

481—655.2(124,148,272C) Standards of practice—appropriate pain management.

655.2(1) Standards. This rule establishes standards of practice for the management of acute and chronic pain. The board encourages the use of nonopioid pharmacologic therapy and nonpharmacologic therapy.

a. This rule is intended to encourage appropriate pain management, including the use of opioids for the treatment of pain, while stressing the need to establish safeguards to minimize the potential for substance abuse and drug diversion.

b. The goal of pain management is to treat each patient's pain in relation to the patient's overall health. At the end of life, the goals may shift to palliative care.

c. Pain management is an important part of medical practice. Unmanaged or inappropriately treated pain impacts patients' quality of life, reduces patients' ability to be productive members of society, and increases patients' use of health care services.

d. Physicians treating pain with opioids in a manner consistent with appropriate pain management practices should not fear board action. Dosage is not the sole measure of determining whether a physician has complied with appropriate pain management practices. The board recognizes the complexity of treating patients with chronic pain or a substance abuse history. Generally, the board is concerned about a pattern of improper pain management or a single occurrence of willful or gross overtreatment or undertreatment of pain.

e. Inappropriate pain management is a departure from the acceptable standard of practice in Iowa and may be grounds for disciplinary action.

655.2(2) Definitions. For the purposes of this rule, the following terms are defined as follows:

"Acute pain" means the normal, predicted physiological response to a noxious chemical, thermal or mechanical stimulus and typically is associated with invasive procedures, trauma and disease. Generally, acute pain is self-limited, lasting no more than a few weeks following the initial stimulus.

"Addiction" means a primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include the following: impaired control over drug use, craving, compulsive use, and continued use despite harm. Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and are not the same as addiction.

"Chronic pain" means pain that lasts longer than three months or past the time of normal tissue healing.

"Pain" means an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage. Pain is an individual, multifactorial experience influenced by culture, previous pain events, beliefs, mood and ability to cope.

"Physical dependence" means a state of adaptation that is manifested by drug class-specific signs and symptoms that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, or administration of an antagonist. Physical dependence, by itself, does not equate with addiction.

"Pseudoaddiction" means an iatrogenic syndrome resulting from the misinterpretation of relief-seeking behaviors as though they are drug-seeking behaviors that are commonly seen with addiction. The relief-seeking behaviors resolve upon institution of effective analgesic therapy.

"Substance abuse" means the use of a drug, including alcohol, by the patient in an inappropriate manner that may cause harm to the patient or others, or the use of a drug for an indication other than that intended by the prescribing clinician. An abuser may or may not be physically dependent on or addicted to the drug.

"Tolerance" means a physiological state resulting from regular use of a drug in which an increased dosage is needed to produce a specific effect, or a reduced effect is observed with a constant dose over time. Tolerance may or may not be evident during opioid treatment and does not equate with addiction.

"Undertreatment of pain" means the failure to properly assess, treat and manage pain or the failure to appropriately document a sound rationale for not treating pain.

655.2(3) Laws and regulations. Nothing in this rule relieves a physician from fully complying with applicable federal and state laws and regulations.

655.2(4) *Undertreatment of pain.* The undertreatment of pain is a departure from the acceptable standard of practice in Iowa. Undertreatment may include a failure to recognize symptoms and signs of pain, a failure to treat pain within a reasonable amount of time, a failure to allow interventions, e.g., analgesia, to become effective before invasive steps are taken, a failure to address pain needs in patients with reduced cognitive status, a failure to use opioids for terminal pain due to the physician's concern with addicting the patient, or a failure to use an adequate level of pain management.

655.2(5) *Assessment and treatment of acute and chronic pain.* Appropriate assessment of the etiology of the pain is essential to the appropriate treatment of acute and chronic pain.

a. Prescribing opioids for the treatment of acute and chronic pain should only be accomplished within an established physician-patient relationship and should be based on clearly diagnosed and documented pain. Appropriate management of acute and chronic pain should include an assessment of the mechanism, type and intensity of pain. The patient's medical record should clearly document a medical history, a pain history, a clinical examination, a medical diagnosis and a treatment plan.

b. A physician who prescribes, dispenses or administers opioids to patients for the treatment of chronic pain should become familiar with the U.S. Centers for Disease Control and Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain published on March 15, 2016.

