

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-12-25
Baltimore, Maryland 21244-1850



Center for Medicaid and State Operations/Survey and Certification Group

Dear Colleague:

I am pleased to send you a draft for comment of revised Guidance to Surveyors of Long Term Care Facilities for the current tag, F309 Quality of Care: Assessment and Management of Pain.

This draft product was developed as part of our contract with the American Institutes for Research to update the Guidance to Surveyors (also known as the interpretive guidelines) and to provide specific information to assist surveyors in making appropriate determinations of severity for deficiencies cited under this Tag. It includes interpretive guidelines, an investigative protocol, and severity guidance for deficiencies cited. This draft was developed with the assistance of a panel of expert clinicians and surveyors.

Attachment A provides biographical information about the members of the Pain Management panel. Attachment B is intended to replace all current text contained in the Guidance to Surveyors for current Tag F309 Quality of Care: Assessment and Management of Pain. We are providing a 30-day comment period for review of the draft materials contained in Attachment B.

We have included a reference sheet entitled “Tips for Reviewers” which contains tips for your review, as well as a copy of the current scope and severity grid that includes the letters for each grid box and the definitions of each severity level. This enclosure directly follows this letter. Be sure to review this information prior to reviewing the draft guidance.

Please provide comment on these materials to the contractor **by Thursday, July 20th**. You may reply via regular mail addressed to:

Nancy Matheson, Ph.D.
Project Director
American Institutes for Research
1000 Thomas Jefferson Street, NW
Washington, DC 20007

You may also reply via email to CMSComment@air.org. Please organize your comments by attachment and page number in order to compare your comment to the text to which you are referring. If you have any questions about this mailout, please contact Dr. Matheson at 202-403-5050.

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We look forward to your comments on this mailout as well as future mailouts of revisions to other Tags, as we proceed with this project to improve our guidance to surveyors.

Sincerely,

/s/

Thomas E. Hamilton
Director

Attachments

TIPS FOR REVIEWERS

This mail-out package includes the following materials for your review:

- F309 Quality of Care: Assessment and Management of Pain (Attachment B)
 - Guidance to Surveyors
 - Investigative Protocol
 - Task 6: Determination of Compliance
 - V. Deficiency Categorization (i.e., Severity Guidance).

Note: V. Deficiency Categorization is considered part of Appendix P, Part V of the same title, but it will be stored in Appendix PP of the State Operations Manual (SOM) along with its tag.

We have included the Scope and Severity Grid for your reference when reviewing the severity guidance for the Accidents and Supervision tags. This is included to assist your review and is not for comment.

Tips for Commenting

When providing comments to the materials included in this mail-out package, please follow the referencing guidelines below. This will aid in our ability to sort comments by section, paragraph, and sentence.

For each comment, please reference the following information, whenever possible:

- **Section within Document** (i.e., Guidance to Surveyors; Investigative Protocol; Task 6; Deficiency Categorization)
- **Page Number**

When relevant, please also reference sub-heading within section, paragraph, and/or sentence to which the comment applies.

Severity Grid for Rating Nursing Home Deficiencies

Severity	Immediate Jeopardy to Resident Health or Safety	J	K	L
	Actual Harm That Is Not Immediate Jeopardy	G	H	I
	No Actual Harm with Potential for More than Minimal Harm That Is Not Immediate Jeopardy	D	E	F
	No Actual Harm with Potential for Minimal Harm	A	B	C
		Isolated	Pattern	Widespread

Level 4: Immediate Jeopardy to resident health or safety. (J, K, L)

Noncompliance that results in immediate jeopardy, a situation in which immediate corrective action is necessary because the facility's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident receiving care in a facility.

Level 3: Actual Harm that is not Immediate Jeopardy. (G, H, I)

Noncompliance that results in a negative outcome that has compromised the resident's ability to maintain and/or reach his/her highest practicable physical, mental, and psychosocial well-being.

Level 2: No Actual Harm with potential for more than minimal harm that is not Immediate Jeopardy. (D, E, F)

Noncompliance that results in no more than minimal physical, mental and/or psychosocial discomfort to the resident and/or has the potential, (not yet realized) to compromise the resident's ability to maintain and/or reach his/her highest practicable physical, mental and/or psychosocial well-being.

Level 1: No Actual Harm with the potential for minimal harm. (A, B, C)

A deficiency that has the potential for causing no more than a minor negative impact on the resident(s).

NOTE: The Severity and Scope Grid is included to assist your review and is not for comment.

ATTACHMENT A

REGULATORY TAG 309—QUALITY OF CARE:

ASSESSMENT AND MANAGEMENT OF PAIN

EXPERT PANEL BIOGRAPHIES

- ***Jiska Cohen-Mansfield, PhD***, currently serves as a Professor of Health Care Sciences and a Professor of Prevention and Community Health, at George Washington University Medical Center and School of Public Health in Washington, D.C. Dr. Cohen-Mansfield is also the Director of the Research Institute on Aging at the Hebrew Home of Greater Washington. She has published extensively, and is noted for her work on behavioral problems in older individuals with dementia, among other gerontological issues.
- ***Stephen R. Connor, PhD***, is currently Vice President for Research and International Development at the National Hospice and Palliative Care Organization in Alexandria, Virginia. Dr. Connor is a licensed clinical psychologist with 30 years of experience in the field of hospice and palliative care as a researcher, administrator, clinician, and association executive. He also serves on the Boards of the Association for Death Education and Counseling and the International Work Group on Death, Dying, and Bereavement.
- ***Catherine Davenport, BS, RN***, is currently a nurse consultant with the Denver Regional office of CMS and conducts federal monitoring surveys in long-term care facilities and other provider types in Region VIII. She is the lead on Home Care and Hospice issues in the Regional Office. Ms. Davenport has over 30 years of experience in health care regulations, including survey experience in home care, hospice, long-term care and complaint investigations with the State of Colorado. Prior to moving to Colorado, Ms. Davenport worked on the “provider side” of the regulations for home care and hospice as an owner of both a home care/hospice consultation firm and a home care agency.
- ***Andrew Dentino, MD, CMD***, is the Chair of the Ethics Committee of the American Medical Directors Association. Dr. Dentino is board certified in internal medicine, psychiatry, geriatric medicine and geriatric psychiatry. He is also specialty society boarded in hospice and palliative medicine. Dr. Dentino has served as a member of the Ethics Committee of the American Geriatrics Society and the American Academy of Hospice and Palliative Medicine Special Interest Group on Ethics. He is a Fellow of the American Geriatrics Society and the American Psychiatric Association. He is broadly published and possesses editorial board service in the field of elder care. Dr. Dentino serves as Medical Director of The Glen Retirement System, Shreveport, LA.
- ***Katherine R. Jones, RN, PhD, FAAN***, currently serves as Professor of Nursing and Health Policy at the Yale School of Nursing, and is an expert in clinical outcomes

research. She has led or participated in several AHRQ-funded studies focused on quality of care issues in the nursing home setting. She is also a member of the Expert Panel on Quality Health Care in the AAN. Dr. Jones is particularly interested in how to improve pain management and chronic wound care in the elderly.

- **Barbara Rode, MS, LNHA**, is currently President/CEO of St. Therese Home, Inc. Ms. Rode serves as a Minnesota Delegate and is on the education committee for the national association, the American Association of Homes and Services for the Aging. She also serves as a Minnesota State Association Board Member and is Chair of the Education Committee for MHHA. Ms. Rode has worked as a licensed Administrator for nine years and has worked in long term care since 1972.
- **Joan M. Teno, MD, MS**, is a Professor of Community Health and Medicine and Associate Director of the Center for Gerontology and Health Care Research at the Brown Medical School. She is a health services researcher, hospice medical director, and board-certified internist with added qualification in Geriatrics and Palliative Medicine. Both as a researcher and clinician, Dr. Teno has devoted her career to understanding how to measure and improve the quality of end of life care for vulnerable populations. She is an Associate Medical Director at Home and Hospice Care of Rhode Island. Her current research is focused on the quality of care for persons with serious illnesses, especially those residing in the nursing home setting.
- **Jan Thompson, JD, RN**, is a health law attorney with Thompson & Knight, LLP and has been a member of the health care coalitions in Texas that have drafted state advance directive legislation for each legislative session since 1991. She authored "End-of-Life Decision-making and Advance Directives," which was published in the Austin Business Journal, and does extensive teaching on end-of-life issues. She is a member of the Board of Directors of Texas Partnership for End of Life Care, a nonprofit organization devoted to improving the quality of life for individuals as they approach the end of life.
- **Bill Vaughan, BS**, currently serves as chief nurse of the Office of Health Care Quality, the agency charged with regulating healthcare institutions throughout the state of Maryland. As chief nurse, he is responsible for the clinical oversight of the agency's approximately 100 surveyors. Prior to assuming his current position, Mr. Vaughan was a health facility surveyor with a focus in long-term care for 14 years. He gained clinical experience at both the Johns Hopkins and University of Maryland hospitals.
- **Aida Won, MD**, is currently an Instructor at Harvard Medical School and is on staff at Beth Israel Deaconess Medical Center. Dr. Won also serves as a pain management consultant for Mariner Health Care. Her major research interests include quality of long-term care, pain management, and palliative care. Dr. Won views end-of-life care as a responsibility and a privilege in helping patients and families achieve comfort, dignity, respect and a peaceful journey towards the end of their lives.

ATTACHMENT B

F309 QUALITY OF CARE: ASSESSMENT AND MANAGEMENT OF PAIN

INTENT: (F309) 42 CFR 483.25 Quality of Care

ASSESSMENT AND MANAGEMENT OF PAIN

The intent of this requirement is that the facility assists each resident with pain to maintain or achieve the highest practicable level of well-being and functioning by:

- Screening to determine if the resident has been or is experiencing pain;
- Comprehensively assessing the pain;
- Identifying circumstances when pain can be anticipated; and
- Developing and implementing a plan, using pharmacologic and/or non-pharmacologic interventions to manage the pain and/or try to prevent the pain consistent with the resident's goals.

DEFINITIONS

- “Adjuvant Analgesics” describes any medication with a primary indication other than pain but with analgesic properties in some painful conditions.¹
- “Adverse Consequence” refers to an unpleasant symptom or event that is due to or associated with a medication such as impairment or decline in the individual's mental or physical condition or functional or psychosocial status. It may include various types of adverse drug reactions and interactions.
- “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.”²
- “Pain” is an “unpleasant sensory and emotional experience that can be acute, recurrent or persistent.”³ 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 and may be associated with surgery, trauma and acute illness.
 - “Breakthrough Pain” refers to a sudden, episodic flare-up of severe pain in a resident taking pain medicine regularly and may occur spontaneously or be associated with activity or with inadequate medication levels, dosing frequency, or type of medication.
 - “Incident Pain” refers to pain that is predictable and is associated with a precipitating event, such as movement (e.g., walking, transferring, or

dressing) or certain actions (e.g., disimpaction or wound care).

