Regulatory Analysis

Notice of Intended Action to be published: 653—Chapter 13
"Standards of Practice and Principles of Medical Ethics"

Iowa Code section(s) or chapter(s) authorizing rulemaking: 124, 124E, 135, 135L, 144E, 146A, 146E, 147, 148, 272C and 280

State or federal law(s) implemented by the rulemaking: Iowa Code chapters 124, 124E, 135, 135L, 144E, 146A, 146E, 147, 148, 272C and 280

Public Hearing

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

November 5, 2024 9 a.m.	6200 Park Avenue Des Moines, Iowa Information on virtual participation will be available on the Department of Inspections, Appeals, and Licensing's website prior to the hearing.

Public Comment

Any interested person may submit written comments concerning this Regulatory Analysis, which must be received by the Department no later than 4:30 p.m. on the date of the public hearing. Comments should be directed to:

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Purpose and Summary

This proposed rulemaking provides Iowans, licensees, and employers with the standards of practice and medical ethics. The rules give definitions relevant to the practice of medicine and guidelines on office practices, including the requirements for recordkeeping, physician behavior, and patient-physician relationships. The Board of Medicine added provisions for emergency medical services within the physician's scope of practice pursuant to 2024 Iowa Acts, House File 2507.

Analysis of Impact

1. Persons affected by the proposed rulemaking:

- Classes of persons that will bear the costs of the proposed rulemaking:

There are costs associated with practice standards since there is often time, effort, and money associated with compliance. However, the costs generally impact the practitioner. These costs may be passed on to the consumer. The Board does not have a mechanism for estimating what these total costs might be to the public and to the licensee.

Costs to the agency are for the staff time needed to manage the full scope of Board activities, which include oversight of practice standards, answering questions from licensees and the public, administration of board meetings, etc. An executive officer and executive director support the work of this Board at approximately 0.5 full-time equivalent (FTE) position. Staff salaries are covered by the

Licensing and Regulation Fund established in 2023 Iowa Acts, Senate File 557. Licensing fees are paid into the fund to cover the costs of the Board's operations.

- Classes of persons that will benefit from the proposed rulemaking:

The public and the members of the profession benefit from this rulemaking. The costs are justified by the benefits achieved because the rules provide required guardrails for providing this important service to Iowans. If this profession was not regulated, it could mean that lower-skilled individuals would provide this service to Iowans, which would be of concern to the Board. Medicine is regulated in all 50 states.

2. Impact of the proposed rulemaking, economic or otherwise, including the nature and amount of all the different kinds of costs that would be incurred:

- Quantitative description of impact:

There are approximately 17,000 licensed individuals who provide these services to Iowans. There is a relatively large number of complaints submitted to this Board. In 2022, there were approximately 660 complaints filed with this Board, with less than 5 percent resulting in public discipline.

There are costs associated with practice standards since there is often time, effort and money associated with compliance. However, the costs generally impact the practitioner. These costs may be passed onto the consumer. The Board does not have a mechanism for estimating what these total costs might be to the public and to the licensee.

Costs to the agency are for the staff time needed to manage the full scope of Board activities, which include oversight of practice standards, answering questions from licensees and the public, administration of Board meetings, etc. An executive officer and executive director support the work of this board at approximately 0.5 FTE position. Staff salaries are covered by the fund.

- Qualitative description of impact:

The Board believes that the costs are justified by the benefits achieved because the rules provide required guardrails for providing this important service to Iowans. Without regulation, the Board has concerns about individuals without proper skills providing service to Iowans. This could cause harm to the public.

3. Costs to the State:

- Implementation and enforcement costs borne by the agency or any other agency:

Costs to the agency are for the staff time needed to manage the full scope of Board activities, which include oversight of practice standards, answering questions from licensees and the public, administration of Board meetings, etc. An executive officer and executive director support the work of this Board at approximately 0.5 FTE position. Staff salaries are covered by the fund.

- Anticipated effect on state revenues:

This rulemaking has no anticipated impact on state revenues. Staff salaries to support the work of the Board are covered by the fund. Licensing fees go to the fund to cover the operations of the regulated professional licensing boards.

4. Comparison of the costs and benefits of the proposed rulemaking to the costs and benefits of inaction:

There are approximately 17,000 licensed individuals who provide these services to Iowans. There is a relatively large number of complaints submitted to this Board. In 2022, there were approximately 660 complaints filed with his board, with less than 5 percent resulting in public discipline. The Board believes that the costs are justified by the benefits achieved because the rules provide required guardrails for providing this important service to Iowans. If this profession was not regulated, it could mean that lower-skilled individuals would provide this service to Iowans, which would be of concern to the Board. Medicine is regulated in all 50 states.

