F697

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§483.25(k) Pain Management.

The facility must ensure that pain management is provided to residents who require such services, consistent with professional standards of practice, the comprehensive person-centered care plan, and the residents' goals and preferences.

INTENT

Based on the comprehensive assessment of a resident, the facility must ensure that residents receive the treatment and care in accordance with professional standards of practice, the comprehensive care plan, and the resident's choices, related to pain management.

DEFINITIONS

"Acute Pain" *refers to pain that is usually sudden in onset and time-limited with a duration of less than 1 month and often is caused by injury, trauma, or medical treatments such as surgery. (From the Centers for Disease Control and Prevention (CDC)).*

"Adjuvant Medication" *refers to* any medication with a primary indication other than pain management but with analgesic properties in some painful conditions.[2]

"Adverse Consequence" *refers to* 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).

*"**Chronic Pain**" refers to pain that typically lasts greater than 3 months and can be the result of an underlying medical disease or condition, injury, medical treatment, inflammation, or unknown cause. (From the CDC).*

"Medication Assisted Treatment" (MAT) *refers to* the use of medications, in combination with counseling and behavioral therapies, to provide a "whole-patient" approach to the treatment of substance use disorders. (From the Substance Abuse and Mental Health Services Administration (SAMHSA)).

"Opioid Use Disorder" (OUD) *refers to* a problematic pattern of opioid use leading to clinically significant impairment or distress. Additional criteria used to assess and diagnose OUD can be found in the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5).

*"**Subacute Pain**" refers to pain that has been present for 1–3 months. (From the CDC).*

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.

GUIDANCE

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 professional standards of practice, and the resident's goals and preferences.

Overview of Pain Recognition and Management

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. 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.

Strategies for Pain Management
Strategies for the prevention and management of pain may include but are not limited to the following:

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

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

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

- Identifying and using specific strategies for preventing or minimizing different levels or sources of pain or pain-related symptoms based on the resident-specific assessment, preferences and choices, a pertinent clinical rationale, and the resident's goals and; 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.

Use of Opioids for Pain Management—Prescribing practitioners may find that opioid medications are the most appropriate treatment for acute pain, *subacute pain, and* chronic pain in some residents. *Opioid treatment for pain needs to be appropriately assessed and individualized for each resident*. However, because of increasing opioid addiction, abuse, and overdoses, prescribers should use caution when prescribing opioids, and

consider using alternative pain management approaches, when appropriate. When opioids are used, the lowest possible effective dosage should be prescribed for the shortest amount of time possible after considering all medical needs and the resident should be monitored for effectiveness and any adverse effects. *When starting opioid therapy for acute, subacute, or chronic pain, clinicians may consider prescribing immediate-release opioids instead of extended-release and long-acting.*

Due to the risk of fatal respiratory depression, combining opioids and benzodiazepines should be avoided unless clinically indicated for an individual resident. Risks related to combining these medications are even greater for adults aged 65 and older and include falls and hip fractures, cognitive impairment/confusion, daytime fatigue, and delirium. If concurrent use of opioids and benzodiazepines is clinically indicated for an individual resident, the resident should be closely monitored for adverse consequences.

Medication regimens for residents receiving end of life, palliative, or hospice care may include opioids alone or combining opioids and benzodiazepines; their use must be consistent with accepted standards of practice for this specialty of care.

When treating pain in a resident with an addiction history or opioid use disorder (OUD), strategies must be used to relieve pain while also considering the OUD or addiction history. These strategies may include continuation of medication assisted treatment (MAT), if appropriate, non-opioid pain medications, and non-pharmacological approaches.

***NOTE**: Requirements at 483.10(c)(5) describe the resident's right to be informed of the risks and benefits of the proposed treatment. For concerns related to informing the resident or resident representative of the risks of opioid use for pain, refer to F552.*

For additional information, refer to:

- *Exposure-Response Association Between Concurrent Opioid and Benzodiazepine Use and Risk of Opioid-Related Overdose in Medicare Part D Beneficiaries, https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2685628.*
- *National Institute on Drug Abuse Benzodiazepines and Opioids, https://nida.nih.gov/research-topics/opioids/benzodiazepines-opioids*
- *Geriatricpain.org, Resources and Tools for Quality Pain Care, https://geriatricpain.org/*
- *The Society for Post-Acute and Long-Term Care Medicine (AMDA) opioid The Society for Post-Acute and Long-Term Care Medicine (AMDA) Opioids in Nursing Homes , https://paltc.org/opioids%20in%20nursing%20homes*
- *Centers for Disease Control Clinical Practice Guidelines for Prescribing Opioids for Pain https://www.cdc.gov/opioids/patients/guideline.html*

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.