- “Discomfort” refers to a level of physical or affective pain that is no more than mild in degree, which may be described by terms such as: annoyance, irritation, nuisance, uncomfortable, distraction, or twinge.
 - “Neuropathic or Neurogenic Pain” is pain that results from stimulation or malfunction of the peripheral or central nervous systems.
 - “Nociceptive Pain” is pain that results from the stimulation of pain receptors; for example, pain of internal organs (visceral pain).
 - “Persistent Pain” or “Chronic Pain” refers to a pain state that continues for a prolonged period of time or recurs 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.
 - “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.⁴

OVERVIEW

Pain in nursing home residents is prevalent but is often not fully reported, recognized, assessed, or treated. Studies have shown that 45 to 80 percent of nursing home residents have substantial pain that is undertreated as a result of suboptimal compliance with guidelines for treating pain in geriatric populations.^{5, 6, 7} Among those persons with pain, 41% of nursing home residents are in persistent severe pain at the next assessment.⁸

Unrelieved persistent pain is not an inevitable consequence of aging. Inadequately treated pain can lead to decreased functioning, sleep disturbances, depression, and decreased emotional well-being. Acute pain may indicate a new and potentially life-threatening disease process. It is important, therefore, that a resident’s reports of pain be taken seriously and be evaluated comprehensively. Some common misconceptions that may contribute to the inadequate management of pain include viewing pain as a sign of weakness or a mechanism for getting attention; believing that older or cognitively impaired residents have a higher tolerance for pain; or a concern that residents may become addicted to pain medication.

Multiple barriers to the evaluation and management of pain exist, such as language and cultural barriers, co-existing illness (co-morbidities), and cognitive impairment. The use of multiple medications may affect a resident’s ability to interpret or report pain, may modify his or her response to pain, and may make it harder to identify pain symptoms.

Cognitively impaired residents may not present with the typical complaints of pain, and instead may present with nonverbal cues such as grimacing and restlessness. In addition, these nonspecific symptoms may represent other significant conditions instead of, or in addition to, pain. This makes it more challenging for nursing home staff to identify, treat and monitor pain.

Other barriers to effective pain management in a facility may be related to the variable knowledge, skill, or training of staff and practitioners. Effective pain management requires an ongoing facility-wide commitment to resident comfort, to identifying and addressing barriers to managing pain, and to correcting the misconceptions of residents, families, and staff.

Effective pain management includes the following processes:

- Screening each resident for pain on a periodic basis;
- Providing a comprehensive pain assessment with attention to identifying underlying causes and circumstances for each resident having pain;
- Developing a plan based on clinical rationale, the resident's goals and consideration of both pharmacologic and non-pharmacologic interventions to manage and/or try to prevent the pain; and
- Implementing the plan and monitoring the resident to determine the response to the interventions including effectiveness and emergence of adverse consequences.

Resources

Some additional clinical resources available for guidance regarding the management of pain include:

- American Geriatrics Society at www.americangeriatrics.org;
- American Medical Directors Association (AMDA) Clinical Practice Guideline "Pain Management in the Long-Term Care Setting" (2003) at www.AMDA.com;
- American Academy of Hospice and Palliative Medicine at www.aahpm.org;
- American Academy of Pain Medicine at www.painmed.org;
- American Pain Society at www.ampainsoc.org;
- Hospice and Palliative Nurses Association at www.hpna.org;
- Partners Against Pain[®] at www.partnersagainstpain.com;

- Quality Improvement Organizations at www.medic.org; and
- Resource Center for Pain Medicine and Palliative Care at Beth Israel Medical Center (2000) at www.stoppain.org/education_research/resources.html.

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

ASSESSMENT

The facility's use of standardized procedures to gather objective information facilitates effectively screening and assessing the resident, planning and implementing interventions to manage the pain, and monitoring the resident's response to the interventions.

Screening

Because pain can significantly affect a person's well-being, it is important that the facility recognize and address pain promptly. Screening for pain at admission helps identify the resident who is experiencing pain or for whom pain may be anticipated during specific procedures, care, or treatment. In addition to the admission screening, it is expected that residents will be screened for pain periodically, when there is a change in condition, and anytime pain is suspected. As with many symptoms, pain in residents with moderate to severe cognitive impairment may be more difficult to recognize and assess.^{9, 10, 11}

Recognizing the presence of pain and identifying those situations where pain may be anticipated involves the participation of multiple health care professionals, direct care staff, therapists and ancillary staff who have contact with the resident (e.g., housekeeping or dietary). Information may be obtained by talking with the resident and his/her family/friends, directly examining the resident, and observing the resident's behaviors. Observations at rest and during movement, particularly during activities that may increase pain (such as dressing changes, exercises, turning, bathing, rising from a chair, walking) are important components of screening for pain.

Pain expressions may be verbal or nonverbal. Words used to report or describe pain may differ by culture and/or region of the country. Examples of descriptions may include heaviness or pressure, stabbing, throbbing, aching, gnawing, cramping, burning, numbness, tingling, shooting 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 of pain are generally nonspecific and need to be viewed in the context of the whole picture of the resident with consideration given to pain as well as other clinically pertinent explanations. Examples of nonspecific symptoms may include:

- 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 and blood pressure);
- A change in behavior (e.g., resisting care, distressed pacing, withdrawing, inability to perform Activities of Daily Living (ADLs), rubbing a specific location of the body, or guarding a limb or other body parts);
- Weight loss; and
- Difficulty sleeping (insomnia).

The Minimum Data Set (MDS) component of the Resident Assessment Instrument (RAI) (which must be documented on admission and quarterly) is another screening mechanism. It includes information about the frequency, intensity, symptoms, and location/site of any pain. For MDS purposes, pain refers to any type of physical pain or discomfort in any part of the body. In addition, many sections could help staff screen for possible indicators of pain, such as: sleep cycle, change in mood, functional limitations, instability of condition, weight loss, and skin conditions. Any of these findings indicate a need for additional discussion and possible evaluation by appropriate practitioners.