655.2(6) *Effective management of chronic pain.* To ensure that chronic pain is properly assessed and treated, a physician who prescribes, dispenses or administers opioids to a patient for the treatment of chronic pain shall exercise sound clinical judgment and establish an effective pain management plan in accordance with the following:

a. Patient evaluation. Prior to the patient starting treatment, a patient evaluation must be conducted that includes a physical examination, a comprehensive medical history, pain assessment, and examination of physical and psychological function. This evaluation should also cover diagnostic studies, past interventions, medication and substance abuse history, and any underlying conditions. Depending on the complexity of the case and the physician's expertise, consultation or referral to specialists in pain medicine, addiction medicine, or areas associated with the patient's pain may be necessary. Interdisciplinary evaluation is recommended.

b. Treatment plan. The physician must create a tailored treatment plan addressing the patient's individual needs, outlining treatment objectives such as pain relief or improved functioning, and indicating any planned diagnostic evaluations or treatments. The plan should include other treatment modalities and rehabilitation programs used. Short- and long-term pain relief needs should be considered, along with the patient's ability to request pain relief and the patient's setting. Whenever possible, opioids should be prescribed by one physician and filled at one pharmacy.

c. Informed consent. A discussion of the risks and benefits of opioids with the patient or person representing the patient must be documented.

d. Periodic review. The physician must regularly review the patient's drug treatment course and pain source. Drug therapy should be adjusted to meet individual patient needs, based on progress toward treatment plan objectives. If reviews show treatment plan objectives are not being met or indicate diversion or substance abuse patterns, the physician should reconsider drug therapy and explore other treatment options. Long-term opioid use may lead to tolerance and abnormal pain sensitivity, meaning increasing doses may not improve pain control or function.

e. Consultation/referral. A specialty consultation, including with a physician with expertise in addiction medicine or substance abuse counseling, may be considered if there is evidence of significant adverse effects, lack of response to the medication, diversion, or a pattern of substance abuse. The board encourages a multidisciplinary approach to chronic pain management.

f. Documentation. The physician shall keep accurate, timely, and complete records that detail compliance with this subrule, including patient evaluation, diagnostic studies, treatment modalities, treatment plan, informed consent, periodic review, consultation, and any other relevant information about the patient's condition and treatment.

g. Pain management agreements. Physicians treating chronic pain with opioids should consider implementing a pain management agreement with each patient outlining medication use rules and consequences for misuse. The decision to use such an agreement should be based on individual patient

evaluation, weighing risks and benefits of long-term opioid treatment. If opioid treatment exceeds 90 days for chronic pain, and there is a concern for drug abuse or diversion, a pain management agreement should be used. If a physician opts not to use a pain management agreement, reasons should be documented in the patient's medical records. Pain management agreements are not required for hospice or nursing home patients.

h. Substance abuse history or comorbid psychiatric disorder. A patient's prior history of substance abuse does not necessarily contraindicate appropriate pain management. However, treatment of patients with a history of substance abuse or with a comorbid psychiatric disorder may require extra care and communication with the patient, monitoring, documentation, and consultation with or referral to an expert in the management of such patients. The board strongly encourages a multidisciplinary approach for pain management of such patients that incorporates the expertise of other health care professionals.

i. Drug testing. A physician who prescribes opioids to a patient for more than 90 days for the treatment of chronic pain should consider utilizing drug testing to ensure that the patient is receiving appropriate therapeutic levels of prescribed medications or if the physician has reason to believe that the patient is at risk of drug abuse or diversion.

j. Termination of care. The physician should consider termination of patient care if there is evidence of noncompliance with the rules for medication use, drug diversion, or a repeated pattern of substance abuse.

655.2(7) Pain management for terminal illness. The provisions of this subrule apply to patients who are at the stage in the progression of cancer or other terminal illness when the goal of pain management is comfort care. When the goal of treatment shifts to comfort care rather than cure of the underlying condition, the board recognizes that the dosage level of opioids to control pain may exceed dosages recommended for chronic pain and may come at the expense of patient function. The determination of such pain management should involve the patient, if possible, and others the patient has designated for assisting in end-of-life care.

