

**MEDICINE BOARD[653]**

**Notice of Intended Action**

**Proposing rule making related to standards of practice for appropriate pain management and providing an opportunity for public comment**

The Board of Medicine hereby proposes to amend Chapter 13, “Standards of Practice and Principles of Medical Ethics,” Iowa Administrative Code.

*Legal Authority for Rule Making*

This rule making is proposed under the authority provided in Iowa Code chapters 147, 148 and 272C and 2018 Iowa Acts, House File 2377.

*State or Federal Law Implemented*

This rule making implements, in whole or in part, 2018 Iowa Acts, House File 2377.

*Purpose and Summary*

This proposed rule making amends the standards of practice for appropriate pain management. This rule making references the U.S. Centers for Disease Control and Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain. The proposed amendments require a physician to register with the Iowa Prescription Monitoring Program at the same time that the physician applies for registration or renews registration to prescribe controlled substances as required by the Iowa Board of Pharmacy. The proposed amendments also require a physician or the physician’s designated agent to utilize the Iowa Prescription Monitoring Program prior to issuing an opioid prescription and, beginning January 1, 2020, to transmit electronically as an electronic prescription every prescription issued for a controlled substance. This rule making makes it a ground for discipline if a physician 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.

*Fiscal Impact*

This rule making has no fiscal impact to the State of Iowa.

*Jobs Impact*

After analysis and review of this rule making, no impact on jobs has been found.

*Waivers*

Any person who believes that the application of the discretionary provisions of this rule making would result in hardship or injustice to that person may petition the Board for a waiver of the discretionary provisions, if any, pursuant to 653—Chapter 3.

*Public Comment*

Any interested person may submit written or oral comments concerning this proposed rule making. Written or oral comments in response to this rule making must be received by the Board no later than 4:30 p.m. on May 3, 2019. Comments should be directed to:

Kent Nebel  
Iowa Board of Medicine  
400 S.W. Eighth Street, Suite C  
Des Moines, Iowa 50309  
Phone: 515.281.7088  
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Email: [kent.nebel@iowa.gov](mailto:kent.nebel@iowa.gov)

*Public Hearing*

A public hearing at which persons may present their views orally or in writing will be held as follows:

May 3, 2019  
9 a.m.

Board Office, Suite C  
400 S.W. Eighth Street  
Des Moines, Iowa

Persons who wish to make oral comments at the public hearing may be asked to state their names for the record and to confine their remarks to the subject of this proposed rule making.

Any persons who intend to attend the public hearing and have special requirements, such as those related to hearing or mobility impairments, should contact the Board and advise of specific needs.

*Review by Administrative Rules Review Committee*

The Administrative Rules Review Committee, a bipartisan legislative committee which oversees rule making by executive branch agencies, may, on its own motion or on written request by any individual or group, review this rule making at its [regular monthly meeting](#) or at a special meeting. The Committee's meetings are open to the public, and interested persons may be heard as provided in Iowa Code section 17A.8(6).

The following rule-making action is proposed:

Amend rule 653—13.2(148,272C) as follows:

**653—13.2(124,148,272C) Standards of practice—appropriate pain management.** This rule establishes standards of practice for the management of acute and chronic pain. The board encourages the use of nonpharmacologic therapy, including but not limited to adjunct therapies such as acupuncture, physical therapy and massage, and nonopioid pharmacologic therapy in the treatment of acute and chronic pain. ~~This rule focuses on prescribing and administering controlled substances to provide relief and eliminate suffering for patients with acute or chronic pain.~~

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

2. The goal of pain management is to treat each patient's pain in relation to the patient's overall health, including physical function and psychological, social and work-related factors. At the end of life, the goals may shift to palliative care.

3. The board recognizes that pain management, ~~including the use of controlled substances,~~ is an important part of ~~general~~ 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.

4. Physicians should not fear board action for treating pain with ~~controlled substances~~ opioids as long as the physicians' prescribing is consistent with appropriate pain management practices. Dosage alone 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.