5. Determination whether less costly methods or less intrusive methods exist for achieving the purpose of the proposed rulemaking:

The Board could be advisory, and registration could be used as opposed to licensing, which is the highest form of regulation. However, the intended benefit of safe medical practice in Iowa may not be met since the Board would not have the authority to carry out discipline against licensees to ensure the minimum safety standards of the profession are being met. There would be additional issues with workforce since the state may no longer qualify for the Interstate Medical Licensure Compact with physicians who are no longer licensed.

6. Alternative methods considered by the agency:

- Description of any alternative methods that were seriously considered by the agency:

The Board could be an advisory body instead of a regulatory body. Registration could also be used as opposed to licensing, which is the highest form of regulation. However, the intended benefit of safe medical practice in Iowa may not be met since the Board would not have the authority to carry out discipline against licensees to ensure that the minimum safety standards of the profession are being met. There would be additional issues with the workforce since the state may no longer qualify for the Compact if it were not licensing physicians.

- Reasons why alternative methods were rejected in favor of the proposed rulemaking:

The intended benefit of a safe medical practice in Iowa may not be met since the Board would not have the authority to carry out discipline against licensees to ensure that the minimum safety standards of the profession are being met. There would be additional issues with workforce since the state may no longer qualify for the Compact if it were not licensing physicians.

Small Business Impact

If the rulemaking will have a substantial impact on small business, include a discussion of whether it would be feasible and practicable to do any of the following to reduce the impact of the rulemaking on small business:

- Establish less stringent compliance or reporting requirements in the rulemaking for small business.
- Establish less stringent schedules or deadlines in the rulemaking for compliance or reporting requirements for small business.
- Consolidate or simplify the rulemaking's compliance or reporting requirements for small business.
- Establish performance standards to replace design or operational standards in the rulemaking for small business.
- Exempt small business from any or all requirements of the rulemaking.

If legal and feasible, how does the rulemaking use a method discussed above to reduce the substantial impact on small business?

The proposed chapter relates to high-stakes public safety concerns that are present whether the business is a small business or a large corporation. The chapter is meant to ensure public safety in terms of practice standards for physicians. While some licensees could be running a small business, some also work for large hospitals and clinics. To exempt small businesses from adhering to this chapter would jeopardize any member of the public who sought services from that small business. The risk to the public is greater than the potential harm or cost to the small business.

Text of Proposed Rulemaking

ITEM 1. Rescind 653—Chapter 13 and adopt the following **new** chapter in lieu thereof:

CHAPTER 13
STANDARDS OF PRACTICE AND PRINCIPLES OF MEDICAL ETHICS

653—13.1(148,272C) Standards of practice—packaging, labeling and records of prescription drugs dispensed by a physician.

13.1(1) A physician shall dispense a prescription drug only in a container that meets the requirements of the Poison Prevention Packaging Act of 1970, 15 U.S.C. Sections 1471-1476 (2001), unless otherwise requested by the patient, and of Section 502G of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. Section 301 et seq. (2001).

13.1(2) A label affixed to a container in which a prescription drug is dispensed by a physician shall include:

a. The name and address of the physician.

b. The name of the patient.

c. The date dispensed.

d. The directions for administering the prescription drug and any cautionary statement deemed appropriate by the physician.

e. The name and strength of the prescription drug in the container.

13.1(3) The provisions of subrules 13.1(1) and 13.1(2) shall not apply to packaged drug samples.

13.1(4) Physicians must document all prescription drugs dispensed to patients, including required label information. Noting such information on the patient's chart or record maintained by the physician is sufficient.

653—13.2(124,148,272C) Standards of practice—appropriate pain management.

13.2(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.

13.2(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.

13.2(3) *Laws and regulations.* Nothing in this rule relieves a physician from fully complying with applicable federal and state laws and regulations.

13.2(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.

13.2(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.

13.2(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.

13.2(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.

13.2(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.

13.2(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.

13.2(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 13.2(4) *"b."*

13.2(11) *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(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.

653—13.3(147,148) Standards of practice—chelation therapy. Chelation therapy or disodium ethylene diamine tetra acetic acid (EDTA) may only be used for the treatment of heavy metal poisoning or in the clinical setting when a licensee experienced in clinical investigations conducts a carefully controlled clinical investigation of its effectiveness in treating other diseases or medical conditions under a research protocol that has been approved by an institutional review board of the University of Iowa or Des Moines University—Osteopathic Medical Center.