Since nursing assistants may be the first to notice a resident's symptoms, it is important that they be trained to recognize the more common signs and descriptors of pain and to report findings to the nurse for follow-up. A nurse should perform a more detailed evaluation, document relevant information, and report it to the practitioner.

Assessment

Older individuals often have more than one active medical condition and may experience pain from several different causes. Acute pain can be caused by repositioning, dressing changes, trauma, surgical procedures, dental caries, myocardial infarction, bowel obstruction, shingles, deep vein thrombosis, infections or other acute illnesses. Some common conditions that often cause persistent pain include cancer, degenerative joint disease, rheumatoid arthritis, spinal stenosis, osteoporosis, neuropathic pain (e.g., post-herpetic neuralgia or multiple sclerosis), peripheral vascular disease, immobility, pressure ulcers, amputations, post-traumatic injuries, and diseases in their terminal stages, such as renal disease, AIDS, and cardiac failure. There are four basic categories of persistent pain: nociceptive pain; neuropathic pain; mixed or unspecified pain; and pain as part of a manifestation of a psychological disorder.¹² Understanding the underlying cause or source of the pain is an important step in determining approaches to manage pain symptoms. For example, generalized aching or discomfort may be due to the effects of

prolonged immobility, conditions such as fibromyalgia, or side effects of current medications.

At a minimum, an initial pain assessment should include:

- A thorough pain history, including:
 - A detailed description or symptom analysis such as the pain PQRSTA mnemonic:
 - P: Palliative and/or provocative factors
 - Q: Quality of pain (burning, stabbing, aching, etc.) and impact on quality of life (e.g., functioning, sleep, appetite, and mood)
 - R: Region of body affected
 - R: Radiation (where it spreads from its origin)
 - S: Severity of pain (e.g., 0-10 scale; verbal descriptor scale)
 - T: Timing of pain (e.g., after meals, in the morning, frequency, duration, etc.)
 - T: Treatments tried
 - A: Associated symptoms (e.g., shortness of breath, chest pressure, inflammation, warmth, tenderness)
 - The effectiveness of past efforts to relieve pain; and
 - Satisfaction with current pain management.

A facility may adopt one or more standard pain scales (see below for some examples) as a way to capture much of this information more systematically. Different scales may emphasize different aspects of pain assessment. For example, some pain scales capture only intensity while others identify the location as well as impact of pain on function.

Description	Web Address
Wong-Baker FACES Pain Rating Scale	http://www3.us.elsevierhealth.com/WOW/faces.html
Verbal Descriptor Scale (VDS)	http://www.intelihealth.com/IH/ihtIH/WSIHW000/29721/32087.html#verbal
Numerical pain scales or visual analogue scales	http://www.intelihealth.com/IH/ihtIH/WSIHW000/29721/32087.html#numerical
Pain map	http://www.medtronic.com/neuro/paintherapies/pain_treatment_ladder/pdf/prestim_pain_assess.pdf
McGill Pain Questionnaire	http://www.physiobase.com/Protocols/assessmentforms/pain_questionnaire_2.pdf

Short-Form McGill Pain Questionnaire ¹³	http://www.med.umich.edu/obgyn/repro-endo/Lebovicresearch/PainSurvey.pdf
Brief Pain Inventory	http://www.ohsu.edu/ahec/pain/paininventory.pdf
Pain Assessment in Advanced Dementia (PAINAD) Scale and Pain Thermometer plus additional tools	http://www.lumetra.com/nursinghomes/resources/pain/index.asp
List of pain scales with evaluations	http://www.chcr.brown.edu/pcoc/Physical.html

- A physical examination including the pain site, the nervous system, and physical, psychological and cognitive functioning;
- Consideration of co-morbidities and/or diagnoses, especially those which may typically be associated with pain;^{14, 15}
- Diagnostic tests, as indicated;
- Additional information, which may include but is not limited to:
 - The degree to which pain is interfering with the individual’s mental, physical, psychosocial and spiritual well-being;¹⁶
 - Medication history including allergies, and whether pain may be associated with any current medications; and
 - History of substance abuse such as alcohol, prescription medications and/or illicit drugs.

MANAGEMENT

It is important for the resident to know that the facility is trying to address his/her needs and for the facility to encourage the resident to participate, to the extent possible, in developing the plan of care and establishing realistic goals for treatment; to be aware of the treatment plan options; and to recognize and report the onset of pain. If a resident says he/she is in pain, the facility is expected to address the pain. However, the approach to pain management should follow appropriate clinical protocols and guidelines. Placebos should never be considered as an intervention for pain management. Since medication may not necessarily be the desired approach or may not be effective in all cases, non-pharmacological approaches need to be considered as well.

Interventions and treatments (both pharmacological and non-pharmacological) should be:

- Preceded by an assessment;
- Developed with respect for whether the pain is episodic or continuous;

- Provided or administered to meet the resident's needs;
- Monitored appropriately for effectiveness and/or adverse consequences; and
- Modified as necessary.

Care planning and Implementation

The resident's needs, risk profile, and goals as well as the etiology, type and severity of pain are paramount considerations when developing a plan for pain management. Depending on the situation and the resident's wishes, the target for pain control may be to achieve a noticeable reduction in pain level, but not necessarily to become pain-free. Depending upon the severity and nature of the pain, it may be necessary to implement interventions to address the pain before the etiology can be determined.

The care plan should include specific, measurable pain management goals (e.g., pain will be reduced sufficiently to allow the resident to ambulate comfortably to the dining room for each meal or to participate in 30 minutes of physical therapy) and should indicate how and when more structured, periodic monitoring with standardized tools is to occur, as appropriate. More consistent pain management may be achieved if the plan identifies the specific strategies to use for different levels of pain or pain related symptoms, who is to implement the care or supply the services (e.g., certified hospice), and what symptoms, behaviors, or consequences might indicate that it is necessary to use additional or alternate approaches.