~~5. The board recognizes that the undertreatment of pain is a serious public health problem that results in decreases in patients' functional status and quality of life, and that adequate access by patients to proper pain treatment is an important objective of any pain management policy.~~

~~6. 5. Inappropriate pain management may include nontreatment, undertreatment, overtreatment, and the continued use of ineffective treatments. Inappropriate pain management is a departure from the acceptable standard of practice in Iowa and may be grounds for disciplinary action.~~

**13.2(1) 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 persistent or episodic pain of a duration or intensity that adversely affects the functioning or well-being of a patient when (1) no relief or cure for the cause of pain is possible; (2) no relief or cure for the cause of pain has been found; or (3) relief or cure for the cause of pain through other medical procedures would adversely affect the well-being of the patient. If pain persists beyond the anticipated healing period of a few weeks, patients should be thoroughly evaluated for the presence of chronic pain. pain that typically lasts longer than three months or past the time of normal tissue healing. Chronic pain can be the result of an underlying medical disease or condition, injury, medical treatment, inflammation, or an unknown cause.

*"Opioid"* means any U.S. Food and Drug Administration (FDA)-approved product or active pharmaceutical ingredient classified as a controlled substance that produces an agonist effect on opioid receptors and is indicated or used for the treatment of pain.

*"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.

**13.2(2) Laws and regulations governing controlled substances.** Nothing in this rule relieves a physician from fully complying with applicable federal and state laws and regulations governing controlled substances.

**13.2(3) 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 ~~controlled substances~~ 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.

**13.2(4) *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. Acute pain is not a diagnosis; it is a symptom.~~

*a.* ~~Prescribing controlled substances~~ opioids for the treatment of acute and chronic pain 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.* 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 unrelieved pain.

*c.* On March 15, 2016, the U.S. Centers for Disease Control and Prevention (CDC) issued the CDC Guideline for Prescribing Opioids for Chronic Pain to provide recommendations for the prescribing of opioid pain medication for patients 18 years of age and older in primary care settings. Recommendations focus on the use of opioids in treating chronic pain (pain lasting longer than three months or past the time of normal tissue healing) outside of active cancer treatment, palliative care, and end-of-life care. A physician who prescribes, dispenses or administers opioids to patients for the treatment of chronic pain should become familiar with the CDC Guideline for Prescribing Opioids for Chronic Pain.

**13.2(5) *Effective management of chronic pain.*** ~~Prescribing controlled substances for the treatment of chronic pain should only be accomplished within an established physician-patient relationship and should be based on clearly diagnosed and documented unrelieved pain.~~ To ensure that chronic pain is properly assessed and treated, a physician who prescribes, dispenses or administers ~~controlled substances~~ 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.* A patient evaluation that includes a physical examination and a comprehensive medical history shall be conducted prior to the initiation of treatment. The evaluation shall also include an assessment of the pain, physical and psychological function, diagnostic studies, previous interventions, including medication history, substance abuse history and any underlying or coexisting conditions. Consultation/referral to a physician with expertise in pain medicine, addiction medicine or substance abuse counseling or a physician who specializes in the treatment of the area, system, or organ perceived to be the source of the pain may be warranted depending upon the expertise of the physician and the complexity of the presenting patient. Interdisciplinary evaluation is strongly encouraged.

*b. Treatment plan.* The physician shall establish a comprehensive treatment plan that tailors drug therapy to the individual needs of the patient. To ensure proper evaluation of the success of the treatment, the plan shall clearly state the objectives of the treatment, for example, pain relief or improved physical or psychosocial functioning. The treatment plan shall also indicate if any further diagnostic evaluations or treatments are planned and their purposes. The treatment plan shall also identify any other treatment modalities and rehabilitation programs utilized. The patient's short- and long-term needs for pain relief shall be considered when drug therapy is prescribed. The patient's ability to request pain relief as well as the patient setting shall be considered. For example, nursing home patients are unlikely to have their pain control needs assessed on a regular basis, making prn (on an as-needed basis) drugs less effective than drug therapy prescribed for routine administration that can be supplemented if pain is found to be worse. The patient should receive prescriptions for ~~controlled substances~~ opioids from a single physician and a single pharmacy whenever possible.

*c. Informed consent.* The physician shall document discussion of the risks and benefits of ~~controlled substances~~ opioids with the patient or person representing the patient.