653—13.4(79GA,HF726) Standards of practice—automated dispensing systems. A physician who dispenses prescription drugs via an automated dispensing system or a dispensing system that employs technology may delegate nonjudgmental dispensing functions to staff assistants in the absence of a pharmacist or physician provided that the physician utilizes an internal quality control assurance plan that ensures that the medication dispensed is the medication that was prescribed. The physician must be physically present to determine the accuracy and completeness of any medication that is reconstituted prior to dispensing.

13.4(1) An internal quality control assurance plan shall include the following elements:

a. The name of the physician responsible for the plan and testing;

b. Methods that the dispensing system employs to ensure the accuracy of the patient's name and medication, dosage, directions and amount of medication prescribed;

c. Standards that the physician expects to be met to ensure the accuracy of the dispensing system and the training and qualifications of staff members assigned to dispense via the dispensing system;

d. The procedures utilized to ensure that the physician(s) dispensing via the automated system provide(s) patients counseling regarding the prescription drugs being dispensed;

e. Staff training and qualifications for dispensing via the dispensing system;

f. A list of staff members who meet the qualifications and who are assigned to dispense via the dispensing system;

g. A plan for testing the dispensing system and each staff member assigned to dispense via the dispensing system;

h. The results of testing that show compliance with the standards prior to implementation of the dispensing system and prior to approval of each staff member to dispense via the dispensing system;

i. A plan for interval testing of the accuracy of dispensing, at least annually; and

j. A plan for addressing inaccuracies, including discontinuing dispensing until the accuracy level can be reattained.

13.4(2) Those dispensing systems already in place shall show evidence of a plan and testing within two months of August 31, 2001.

13.4(3) The internal quality control assurance plan shall be submitted to the board of medicine upon request.

653—13.5(147,148,272C) Standards of practice—office practices.

13.5(1) *Termination of the physician-patient relationship.* A physician may choose whom to serve. Having undertaken the care of a patient, the physician may not neglect the patient. A physician must provide a patient written notice of the termination of the physician-patient relationship. A

physician shall ensure that emergency medical care is available to the patient during the 30-day period following notice of the termination of the physician-patient relationship.

13.5(2) *Patient referrals.* A physician shall not pay or receive compensation for patient referrals.

13.5(3) *Confidentiality.* A physician shall maintain the confidentiality of all patient information obtained in the practice of medicine. Information shall be divulged by the physician when authorized by law or the patient or when required for patient care.

13.5(4) *Sexual conduct.* It is unprofessional and unethical conduct, and is grounds for disciplinary action, for a physician to engage in conduct that violates the following prohibitions:

a. In the course of providing medical care, a physician shall not engage in contact, touching, or comments of a sexual nature with a patient, or with the patient's parent or guardian if the patient is a minor or under a guardianship.

b. A physician shall not engage in any sexual conduct with a patient when that conduct occurs concurrent with the physician-patient relationship, regardless of whether the patient consents to that conduct.

c. A physician shall not engage in any sexual conduct with a former patient unless the physician-patient relationship was completely terminated before the sexual conduct occurred. In considering whether that relationship was completely terminated, the board will consider the duration of the physician-patient relationship, the nature of the medical services provided, the lapse of time since the physician-patient relationship ended, the degree of dependence in the physician-patient relationship, and the extent to which the physician used or exploited the trust, knowledge, emotions, or influence derived from the physician-patient relationship.

d. A psychiatrist, or a physician who provides mental health counseling to a patient, shall never engage in any sexual conduct with a current or former patient, or with that patient's parent or guardian if the patient was a minor or under guardianship, regardless of whether the patient consents to that conduct.

13.5(5) *Disruptive behavior.* A physician shall not engage in disruptive behavior. Disruptive behavior is defined as a pattern of contentious, threatening, or intractable behavior that interferes with, or has the potential to interfere with, patient care or the effective functioning of health care staff.

13.5(6) *Sexual harassment.* A physician shall not engage in sexual harassment. Sexual harassment is defined as verbal or physical conduct of a sexual nature that interferes with another health care worker's performance or creates an intimidating, hostile or offensive work environment.

13.5(7) *Transfer of medical records.* A physician must provide a copy of all medical records generated by the physician in a timely manner to the patient or another physician designated by the patient, upon written request when legally requested to do so by the subject patient or by a legally designated representative of the subject patient, except as otherwise required or permitted by law.