Non-Pharmacological Interventions or Complementary Therapies

Non-pharmacologic interventions frequently are effective for managing pain when used either independently or in conjunction with pharmacologic agents. Complementary and alternative medicine (CAM) therapies used alone are often referred to as "alternative" therapies. When used in addition to conventional medicine, they are often referred to as "complementary" therapies. Non-pharmacologic approaches may include:

- Altering the environment for comfort (such as room temperature, body alignment and repositioning, tightening and smoothing linens, supportive mattress and positioning devices);
- Cognitive interventions (e.g., relaxation techniques, reminiscing, diversions, activities, music therapy, coping techniques and education about pain);
- Physical modalities (such as ice packs or cold to reduce swelling and lessen sensation, mild heat to decrease joint stiffness and increase blood flow to an area, massage, and baths); and
- Transcutaneous Electrical Nerve Stimulation (TENS), acupuncture/acupressure, chiropractic, or rehabilitation therapy.

Exercises (such as sequentially contracting and relaxing specific muscle groups; active or passive range of motion and other light to moderate exercises such as walking and wheelchair bowling) may prevent or address stiffness, prevent contractures, improve blood and oxygen flow, and enhance a resident's overall sense of well-being. Depending upon the nature and intensity of the pain, it may be more appropriate to start with these types of approaches, and if ineffective in relieving the resident's pain, proceed to pharmacological interventions. If non-pharmacological interventions were not used at all over time, the resident's medical record should include the reasons why they were not pertinent.

The list of CAM options changes frequently, as those therapies that are proven to be safe and effective become adopted into conventional health care and as new approaches to pain management emerge.

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.

Pharmacological Interventions

Analgesic medication(s) may help manage pain; however, they do not usually address the underlying cause of pain. In some cases, “adjuvant” analgesic or “coanalgesics” are utilized (e.g., antidepressants or anticonvulsants). Since all medications potentially have adverse consequences, it is important to identify and address the cause(s) of the pain, to the extent possible. Determining which pain medications and adjuvant therapies and doses to use is specific to each resident (including consideration of the causes and severity of the pain). This requires balancing the potential risks and side effects of medications with the potential benefits for the resident, including the resident's wishes regarding the balance of analgesic effects and side effects. Some patients/residents may desire to remain alert and may accept partial pain relief in order to experience fewer significant side effects.

It is important that pharmacologic interventions for pain management follow a rational approach. General guidelines for choosing appropriate categories of medications in various situations are widely available. For example, the World Health Organization (WHO) pain ladder at www.who.int/cancer/palliative/painladder/en/ provides stepwise guidance on the types of medications appropriate for various levels of pain.¹⁹ If pain is present and medication is determined to be necessary, the recommended stepwise approach depends on the severity of the pain often beginning with: non-opioids (e.g., acetaminophen or nonsteroidal anti-inflammatory medications); then, as necessary, mild opioids (e.g., hydrocodone); then strong opioids (e.g., morphine), until the resident's pain has improved.

Developing an effective, individualized approach to managing a resident's pain may involve numerous attempts to arrive at the right pharmacologic intervention. Important advice on the use of medication is to "start low, go slow", which means start with a low dose and titrate carefully especially in frail, older individuals. All pharmacologic interventions should be combined with non-pharmacologic interventions.

For more persistent or recurrent pain, medications may be given "around the clock" rather than "on demand" (PRN) or a combination of longer acting routine medications plus PRN medications (for breakthrough pain) may be appropriate. Surgical interventions may be appropriate for some residents to provide additional pain relief (e.g., dissection of nerve, vertebroplasty, or debridement). To the extent analgesics are part of the plan or admission orders, they must be accessible in the facility and be administered when they are needed.

Monitoring

The interdisciplinary team should identify target signs and symptoms (including verbal reports from the resident) to help evaluate the resident's response to pain management interventions. It is important to monitor the effectiveness of the medication(s) being used before adding medications or changing the medication regimen. If the pain has not been adequately controlled or if it increased due to disease progression or tolerance of the medication, the dose, frequency, and prescribed medication(s) may need to be re-evaluated.

Periodic use of a facility selected standardized pain assessment tool facilitates an objective determination of the success of pain management interventions; the need for altering the current treatment regimen; and the potential for reducing or eliminating the pain medication(s). If there is no longer an indication or need for a pain medication, it is expected the facility will discontinue or taper the medication to prevent withdrawal symptoms. The clinical record should reflect if discontinuing or tapering the medication is not appropriate.

Adverse consequences may be anticipated which require on-going monitoring. Examples include constipation, fecal impaction, anorexia, increased somnolence, urinary retention, and decreased physical or cognitive functioning. In order to prevent, minimize or eliminate adverse consequences interventions such as prophylaxis laxatives, dosing modifications or utilizing alternative approaches may be indicated.

Staff who are involved in a resident's care should monitor the individual closely over time to identify signs and symptoms that could indicate pain and possible adverse medication consequences. Consistent staff assignments have been shown to improve the identification of pain, consistency of interventions, and evaluation of the effectiveness of pain management.¹⁷

If pain cannot be adequately controlled despite repeated attempts and various approaches, referral to other resources such as a hospice program, if eligible, pain management

specialists or a pain center may be appropriate.

Staff Training Regarding Pain Management

In order to provide effective pain management, it is important that the facility provide orientation and ongoing staff education to correct misconceptions, myths, and biases about pain. Training may include, but is not limited to:

- Using standardized scales to promote objective evaluation and effective management of pain;
- Recognizing and assessing pain, reporting and documenting findings, and monitoring interventions;
- Overcoming misconceptions and increasing understanding of the distinctions between addiction, physical dependence, and tolerance; and
- Identifying appropriate treatment modalities including the use of and when and how to use non-pharmacological interventions.