Expressions of pain may be verbal or nonverbal and are subjective. 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) (e.g., rubbing a specific location of the body, or guarding a limb or other body parts);
- Difficulty eating or loss of appetite; and
- Difficulty sleeping (insomnia).

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

Many residents have more than one active medical condition and may experience pain from several different causes simultaneously. Many medical conditions may be painful such as pressure injuries, diabetes with neuropathic pain, immobility, amputation, post-CVA, venous and arterial ulcers, multiple sclerosis, oral health conditions, and infections. In addition, common procedures, such as moving a resident or performing physical or

occupational therapies or changing a wound dressing may be painful. Understanding the underlying causes of pain is an important step in determining optimal approaches to prevent, minimize, or manage pain.

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

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

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

Assessment

In addition to the Resident Assessment Instrument (RAI), it is important that the facility identifies how they will consistently assess pain. Some facilities may use assessment tools that are appropriate for use with their resident population. There are many reliable and valid evidenced based practice tools available to facility staff to assist in the assessment of pain. Pain assessment tools that can be used with cognitively intact and impaired residents can be obtained on the Geriatric Pain website at *https://geriatricpain.org/clinicians/pain-assessment-information.*

An assessment or an evaluation of pain based on professional 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 and whether or not each treatment has been effective);
- History of addiction, past and/or ongoing and related treatment for OUD;

- Characteristics of pain, such as: (intensity, pattern, location, frequency and duration)

- 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 as well as those that reduce or eliminate the pain;

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

- Physical and psychosocial issues (physical examination of the site of the pain,

- movement, or activity that causes the pain, as well as any discussion with resident about any psychological or psychosocial concerns that may be causing or exacerbating the pain);

- Current medical conditions and medications including medication assisted treatment for OUD; and

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

While it may be difficult to conduct a thorough assessment of all of the above factors in a cognitively impaired or non-responsive resident, the facility staff is responsible for obtaining as much information as possible and evaluating the resident's pain through all available means. 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.

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 and/or representative 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 professional 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 professional standards of practice may provide recommended approaches to pain management even when the cause cannot be or has not been determined.

Non-pharmacological interventions

Research supports physical activity and exercise as a part of most treatment programs for chronic pain. Activity can be supported by conventional physical therapy and exercise approaches, or by a wide range of movement therapies.

Some non-pharmacologic interventions may need to be ordered by the provider while others can be provided by facility staff during routine care. Examples of non-pharmacological interventions 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), mid 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 as well as restorative nursing programs to maintain joint mobility; and

- Cognitive/Behavioral interventions (e.g., relaxation techniques, reminiscing, diversions, activities, music therapy, offering spiritual support and comfort, as well as teaching the resident coping techniques and education about pain).

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, rectally, 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 to the provider, pharmacist and nurses.

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 professional 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 such as radiation therapy, neurostimulation, spinal delivery of analgesics (implanted catheters and pump systems), and neurolytic procedures (chemical or surgical) *that* are administered under the close supervision of expert practitioners. Referrals to pain management clinics and pain management specialists may also be appropriate in these situations.

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.

Additionally, a facility should evaluate whether there is a time or day pattern to a resident's reports or signs of increased pain to ensure that the problem is not due to drug diversion.

The CDC describes a number of side effects which prescription opioids can cause even when given as directed. Some side effects for which residents should be monitored include:

- Tolerance, meaning more medication may be needed to achieve the same level of pain relief;

- Physical dependence which causes symptoms of withdrawal when opioid medication is stopped, or a dose is held or missed;

- Increased sensitivity to pain;

- Constipation;
- Nausea, vomiting, and dry mouth;
- Sleepiness, dizziness, and/or confusion;
- Depression; and
- Itching and sweating.