13.5(8) *Retention of medical records.*

a. A physician shall retain all medical records, not appropriately transferred to another physician or entity, for at least seven years from the last date of service for each patient, except as otherwise required by law.

b. A physician must retain all medical records of minor patients, not appropriately transferred to another physician or entity, for a period consistent with that established by Iowa Code section 614.8.

c. Beginning July 1, 2023, a physician must appoint another Iowa-licensed physician, or other representative or entity that is held to the same standards of confidentiality as the physician, to ensure that all requirements of this subrule are met in the event of the physician's death or incapacitation. Upon request by the board, the physician must be able to establish by sufficient proof the appointment of a representative pursuant to this paragraph.

d. Upon a physician's death or retirement, the sale of a medical practice, or a physician's departure from the physician's medical practice:

(1) The physician or the physician's representative must ensure that all medical records are transferred to another physician or entity that is held to the same standards of confidentiality and agrees to act as custodian of the records.

(2) The physician or the physician's representative shall notify all active patients that their records will be transferred to another physician or entity that will retain custody of their records and that, at their written request, the records will be sent to the physician or entity of the patient's choice.

653—13.6(148,272C) Standards of practice—medical directors at medical spas—delegation and supervision of medical aesthetic services performed by qualified licensed or certified nonphysician persons or qualified laser technicians. This rule establishes standards of practice for a physician or surgeon or osteopathic physician or surgeon who serves as a medical director at a medical spa. This rule does not apply to the standards of practice for a nonphysician licensed health professional who serves as a medical director at a medical spa pursuant to the rules of the professional's licensing authority.

13.6(1) *Definitions.* As used in this rule:

"Alter" means to change the cellular structure of living tissue.

"Capable of" means any means, method, device or instrument that, if used as intended or otherwise to its greatest strength, has the potential to alter or damage living tissue below the superficial epidermal cells.

"Damage" means to cause a harmful change in the cellular structure of living tissue.

"Delegate" means to entrust or transfer the performance of a medical aesthetic service to qualified licensed or certified nonphysician persons or qualified laser technicians.

"Medical aesthetic service" means the diagnosis, treatment, or correction of human conditions, ailments, diseases, injuries, or infirmities of the skin, hair, nails and mucous membranes by any means, methods, devices, or instruments including the use of a biological or synthetic material, chemical application, mechanical device, or displaced energy form of any kind if it alters or damages or is capable of altering or damaging living tissue below the superficial epidermal cells, with the exception of hair removal. Medical aesthetic service includes, but is not limited to, the following services: ablative laser therapy; vaporizing laser therapy; nonsuperficial light device therapy; injectables; tissue alteration services; nonsuperficial light-emitting diode therapy; nonsuperficial intense pulse light therapy; nonsuperficial radiofrequency therapy; nonsuperficial ultrasonic therapy; nonsuperficial exfoliation; nonsuperficial microdermabrasion; nonsuperficial dermaplane exfoliation; nonsuperficial lymphatic drainage; collagen induction therapy (microneedling); fat-freezing treatment (cool sculpting); botox injections; collagen injections; and tattoo removal.

"Medical director" means a physician who assumes the role of, or holds oneself out as, medical director at a medical spa. The medical director is responsible for implementing policies and procedures to ensure quality patient care and for the delegation and supervision of medical aesthetic services performed by qualified licensed or certified nonphysician persons or qualified laser technicians at a medical spa. The medical director is ultimately responsible for all medical aesthetic services performed by qualified licensed or certified nonphysician persons or qualified laser technicians at a medical spa.

"Medical spa" means any entity, however organized, that is advertised, announced, established, or maintained for the purpose of providing medical aesthetic services. Medical spa shall not include a dermatology practice that is wholly owned and controlled by one or more Iowa-licensed physicians if at least one of the owners is actively practicing at each location.

"Nonsuperficial" means that the therapy alters or damages or is capable of altering or damaging living tissue below the superficial epidermal cells.

"Qualified laser technician" means any person, licensed or unlicensed, who has successfully completed a minimum of 120 hours of training, including a minimum of 40 hours of didactic study and 80 hours of clinical training, in the safe and effective use of lasers in the performance of medical aesthetic services at an accredited laser training program. For the purposes of this rule, a qualified laser technician may only use lasers in the performance of delegated medical aesthetic services under the supervision of a qualified supervising physician at a medical spa. An unlicensed qualified laser technician may not perform any other medical aesthetic services defined in this rule.

"Qualified licensed or certified nonphysician person" means any person who is not licensed to practice medicine and surgery or osteopathic medicine and surgery but who is licensed or certified by another health- or skin care-related licensing board in Iowa and is qualified to perform delegated medical aesthetic services under the supervision of a qualified supervising physician at a medical spa.