It is also important that staff understand and implement facility's policies, procedures and protocols regarding pain management.

ELECTION OF HOSPICE BENEFIT

When a resident elects the hospice benefit at the end of life, the facility remains his/her primary care provider, but the hospice assumes professional management responsibility for assessing, planning, monitoring, directing, and evaluating the resident's pain management program and other symptoms related to terminal illness.¹⁸

NOTE: Although hospice regulations use the term "patient", the term "resident" is used in this section.

Coordinated Care Plan

The facility and hospice are jointly responsible for developing a coordinated and compatible plan of care based upon their assessment and the needs and goals of the resident. The plan of care must be consistent with the hospice philosophy of care, include directives for managing pain and other uncomfortable symptoms, and be revised and updated as necessary to reflect the resident's current status.

Procedures should be in place to assure that the resident receives timely medication and treatments for optimal palliation. The hospice and facility need to work together to assure that facility staff is trained on the resident's pain management regimen and any special equipment. The hospice works with the nursing facility to monitor the effectiveness of treatments related to pain and symptom control, as well as undesirable

side effects that may affect resident comfort. The hospice and nursing facility coordinate care to assure that the resident receives needed drugs and treatment in a timely manner.

The facility has ultimate responsibility for a resident's overall care and comfort and is responsible for notifying the hospice when the resident experiences a change in condition, is experiencing uncontrolled, increased or breakthrough pain; or is experiencing adverse consequences that may affect patient/resident comfort or increase pain. In order to reduce confusion and conflict about each provider's responsibilities, the arrangement between the facility and the hospice should include mechanisms to resolve issues regarding timely and effective pain control, supplies, medications and durable medical equipment that may be needed for the palliation and management of the terminal illness and related conditions.

ENDNOTES

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INVESTIGATIVE PROTOCOL

QUALITY OF CARE: ASSESSMENT AND MANAGEMENT OF PAIN

Objectives

- To determine if the facility screens, assesses and provides ongoing monitoring to each resident who:
 - Is experiencing pain, or
 - May have a condition or receives care/services in which pain may reasonably be anticipated.
- To determine if the facility provided resident-centered care and services to address and manage pain and to support the resident's highest practicable level of physical, mental, and psychosocial functioning.

Use

Use this protocol for a sampled resident:

- Who states he/she has pain or discomfort;
- Who displays possible symptoms of pain such as moaning, crying, or pained facial expressions, that cannot be readily attributed to other identified causes;
- Who has a disease or condition (e.g., arthritis, osteoporosis, pressure ulcers, fractures, cancer, or bone metastases) that causes or can reasonably be anticipated to cause pain;
- Who receives treatments that can be anticipated to cause pain (e.g., wound care or dressing changes or therapies or exercises for residents with painful joints or limited range of motion);
- Whose assessment indicates the resident experiences pain; or
- Who receives or has orders for treatment for pain or has elected the Medicare hospice benefit.

Procedures

Briefly review the care plan and orders to identify any pain management interventions and to guide observations to be made. For a resident with pain or for whom pain can be anticipated, the staff is expected to assess the circumstances and characteristics of the pain and provide appropriate care. Corroborate observations by interview and record

review.

NOTE: Determine whether the resident is receiving pain management and/or symptom control from another entity such as a Medicare-certified hospice.

1. Observation

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

- Whether the resident exhibits signs or symptoms of pain, verbalizes the presence of pain, requests interventions for pain, and 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 or care and services being provided which reasonably could cause pain, whether staff have implemented interventions to prevent or address the pain and whether the interventions were effective. Also, determine how staff respond when advised by others that a resident is experiencing pain;
- If there is a pain management program for the resident, whether the staff implements the identified interventions consistently. Follow up on:
 - Deviations from the care plan;
 - Deviations from current standards of practice; and
 - Evidence that the resident may be experiencing a potential adverse consequence associated with the pain management program (e.g., medications).

2. Resident/Representative Interviews

Interview the resident, family or representative to the degree possible to determine:

- Whether the resident is presently or periodically experiencing pain;
- Characteristics of the pain (e.g., PQRSTA);
- Who has been told about the pain/discomfort;
- Whether the resident and/or his/her representative have been involved in the development of a plan of care to manage pain, including the use of non-pharmacological and/or pharmacological interventions, and involved in a discussion of the types of medications, if used, and their potential benefits, risks and effects (e.g., sedating effects);

- Whether the interventions have been helpful; and whether the interventions were provided as indicated in the care plan; and
- If interventions have been refused, whether there was a discussion of consequences and pertinent alternatives or other approaches were offered.

3. Staff Interviews

Nurse Aide(s) Interview. Interview staff on various shifts to determine:

- If they are aware of pain complaints expressed by a resident or of symptoms such as moaning, crying, and/or restlessness that may be indicators of pain;
- To whom they report the resident's complaints or non-verbal indications of pain/discomfort; and
- Whether they are aware of and implemented the identified interventions for pain/discomfort management for a given resident, including when/how to provide or modify activities, care, and treatments to optimize pain management (e.g., allowing time for a pain medication to take effect before bathing and/or dressing, repositioning, or distracting the resident with reading or conversation).