*d. Periodic review.* The physician shall periodically review the course of drug treatment of the patient and the etiology of the pain. The physician should adjust drug therapy to the individual needs of each patient. Modification or continuation of drug therapy by the physician shall be dependent upon evaluation of the patient's progress toward the objectives established in the treatment plan. The physician shall consider the appropriateness of continuing drug therapy and the use of other treatment modalities if periodic reviews indicate that the objectives of the treatment plan are not being met or that there is evidence of diversion or a pattern of substance abuse. Long-term opioid treatment is associated with the development of tolerance to its analgesic effects. There is also evidence that opioid treatment may paradoxically induce abnormal pain sensitivity, including hyperalgesia and allodynia. Thus, increasing opioid doses may not improve pain control and function.

*e. Consultation/referral.* A specialty consultation may be considered at any time if there is evidence of significant adverse effects or lack of response to the medication. Pain, physical medicine, rehabilitation, general surgery, orthopedics, anesthesiology, psychiatry, neurology, rheumatology, oncology, addiction medicine, or other consultation may be appropriate. The physician should also consider consultation with, or referral to, a physician with expertise in addiction medicine or substance abuse counseling, if there is evidence of diversion or a pattern of substance abuse. The board encourages a multidisciplinary approach to chronic pain management, including the use of adjunct therapies such as acupuncture, physical therapy and massage.

*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.* A physician who treats patients for chronic pain with ~~controlled substances~~ opioids shall consider using a pain management agreement with each patient being treated that specifies the rules for medication use and the consequences for misuse. In determining whether to use a pain management agreement, a physician shall evaluate each patient, taking into account the risks to the patient and the potential benefits of long-term treatment with ~~controlled substances~~ opioids. A physician who prescribes ~~controlled substances~~ opioids to a patient for more than 90 days for the treatment of chronic pain shall utilize a pain management agreement if the physician has reason to believe a patient is at risk of drug abuse or diversion. If a physician prescribes ~~controlled substances~~ opioids to a patient for more than 90 days for the treatment of chronic pain and chooses not to use a pain management agreement, then the physician shall document in the patient's medical records the reason(s) why a pain management agreement was not used. Use of pain management agreements is not necessary for hospice or nursing home patients. A sample pain management agreement and prescription drug risk assessment tools may be found on the board's website at [www.medicalboard.iowa.gov](http://www.medicalboard.iowa.gov).

*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 ~~controlled substances~~ opioids to a patient for more than 90 days for the treatment of chronic pain shall 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 shall 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.

**13.2(6) 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 or controlled substances~~ 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.

**13.2(7) Prescription monitoring program.** The Iowa board of pharmacy has established a prescription monitoring program pursuant to Iowa Code sections 124.551 to 124.558 to assist prescribers and pharmacists in monitoring the prescription of controlled substances to patients. ~~The board recommends that physicians~~ A physician shall register for the prescription monitoring program at the same time the physician applies for registration or renews registration to prescribe controlled substances as required by the Iowa board of pharmacy. A physician or the physician's designated agent shall utilize the prescription monitoring program when prescribing controlled substances to patients if the physician has reason to believe that a patient is at risk of drug abuse or diversion prior to issuing an opioid prescription to assist the physician in determining appropriate treatment options and to improve the quality of patient care. A physician is not required to utilize the prescription monitoring program to assist in the treatment of a patient receiving inpatient hospice care or long-term residential facility patient care. An order issued in an inpatient hospital setting is not considered a prescription for the purposes of these rules. Patient safety is adequately protected in an inpatient hospital setting, and physicians caring for patients in an inpatient hospital setting do not prescribe. A link to the prescription monitoring program may be found at the board's website at [www.medicalboard.iowa.gov](http://www.medicalboard.iowa.gov).

**13.2(8) Electronic prescriptions.** Beginning January 1, 2020, every prescription issued for a controlled substance shall be transmitted electronically as an electronic prescription pursuant to Iowa Code section 124.308. The 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.

~~13.2(8)~~ **13.2(9) 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) 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. On March 15, 2016, the U.S. Centers for Disease Control and Prevention (CDC) issued a guideline to provide recommendations for the prescribing of opioid pain medication for patients 18 years of age and older in primary care settings. Recommendations focus on the use of opioids in treating chronic pain (pain lasting longer than three months or past the time of normal tissue healing) outside of active cancer treatment, palliative care, and end-of-life care.

**13.2(10) Grounds for discipline.** A physician may be subject to disciplinary action for violation of these rules, the rules found in 653—Chapter 23, 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.

**13.2(11) 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.

This rule is intended to implement Iowa Code chapters 124, 148 and 272C.