"Supervision" means the oversight of qualified licensed or certified nonphysician persons or qualified laser technicians who perform medical aesthetic services delegated by a medical director.

13.6(2) *Delegation by a medical director.* A medical aesthetic service shall only be performed by qualified licensed or certified nonphysician persons or qualified laser technicians if the service has been delegated by a medical director who is responsible for supervision of the services performed at a medical spa in Iowa. Nothing in this rule shall be interpreted to prevent a qualified nonphysician licensed health professional from serving as a medical director at a medical spa or from appropriately delegating medical aesthetic services pursuant to the rules of the professional's licensing authority.

13.6(3) *Medical director.* A medical director at a medical spa shall:

a. Hold an active unrestricted Iowa medical license to supervise each delegated medical aesthetic service;

b. Possess the appropriate education, training, experience and competence to safely supervise each delegated medical aesthetic service;

c. Retain responsibility for the supervision of each medical aesthetic service performed by qualified licensed or certified nonphysician persons or qualified laser technicians;

d. Ensure that advertising activities do not include false, misleading, or deceptive representations; and

e. Be clearly identified as the medical director in all advertising activities, Internet websites and signage related to the medical spa.

13.6(4) *Delegated medical aesthetic service.* When a medical director delegates a medical aesthetic service to qualified licensed or certified nonphysician persons or qualified laser technicians, the service shall be:

a. Within the medical director's scope of practice and medical competence to supervise;

b. Of the type that a reasonable and prudent physician would conclude is within the scope of sound medical judgment to delegate; and

c. A routine and technical service, the performance of which does not require the skill of a licensed physician.

13.6(5) *Supervision.* A medical director who delegates performance of a medical aesthetic service to qualified licensed or certified nonphysician persons or qualified laser technicians is responsible for providing appropriate supervision. The medical director shall:

a. Ensure that all licensed or certified nonphysician persons or qualified laser technicians are qualified and competent to safely perform each delegated medical aesthetic service by personally assessing the person's education, training, experience and ability;

b. Ensure that a qualified licensed or certified nonphysician person does not perform any medical aesthetic services that are beyond the scope of that person's license or certification unless the person is supervised by a qualified supervising physician or other qualified supervising nonphysician licensed health professional;

c. Ensure that all qualified licensed or certified nonphysician persons or qualified laser technicians receive direct, in-person, on-site supervision from the medical director or other qualified licensed physician or other qualified supervising nonphysician licensed health professional at least four hours each week and that the regular supervision is documented;

d. Provide on-site review of medical aesthetic services performed by qualified licensed or certified nonphysician persons or qualified laser technicians each week and review at least 10 percent of patient charts for medical aesthetic services performed by qualified licensed or certified nonphysician persons or qualified laser technicians;

e. Be physically located, at all times, within 60 miles of the location where delegated medical aesthetic services are performed;

f. Be available, in person or electronically, at all times, to consult with qualified licensed or certified nonphysician persons or qualified laser technicians who perform delegated medical aesthetic services, particularly in case of injury or an emergency;

g. Assess the legitimacy and safety of all equipment or other technologies being used by qualified licensed or certified nonphysician persons or qualified laser technicians who perform delegated medical aesthetic services;

h. Develop and implement protocols for responding to emergencies or other injuries suffered by persons receiving delegated medical aesthetic services performed by qualified licensed or certified nonphysician persons or qualified laser technicians;

i. Ensure that all qualified licensed or certified nonphysician persons or qualified laser technicians maintain accurate and timely medical records for the delegated medical aesthetic services they perform;

j. Ensure that each patient provides appropriate informed consent for medical aesthetic services performed by the medical director or other qualified licensed physician and all qualified licensed or certified nonphysician persons or qualified laser technicians and that such informed consent is timely documented in the patient's medical record;

k. Ensure that the identity and licensure and certification of the medical director, other qualified licensed physicians, and all qualified licensed or certified nonphysician persons or qualified laser technicians are visibly displayed at each medical spa where they perform medical aesthetic services and provided in writing to each patient receiving medical aesthetic services at a medical spa; and

l. Ensure that the board receives written verification of the education and training of all qualified licensed or certified nonphysician persons or qualified laser technicians who perform delegated medical aesthetic services at a medical spa, within 14 days of a request by the board.

13.6(6) *Continuing medical education.* A medical director shall complete and shall ensure that all other physicians, qualified licensed or certified nonphysician persons, and qualified laser technicians who practice at the medical spa complete a minimum of 20 hours of continuing medical education in the safe and effective performance of medical aesthetic services each year.