Nurse Interview. Interview a nurse who is knowledgeable about the resident to determine:

- The mechanisms and frequency used to identify when the resident is in pain or the circumstances in which pain can be anticipated;
- How the facility objectively assessed the resident for pain, and whether he/she is cognitively intact or impaired;
- Whether a plan for pain management was developed and how the staff determined which interventions were appropriate;
- How staff monitor the therapeutic benefits and risk for adverse consequences of interventions, and if the interventions were not successful, how the approach was modified;
- If the resident receives routine pain medication, how and when pain assessments are completed, and by whom;
- How often the resident requests or the nurse has to offer a PRN pain medication, and what is done if there are frequent PRN pain requests over time;

- How staff communicate with the physician about issues related to plans for pain management (e.g., when and how often interventions are provided and discussions regarding whether the pain management plan needs revision); and
- For a resident who has elected the Medicare 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 health care practitioners and professionals. If the interventions or care provided appear not to be consistent with current standards of practice and/or the interventions defined in the care plan or the resident's pain are not being managed effectively, interview one or more health care practitioners and professionals as necessary (e.g., attending physician, medical director, hospice nurse, facility charge nurse, or director of nursing). These individuals, by virtue of training and knowledge of the resident, should be able to provide information about the management and evaluation of the resident's pain/symptoms. Depending on the issue, ask about:

- How it was determined that chosen interventions were appropriate;
- Whether needs were identified for which there were no interventions, and the rationale for not intervening;
- Changes in condition that may potentially warrant additional or different interventions; or
- How and when the practitioner discussed the effectiveness, ineffectiveness and possible adverse consequences of pain management interventions with the staff.

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

4. Record review

Assessment. Review physician orders, multidisciplinary progress notes, and other information and assessment tools regarding pain assessment. Determine if assessment information:

- Accurately and comprehensively reflects that resident's current condition;
- Identifies causes, risks and contributing factors related to pain;
- Identifies a previous history of pain and effectiveness of prior interventions, and any prior adverse consequences;
- Identifies the characteristics (location, nature, intensity pattern, etc.) of pain;
- Identifies whether pain has adversely affected function and quality of life;

- Consistently utilizes a valid instrument to evaluate pain for both the cognitively impaired and the cognitively intact resident;
- Identifies and evaluates the appropriateness of medications including the dosing and dosing interval; and
- Identifies factors that increase or effectively reduce pain.

Care Plan. Review the care plan for specific interventions, measurable objectives and timetables, risks and causes, and their relevance to the resident. Determine if the plan of care addresses:

- Pertinent non-pharmacological and/or pharmacologic interventions;
- Identified pain management goals;
- Monitoring outcomes of the interventions;
- Identification of potential medication-related adverse consequences such as falling, constipation, drowsiness, etc. and a plan to try to minimize those adverse consequences; and
- Identification of non-pharmacologic interventions as applicable, such as positioning, relaxation therapy, or massage, and evaluation to identify their effectiveness.

If the care plan refers to a specific facility pain management protocol, determine whether interventions are consistent with that protocol, including documentation of the reasons for significantly deviating from the protocol for a particular resident.

If the patient has elected the Medicare hospice benefit, the providers may develop one common care plan to be utilized by both providers, or two care plans following the documentation policies for each provider. The care plans should reflect the identification of a common problem list, palliative interventions, palliative outcomes, responsible discipline and responsible provider.

NOTE: After verifying that the hospice was advised of concerns by the facility and failed to resolve issues related to the management of a resident's pain, coordination of care or implementation of appropriate services, file a complaint with the State Agency responsible for oversight of hospice programs, identifying the specific resident(s) involved and the concerns identified.

DETERMINATION OF COMPLIANCE (Task 6, Appendix P)

Synopsis of regulation (F309)

The requirement for Quality of Care with regard to the Assessment and Management of Pain has three aspects:

- The facility must identify each resident having or at risk for pain and anticipate what procedures, care, or treatments might produce pain, and evaluate the resident regarding the characteristics and causes of the pain;
- The facility must provide the care and services for the resident to attain or maintain his/her goals for pain management and comfort that is consistent with current standards of practice, assessment, and plan of care; and
- The level of pain management is consistent with a resident's potential to achieve or maintain his/her highest practicable level of physical, mental, and psychosocial well-being.

Criteria for Compliance

The facility is in compliance with 42 CFR 483.25, F309, Quality of Care, for assessment and management of pain if staff have:

- Screened residents on admission and periodically for the presence of pain;
- Recognized and evaluated residents who are experiencing pain to determine (to the extent possible) causes and characteristics (nature, intensity, location, frequency and duration) of the pain, as well as factors influencing the pain;
- Developed a care plan to address the pain, consistent with the resident's goals, risks, and current standards of practice;
- Provided care and services to control the pain to the greatest extent possible or to the level defined by the resident, in accordance with current standards of practice, or explained adequately in the medical record why they could not or should not do so;
- Recognized and provided pain control measures for situations such as treatments or activities known to potentially cause or exacerbate pain;
- Monitored the effects of interventions and modified the approaches as indicated;
- Contacted the health care practitioner with pertinent information to advise him/her when a resident was having pain that was not adequately managed or was having a potential adverse consequence related to the treatment; and

- Revised the approaches as appropriate, or verified their continued relevance.

If not, cite at F309.

Noncompliance for F309

After analyzing the data in order to determine whether or not noncompliance with the regulation exists, a clear understanding of the facility's noncompliance with requirements (e.g., deficient practices) and the relationship of the deficient practice(s) to the actual harm or potential for harm to the resident must be established before determining severity.

Noncompliance for F309 may include, for example, failure to:

- Screen and assess a resident at risk for pain;
- Evaluate the resident who is experiencing pain in sufficient detail (nature, intensity, location, influencing factors, frequency, duration, likely causes, etc.) to permit pertinent individualized pain management;
- Recognize and provide pain control measures for those situations (treatments, activities, etc.) where pain can be anticipated;
- Develop a pain management care plan for a resident in pain (either specifically or as part of another aspect of the care plan);
- Implement interventions to address the pain to the greatest extent possible or to the level defined by the resident in accordance with current standards of practice, or explain adequately why they could not or should not do so in the medical record; and
- Monitor the effects of interventions, including both desired and ineffective outcomes, and complications of interventions and treatments, and either validate or modify the approaches as indicated.