According to the Substance Abuse and Mental Health Administration (SAMHSA), opioid overdose deaths can be prevented by administering naloxone, a medication approved by the Food and Drug Administration to reverse the effects of opioids. The United States Surgeon General has recommended that naloxone be kept on hand where there is a risk for an opioid overdose. Facilities should have a written policy to address opioid overdoses.

The SAMHSA website houses a number of resources related to opioid management including this document intended for prescribers which addresses appropriate prescribing, monitoring for adverse effects, and treating overdoses: SAMHSA Opioid Overdose Prevention Toolkit:
Information for Prescribers, https://www.samhsa.gov/resource/ebp/opioid-overdose-prevention-toolkit.

For concerns related to staff monitoring for adverse effects of opioid use, see F757, Unnecessary Medications.

INVESTIGATIVE *PROCEDURES*

Use the Pain Recognition and Management Critical Element (CE) Pathway, along with the above interpretive guidelines, when determining if the facility provides pain management that meets professional standards of practice; and that is in accordance with the resident's comprehensive care plan, goals for care and preferences.

Briefly review the most recent comprehensive assessments, comprehensive care plan and orders to identify whether the facility has assessed and developed an individualized care plan based on professional standards of practice and provided by qualified, competent staff. During this review, identify the extent to which the facility has implemented interventions in accordance with the resident's needs, goals for care and professional standards of practice, consistently across all shifts. This information will guide observations and interviews to be made in order to corroborate concerns identified.

NOTE: Always observe for visual cues of psychosocial distress and harm (see Guidance on Severity and Scope Levels and Psychosocial Outcome Severity Guide).

KEY ELEMENTS OF NONCOMPLIANCE

To cite deficient practice at F697, the surveyor's investigation will generally show that the facility failed to do *any* one or more of the following:

- Provide pain management to a resident experiencing pain; or
- Provide pain management that met professional standards of practice; or
- Provide pain management that was in accordance with the resident's comprehensive care plan, and the resident's goals for care and preferences.

DEFICIENCY CATEGORIZATION

An example of Level 4*, immediate jeopardy to resident health or safety* includes, but is not limited to:

- Facility failed to implement an effective pain management regime for a resident who sustained a fracture of the hip and was determined to not be a surgical candidate. Resident stated that pain medication was not effective, and she was in continuous pain. She indicated she had notified staff of the pain, but nothing was done. Interview of staff indicated no one had contacted the practitioner to discuss the ineffective pain relief. The staff stated that they were concerned regarding the amount of pain medication the resident was receiving and that they were concerned that she would become increasingly tolerant and addicted to the medication. They stated they were aware that the resident declined assistance with ADL's due to "pain" and felt that the resident was not having the amount of pain that she stated she had. The resident was observed on multiple occasions to, holding her hip area, moaning and crying out, sweating, and striking out when staff attempted to move her.

An example of Level 3*, actual harm* that is not *i*mmediate *j*eopardy includes, but is not limited to:

- The facility failed to provide effective pain management to a resident with a diagnosis of bone cancer. Record review revealed the resident only had PRN (as needed) pain medication every six hours. According to the resident this pain regime was not effective resulting in excruciating breakthrough pain multiple times each day. The resident said that staff would tell her she had to wait, and often would not get the PRN medicine promptly when it was due. The surveyor observed the resident to be tearful and unable to participate in activities.

Examples of *Level 2, no actual harm,* with potential for more than minimal harm, that is *not immediate jeopardy* includes, but is not limited to:

- Facility failed to provide an effective pain management treatment per the resident's choice and preference. A resident request a hot shower on the evening shift as an effective intervention for back pain. The staff member assigned to her informed her that she would not be able to be showered until later in the evening. A staff member who understood what the resident was experiencing quickly intervened and gave her a hot shower relieving her back pain.

- The facility staff failed to consistently evaluate the effectiveness of regularly scheduled pain medication on a resident. The resident was receiving the pain medication on a routine basis; however, the record did not reflect the resident's response to the administration of the pain medication. In interviews, the resident stated that her pain was being managed for the most part, but that staff did not ask her if she received relief from the medication. She stated that occasionally, she would not attend an activity due to discomfort, but this did not routinely occur. When she mentioned it to staff, they would tell her to lie down for a while and would check on her later. However, she stated that they usually did not recheck her. Staff interviewed stated they didn't have the time to go back, check, and record the resident's response, but, if she complained, they would recheck her and see if she needed anything else.

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