13.6(7) *Exceptions.* This rule is not intended to apply to physicians who serve as medical directors of licensed medical facilities, clinics or practices that provide medical aesthetic services as part of or incident to their other medical services.

13.6(8) *Other qualified nonphysician licensed health professionals.* Nothing in this rule shall be interpreted to contradict or supersede the rules established in 481—Chapters 617, 621, 780 and 781.

653—13.7(147,148,272C) Standards of practice—interventional chronic pain management. This rule establishes standards of practice for the practice of interventional chronic pain management. The purpose of this rule is to assist physicians who consider interventional techniques to treat patients with chronic pain.

13.7(1) *Definition.* As used in this rule:

"Interventional chronic pain management" means diagnosing and treating pain-related disorders using interventional techniques for subacute, chronic, persistent, and intractable pain. These techniques include percutaneous needle placement for drug injection, nerve ablation, and certain surgeries. Common procedures involve injecting steroids, analgesic, and anesthetics into targeted areas such as the spine, joints, or nerves. This may include lumbar, thoracic, and cervical spine injections; nerve blocks; and processes like vertebroplasty. Fluoroscopy is used to assess chronic pain causes or aid in identifying anatomical landmarks during these techniques. Specific procedures include joint injections, nerve blocks, epidural injections, and nerve destruction.

13.7(2) *Interventional chronic pain management.* The practice of interventional chronic pain management shall include the following:

a. Comprehensive assessment of the patient;

b. Diagnosis of the cause of the patient's pain;

c. Evaluation of alternative treatment options;

d. Selection of appropriate treatment options;
e. Termination of prescribed treatment options when appropriate;
f. Follow-up care; and
g. Collaboration with other health care providers.

13.7(3) *Practice of medicine.* Interventional chronic pain management is the practice of medicine.

653—13.8(147,148,272C) Standards of practice—physicians who prescribe or administer abortion-inducing drugs.

13.8(1) *Definition.* As used in this rule:

"Abortion-inducing drug" means a drug, medicine, mixture, or preparation, when it is prescribed or administered with the intent to terminate the pregnancy of a woman known to be pregnant.

13.8(2) *Review of patient record.* A physician shall not induce an abortion by providing an abortion-inducing drug unless the physician has first reviewed the lab results, ultrasound images, and medical history provided by the patient to determine, and document in the woman's medical record, the gestational age and intrauterine location of the pregnancy. A physician may utilize telemedicine pursuant to rule 653—13.9(147,148,272C).

13.8(3) *Follow-up appointment required.* If an abortion is induced by an abortion-inducing drug, the physician or designee shall use all reasonable efforts to ensure a follow-up appointment is scheduled with the patient at the same facility within 12 to 18 days after the patient's use of an abortion-inducing drug to confirm the termination of the pregnancy and evaluate the woman's medical condition.

13.8(4) *Parental notification regarding pregnant minors.* A physician shall not induce an abortion by providing an abortion-inducing drug to a pregnant minor prior to compliance with the requirements of Iowa Code chapter 135L and rules 641—89.12(135L) and 641—89.21(135L).

653—13.9(147,148,272C) Standards of practice—telemedicine. This rule establishes standards of practice for the practice of medicine using telemedicine.

13.9(1) *Definitions.* As used in this rule:

"Asynchronous store-and-forward transmission" means the collection of a patient's relevant health information and the subsequent transmission of the data from an originating site to a health care provider at a distant site without the presence of the patient.

"Board" means the Iowa board of medicine.

"In-person encounter" means that the physician and the patient are in the physical presence of each other and are in the same physical location during the physician-patient encounter.

"Licensee" means a medical physician or osteopathic physician licensed by the board.

"Telemedicine" means the practice of medicine using electronic audio-visual communications and information technologies or other means, including interactive audio with asynchronous store-and-forward transmission, between a licensee in one location and a patient in another location with or without an intervening health care provider. Telemedicine includes asynchronous store-and-forward technologies, remote monitoring, and real-time interactive services, including teleradiology and telepathology. Telemedicine shall not include the provision of medical services only through an audio-only telephone, email messages, facsimile transmissions, or U.S. mail or other parcel service, or any combination thereof.

"Telemedicine technologies" means technologies and devices enabling secure electronic communications and information exchanges between a licensee in one location and a patient in another location with or without an intervening health care provider.

13.9(2) *Practice guidelines.* A licensee who uses telemedicine shall utilize evidence-based telemedicine practice guidelines and standards of practice, to the degree they are available, to ensure patient safety, quality of care, and positive outcomes. The board acknowledges that some nationally recognized medical specialty organizations have established comprehensive telemedicine practice

guidelines that address the clinical and technological aspects of telemedicine for many medical specialties.

