Pain or the Potential for Pain

For a resident with pain or the potential for pain (such as pain related to treatments), the facility is in compliance with F309 Quality of Care as it relates to the recognition and management of pain, if each resident has received and the facility has provided the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care i.e., the facility:

- Recognized and evaluated the resident who experienced pain to determine (to the extent possible) causes and characteristics of the pain, as well as factors influencing the pain;*
- Developed and implemented interventions for pain management for a resident experiencing pain, consistent with the resident's goals, risks, and current standards of practice; or has provided a clinically pertinent rationale why they did not do so;*
- Recognized and provided measures to minimize or prevent pain for situations where pain could be anticipated;*
- Monitored the effects of interventions and modified the approaches as indicated; and*
- Communicated with the health care practitioner when a resident was having pain that was not adequately managed or was having a suspected or confirmed adverse consequence related to the treatment.*

If not, cite at F309.

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

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

- Recognize and evaluate the resident who is experiencing pain in enough detail to permit pertinent individualized pain management;*
- Provide interventions for pain management in situations where pain can be anticipated;*

- *Develop interventions for a resident who is experiencing pain (either specific to an overall pain management goal or as part of another aspect of the care plan);*
- *Implement interventions to address pain to the greatest extent possible consistent with the resident's goals and current standards of practice and have not provided a clinically pertinent rationale why this was not done;*
- *Monitor the effectiveness of intervention to manage pain; or*
- *Coordinate pain management as needed with an involved hospice to meet the resident's needs.*

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

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

- *42 CFR 483.10(b)(4) F155, The Right to Refuse Treatment*

If a resident has refused treatment or services, determine whether the facility has assessed the reason for this resident's refusal, clarified and educated the resident as to the consequences of refusal, offered alternative treatments, and continued to provide all other services.

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

Determine if staff notified:

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

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

Determine if the facility has provided the resident with relevant choices about aspects of pain management.

- *42 CFR 483.15(e)(1), F246, Accommodation of Needs*

Determine whether the facility has adapted the resident's physical environment (room, bathroom, furniture) to reasonably accommodate the resident's individual needs, related to pain management.

- *42 CFR 483.20, F272, Comprehensive Assessments*

Determine if the facility comprehensively assessed the resident's physical, mental, and psychosocial needs to identify characteristics and determine underlying causes (to the extent possible) of the resident's pain and the impact of the pain upon the resident's function, mood, and cognition.

- *42 CFR 483.20(g) F278, Accuracy of Assessments*

Determine whether the assessment accurately reflects the resident's status.

- *42 CFR 483.20(k), F279, Comprehensive Care Plans*

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

- *42 CFR 483.20(k)(2)(iii), 483.10(d)(3), F280, Comprehensive Care Plan Revision*

Determine if the care plan was periodically reviewed and revised by a team of qualified persons with input from the resident or representative to try to reduce pain or discomfort.

- *42 CFR 483.20(k)(3)(i), F281, Services provided meet professional standards of quality*

Determine if care was provided in accordance with accepted professional standards of quality for pain management.

- *42 CFR 483.20(k)(3)(ii), F282, Care provided by qualified persons in accordance with the plan of care*

Determine whether care is being provided by qualified staff, and/or whether the care plan is adequately and/or correctly implemented.

- *42 CFR 483.25(l), F329, Unnecessary Drugs*

Determine whether medications ordered to treat pain are being monitored for effectiveness and for adverse consequences, including whether any symptoms could be related to the medications.

- *42 CFR 483.40(a), F385, Physician Supervision*

Determine if pain management is being supervised by a physician, including participation in the comprehensive assessment process, development of a treatment regimen consistent with current standards of practice, monitoring, and response to notification of change in the resident's medical status related to pain.

- *42 CFR 483.60, F425, Pharmacy Services*

Determine if the medications required to manage a resident's pain were available and administered as indicated and ordered at admission and throughout the stay.

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

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

- *42 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.*

DEFICIENCY CATEGORIZATION (Part IV, Appendix P) for a resident with pain or potential for pain

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

1. *Presence of harm/negative outcome(s) or potential for negative outcomes because of lack of appropriate treatment and care. Actual or potential harm/negative outcome for F309 related to pain assessment and management may include, but is not limited to:*
 - *Persisting or recurring pain and discomfort related to failure to recognize, assess, or implement interventions for pain; and*

- *Decline in function resulting from failure to assess a resident after facility clinical staff became aware of new onset of moderate to severe pain.*
2. *Degree of harm (actual or potential) related to the non-compliance. Identify how the facility practices caused, resulted in, allowed or contributed to the actual or potential for harm:*
 - *If harm has occurred, determine if the harm is at the level of serious injury, impairment, death, compromise, or discomfort; and*
 - *If harm has not yet occurred, determine the potential for serious injury, impairment, death, compromise, or discomfort to occur to the resident.*
 3. *The immediacy of correction required. Determine whether the noncompliance requires immediate correction in order to prevent serious injury, harm, impairment, or death to one or more residents.*

The survey team must evaluate the harm or potential for harm based upon the following levels of severity for Tag F309 when related to recognition, assessment and management of pain. First, the team must rule out whether Severity Level 4, Immediate Jeopardy to a resident's health or safety, exists by evaluating the deficient practice in relation to immediacy, culpability, and severity, (Follow the guidance in Appendix Q, Determining Immediate Jeopardy).

Severity Level 4 Considerations: Immediate Jeopardy to Resident Health or Safety for a resident with pain or potential for pain.

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

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

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

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

Examples may include, but are not limited to:

- *Resident experienced continuous, unrelenting, excruciating pain or incapacitating distress because the facility has failed to recognize or address the situation, or failed to*

develop, implement, monitor, or modify a pain management plan to try to meet the resident's needs; or

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

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

Severity Level 3 Considerations: Actual Harm that is not Immediate Jeopardy for a resident with pain or potential for pain.

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

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

Examples may include, but are not limited to:

- *The resident experienced pain that compromised his/her function (physical and/or psychosocial) and/or ability to reach his/her highest practicable well-being as a result of the facility's failure to recognize or address the situation, or failure to develop, implement, monitor, or modify a pain management plan to try to meet the resident's needs. For example, the pain was intense enough that the resident experienced recurrent insomnia, anorexia with resultant weight loss, reduced ability to move and perform ADLs, a decline in mood, or reduced social engagement and participation in activities; or*
- *The resident experienced significant episodic pain (that was not all-consuming or overwhelming but was greater than minimal discomfort to the resident) related to care/treatment, as a result of the facility's failure to develop, implement, monitor, or modify pain management interventions. Some examples include lack of pain management interventions prior to dressing changes, wound care, exercise or physical therapy.*

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

Severity Level 2 Considerations: No Actual Harm with potential for more than minimal harm that is Not Immediate Jeopardy for a resident with pain or potential for pain.

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

Level 2 indicates noncompliance that results in feelings and/or complaints of discomfort or moderate pain. The resident may be irritable and/or express discomfort.

Examples may include, but are not limited to:

- The resident experienced daily or less than daily discomfort with no compromise in physical, mental, or psychosocial functioning as a result of the facility's failure to adequately recognize or address the situation, or failure to develop, implement, monitor, or modify a pain management plan to try to meet the resident's needs; or*
- The resident experienced minimal episodic pain or discomfort (that was not significant pain) related to care/treatment, as a result of the facility's failure to develop, implement, monitor, or modify a pain management plan.*

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

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

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.

SLIDE #3

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).

SLIDE #4

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

SLIDE #6

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.

SLIDE #11

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.

SLIDE #24

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.

SLIDE #26

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.

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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.

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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.

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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

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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.