655.2(8) Prescription monitoring program. The board of pharmacy established a prescription monitoring program pursuant to Iowa Code sections 124.551 through 124.558 to help prescribers and pharmacists track controlled substance prescriptions. Physicians must register for this program when applying for or renewing their controlled substance prescribing registration. Before prescribing opioids, physicians or their agents must use the program to guide treatment decisions and enhance patient care quality. However, utilization is not required for patients in inpatient hospice care or long-term residential facilities. Orders in hospital settings are not considered prescriptions under these rules, as patient safety is managed within these settings.

655.2(9) Electronic prescriptions. Beginning January 1, 2020, all prescriptions (controlled and noncontrolled substances) are to be transmitted electronically as electronic prescriptions pursuant to Iowa Code section 124.308. A prescription shall be transmitted to a pharmacy by the physician or the physician's authorized agent in compliance with federal law and regulation for electronic prescriptions of controlled substances.

655.2(10) Pain management resources. The board strongly recommends that physicians consult the following resources regarding the proper treatment of chronic pain. This list is provided for the convenience of licensees, and the publications included are not intended to be incorporated in the rule by reference.

a. American Academy of Hospice and Palliative Medicine or AAHPM is the American Medical Association-recognized specialty society of physicians who practice in hospice and palliative medicine in the United States. The mission of the AAHPM is to enhance the treatment of pain at the end of life.

b. American Academy of Pain Medicine or AAPM is the American Medical Association-recognized specialty society of physicians who practice pain medicine in the United States. The mission of the AAPM is to enhance pain medicine practice by promoting a climate conducive to the effective and efficient practice of pain medicine.

c. American Pain Society or APS is the national chapter of the International Association for the Study of Pain, an organization composed of physicians, nurses, psychologists, scientists and other

professionals who have an interest in the study and treatment of pain. The mission of the APS is to serve people in pain by advancing research, education, treatment and professional practice.

d. DEA Policy Statement: Dispensing Controlled Substances for the Treatment of Pain. On August 28, 2006, the Drug Enforcement Agency (DEA) issued a policy statement establishing guidelines for practitioners who dispense controlled substances for the treatment of pain. This policy statement may be helpful to practitioners who treat pain with controlled substances.

e. Interagency Guideline on Prescribing Opioids for Pain. Developed by the Washington State Agency Medical Directors' Group in collaboration with an expert advisory panel, actively practicing providers and public stakeholders, the guideline focuses on evidence-based treatment for chronic-pain patients. The guideline was published in 2007 and updated in 2015.

f. Responsible Opioid Prescribing: A Physician's Guide. In 2007, in collaboration with author Scott Fishman, M.D., the Federation of State Medical Boards' (FSMB's) Research and Education Foundation published a book on responsible opioid prescribing based on the FSMB Model Policy for the Use of Controlled Substances for the Treatment of Pain.

g. World Health Organization: Pain Relief Ladder. Cancer pain relief and palliative care. Technical report series 804. Geneva: World Health Organization.

h. CDC Guideline for Prescribing Opioids for Chronic Pain as referenced in paragraph 655.2(4) "b."

655.2(11) *Grounds for discipline.* A physician may be subject to disciplinary action for violation of these rules, the rules found in 481—Chapter 661, or any of the following:

a. A physician who prescribes opioids in dosage amounts exceeding what would be prescribed by a reasonably prudent physician in the state of Iowa acting in the same or similar circumstances.

b. A physician who knowingly fails to comply with the confidentiality requirements of Iowa Code section 124.553 or who delegates program information access to another individual except as provided in Iowa Code section 124.553.

c. A physician who knowingly fails to comply with other requirements of Iowa Code chapter 124.

655.2(12) *Unlawful access, disclosure, or use of information.* A person who intentionally or knowingly accesses, uses, or discloses information from the prescription monitoring program in violation of Iowa Code section 124.553, unless otherwise authorized by law, is guilty of a class "D" felony. This subrule shall not preclude a physician who requests and receives information from the prescription monitoring program consistent with the requirements of Iowa Code section 124.553 from otherwise lawfully providing that information to any other person for medical care purposes.

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