13.9(3) *Iowa medical license required.* A physician who uses telemedicine in the diagnosis and treatment of a patient located in Iowa shall hold an active Iowa medical license consistent with state and federal laws. Nothing in this rule shall be construed to supersede the exceptions to licensure contained in 653—subrule 9.2(2).

13.9(4) *Standards of care and professional ethics.* A licensee who uses telemedicine is held to the same standards of care and professional ethics as a licensee using traditional in-person encounters with patients. Failure to conform to the appropriate standards of care or professional ethics while using telemedicine may be a violation of the laws and rules governing the practice of medicine and may subject the licensee to potential discipline by the board.

13.9(5) *Scope of practice.* A licensee who uses telemedicine shall ensure that the services provided are consistent with the licensee's scope of practice, including the licensee's education, training, experience, ability, licensure, and certification.

13.9(6) *Identification of patient and physician.* A licensee who uses telemedicine shall verify the identity of the patient and ensure that the patient has the ability to verify the identity, licensure status, certification, and credentials of all health care providers who provide telemedicine services prior to the provision of care.

13.9(7) *Physician-patient relationship.*

a. A licensee who uses telemedicine shall establish a valid physician-patient relationship with the person who receives telemedicine services. The physician-patient relationship begins when:

(1) The person with a health-related matter seeks assistance from a licensee;

(2) The licensee agrees to undertake diagnosis and treatment of the person; and

(3) The person agrees to be treated by the licensee whether or not there has been an in-person encounter between the physician and the person.

b. A valid physician-patient relationship may be established by:

(1) In-person encounter. Through an in-person medical interview and physical examination where the standard of care would require an in-person encounter;

(2) Consultation with another licensee. Through consultation with another licensee (or other health care provider) who has an established relationship with the patient and who agrees to participate in, or supervise, the patient's care; or

(3) Telemedicine encounter. Through telemedicine, if the standard of care does not require an in-person encounter, and in accordance with evidence-based standards of practice and telemedicine practice guidelines that address the clinical and technological aspects of telemedicine.

13.9(8) *Medical history and physical examination.* Generally, a licensee shall perform an in-person medical interview and physical examination for each patient. However, the medical interview and physical examination may not be in-person if the technology utilized in a telemedicine encounter is sufficient to establish an informed diagnosis as though the medical interview and physical examination had been performed in-person. Prior to providing treatment, including issuing prescriptions, electronically or otherwise, a licensee who uses telemedicine shall interview the patient to collect the relevant medical history and perform a physical examination, when medically necessary, sufficient for the diagnosis and treatment of the patient. An Internet questionnaire that is a static set of questions provided to the patient, to which the patient responds with a static set of answers, in contrast to an adaptive, interactive and responsive online interview, does not constitute an acceptable medical interview and physical examination for the provision of treatment, including issuance of prescriptions, electronically or otherwise, by a licensee.

13.9(9) *Nonphysician health care providers.* If a licensee who uses telemedicine relies upon or delegates the provision of telemedicine services to a nonphysician health care provider, the licensee shall:

a. Ensure that systems are in place to ensure that the nonphysician health care provider is qualified and trained to provide that service within the scope of the nonphysician health care provider's practice;

b. Ensure that the licensee is available in person or electronically to consult with the nonphysician health care provider, particularly in the case of injury or an emergency.

13.9(10) *Informed consent.* A licensee who uses telemedicine shall ensure that the patient provides appropriate informed consent for the medical services provided, including consent for the use of telemedicine to diagnose and treat the patient, and that such informed consent is timely documented in the patient's medical record.

13.9(11) *Coordination of care.* A licensee who uses telemedicine shall, when medically appropriate, identify the medical home or treating physician(s) for the patient, when available, where in-person services can be delivered in coordination with the telemedicine services. The licensee shall provide a copy of the medical record to the patient's medical home or treating physician(s).

13.9(12) *Follow-up care.* A licensee who uses telemedicine shall have access to, or adequate knowledge of, the nature and availability of local medical resources to provide appropriate follow-up care to the patient following a telemedicine encounter.

13.9(13) *Emergency services.* A licensee who uses telemedicine shall refer a patient to an acute care facility or an emergency department when referral is necessary for the safety of the patient or in the case of an emergency.