Potential Tags for Additional Investigation

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

- 42 CFR 483.10(b)(3), F154, Notice of rights and services

- Determine whether the resident and/or representative have been informed of and indicates a basic understanding of her/his total health status.
- 42 CFR 483.10(b)(4), F155, Notice of rights and services
 - Determine whether the resident or representative has been advised and offered an opportunity to formulate an advance directive;
 - If experimental treatment options are used, determine if the resident was advised and participated in the treatment decision; and
 - Determine if the resident was advised of her/his right to refuse treatment.
- 42 CFR 483.10(b)(11), F157, Notification of changes
 - Determine if staff notified:
 - The physician of significant changes in the resident’s condition or need to alter the treatment plan because pain was not being managed adequately or the resident was experiencing potential adverse consequences related to treatments; 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(g), F250, Social services
 - Determine if the facility is providing medically-related social services, including services to meet the needs of a resident who has pain, discomfort, or unrelenting pain; maintaining contact with family; providing or arranging for provision of needed counseling services; supporting preferences, customary routines, concerns and choices; and assisting residents/families in decision-making.
- 42 CFR 483.20(b)(1), F272, Comprehensive assessments
 - Determine if the facility comprehensively assessed the resident’s physical, mental, and psychosocial needs to 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(k), F279, Comprehensive care plans
 - Determine if the facility developed a care plan that included measurable objectives, timeframes, 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), F280, Comprehensive care plan revision
 - Determine if the care plan was periodically reviewed and revised as necessary to try to reduce pain or discomfort.
- 42 CFR 483.20(k)(3)(i), F281, Services provided meet professional standards
 - Determine if care was provided in accordance with accepted professional standards of quality for pain management, including recognizing, evaluating, reporting, and managing pain present at admission or during the stay.
- 42 CFR 483.25(l), F329, Unnecessary drugs
 - Determine whether medications being used to treat pain are being monitored for effectiveness and for adverse consequences, including measures to determine whether symptoms could be due to the medications.
- 42 CFR 483.40(a), F385, Physician supervision
 - Determine if the physician had assessed and developed a treatment regimen relevant to preventing or managing pain, based on applicable standards of practice and recommendations of relevant professional associations; and if the physician responded to notification of the status of a resident's pain management efforts.
- 42 CFR 483.60, F425, Pharmacy services
 - Determine if the medications and treatments 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.

V. DEFICIENCY CATEGORIZATION (Part V, Appendix P)

Once the survey team has completed its investigation, analyzed the data, reviewed the regulatory requirements, and determined that non-compliance 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 Pain Assessment and Management may include but is not limited to:

- 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 nursing assistant notification 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. First, the team must rule out whether Severity Level 4, Immediate Jeopardy to a resident's health or safety, exists by evaluating the deficient practice in relation to immediacy, culpability, and severity. (Follow the guidance in Appendix Q.)

Severity Level 4 Considerations: Immediate Jeopardy to resident health or safety

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

- Has 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 non-compliance does not remove a finding of immediate jeopardy. The facility is required to implement specific actions to correct the non-compliance, which allowed or caused the immediate jeopardy.

Examples may include but are not limited to:

- Resident experienced continuous, unrelenting, excruciating pain or incapacitating distress or the potential exists for excruciating pain or incapacitating distress and 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.
- 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;
- A cognitively impaired resident with bone metastases experienced or had the potential to experience continuous, unrelenting, excruciating pain or incapacitating distress as a result of the facility's failure to adequately screen, assess, or treat pain; or
- A resident who had elected the hospice benefit experienced excruciating pain, because he/she did not receive the designated pain medication as a result of lack of coordination between the hospice and the facility.

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

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

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

- The resident experienced daily moderate to severe pain or distress for the first month after admission that compromised the resident's 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 screen for pain or have a system that facilitates recognition of residents with pain. For example, the pain was severe enough that the resident experienced insomnia; anorexia with resultant weight loss; reduced ability to move and perform ADLs; a decline in mood; or inhibited social engagement and participation in activities;
- The resident experienced moderate or severe pain or distress as a result of the facility's failure to adequately screen, assess, or treat pain; or
- The resident continued to experience moderate to severe pain or experienced significant adverse consequences related to treatment, as a result of the facility's failure to assess pain characteristics or attempt to individualize the pain management plan to address the causes and characteristics of a resident's pain. Some examples include:
 - Unrelieved moderate to severe pain due to failure to pre-medicate resident prior to dressing changes, wound care, ambulation, exercises or physical therapy; or
 - The resident continued to experience moderate to severe pain as a result of facility's failure to assess the nature of the resident's pain and monitor the pain management interventions.

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

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. Examples may include, but are not limited to:

- The resident experienced daily or less than daily mild pain or discomfort with no compromise in physical or psychosocial functioning as a result of the facility's failure to adequately screen, assess, or treat pain;
- The resident experienced daily or less than daily mild pain or discomfort with no compromise in physical or psychosocial functioning as a result of the facility's failure to notify the practitioner that the resident was experiencing pain or that the

treatment plan was ineffective in controlling pain;

- The resident experienced repeated episodic mild pain during and immediately after dressing changes, therapies, and other anticipated sources of pain or distress as a result of the failure to implement the defined pain-reduction plan; or
- The resident had persistent mild pain resulting from a failure to implement policies and procedures to recognize and evaluate a resident for pain, or to develop or evaluate the effectiveness of treatments and interventions for mild pain or symptom control.

Severity Level 1: No actual harm with potential for minimal harm

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.