13.9(14) *Medical records.* A licensee who uses telemedicine shall ensure that complete, accurate and timely medical records are maintained for the patient when appropriate, including all patient-related electronic communications, records of past care, physician-patient communications, laboratory and test results, evaluations and consultations, prescriptions, and instructions obtained or produced in connection with the use of telemedicine technologies. The licensee shall note in the patient's record when telemedicine is used to provide diagnosis and treatment. The licensee shall ensure that the patient or another licensee designated by the patient has timely access to all information obtained during the telemedicine encounter. The licensee shall ensure that the patient receives, upon request, a summary of each telemedicine encounter in a timely manner.

13.9(15) *Privacy and security.* A licensee who uses telemedicine shall ensure that all telemedicine encounters comply with the privacy and security measures of the Health Insurance Portability and Accountability Act of 1996, Pub.L. 104-191, August 21, 1996, 110 Stat. 1936, and any amendments as of October 16, 2024, to ensure that all patient communications and records are secure and remain confidential.

a. Written protocols shall be established that address the following:

(1) Privacy;

(2) Health care personnel who will process messages;

(3) Hours of operation;

(4) Types of transactions that will be permitted electronically;

(5) Required patient information to be included in the communication, including patient name, identification number and type of transaction;

(6) Archiving and retrieval; and

(7) Quality oversight mechanisms.

b. The written protocols should be periodically evaluated for currency and should be maintained in an accessible and readily available manner for review. The written protocols shall include sufficient privacy and security measures to ensure the confidentiality and integrity of patient-identifiable information, including password protection, encryption or other reliable authentication techniques.

13.9(16) *Technology and equipment.* The board recognizes that three broad categories of telemedicine technologies currently exist, including asynchronous store-and-forward technologies, remote monitoring, and real-time interactive services. While some telemedicine programs are multispecialty in nature, others are tailored to specific diseases and medical specialties. The technology and equipment utilized for telemedicine shall comply with the following requirements:

a. Comply with relevant safety laws, rules, regulations, and codes for technology and technical safety for devices that interact with patients or are integral to diagnostic capabilities;

b. Be of sufficient quality, size, resolution and clarity such that the licensee can safely and effectively provide the telemedicine services; and

c. Be compliant with the Health Insurance Portability and Accountability Act of 1996, Pub.L. 104-191, August 21, 1996, 110 Stat. 1936, and any amendments as of October 16, 2024.

13.9(17) *Disclosure and functionality of telemedicine services.* A licensee who uses telemedicine shall ensure that the following information is clearly disclosed to the patient:

a. Types of services provided;

b. Contact information for the licensee;

c. Identity, licensure, certification, credentials, and qualifications of all health care providers who are providing the telemedicine services;

d. Limitations in the drugs and services that can be provided via telemedicine;

e. Fees for services, cost-sharing responsibilities, and how payment is to be made, if these differ from an in-person encounter;

f. Financial interests, other than fees charged, in any information, products, or services provided by the licensee(s);

g. Appropriate uses and limitations of the technologies, including in emergency situations;

h. Uses of and response times for emails, electronic messages and other communications transmitted via telemedicine technologies;

i. To whom patient health information may be disclosed and for what purpose;

j. Rights of patients with respect to patient health information; and

k. Information collected and passive tracking mechanisms utilized.

13.9(18) *Patient access and feedback.* A licensee who uses telemedicine shall ensure that the patient has easy access to a mechanism for the following purposes:

a. To access, supplement and amend patient-provided personal health information;

b. To provide feedback regarding the quality of the telemedicine services provided; and

c. To register complaints. The mechanism shall include information regarding the filing of complaints with the board.

13.9(19) *Financial interests.* Advertising or promotion of goods or products from which the licensee(s) receives direct remuneration, benefit or incentives (other than the fees for the medical services) is prohibited to the extent that such activities are prohibited by state or federal law. Notwithstanding such prohibition, Internet services may provide links to general health information sites to enhance education; however, the licensee(s) should not benefit financially from providing such links or from the services or products marketed by such links. When providing links to other sites, licensees should be aware of the implied endorsement of the information, services or products offered from such sites. The maintenance of a preferred relationship with any pharmacy is prohibited. Licensees shall not transmit prescriptions to a specific pharmacy, or recommend a pharmacy, in exchange for any type of consideration or benefit from the pharmacy.

13.9(20) *Circumstances where the standard of care may not require a licensee to personally interview or examine a patient.* Under the following circumstances, whether or not such circumstances involve the use of telemedicine, a licensee may treat a patient who has not been personally interviewed, examined and diagnosed by the licensee:

a. Situations in which the licensee prescribes medications on a short-term basis for a new patient and has scheduled or is in the process of scheduling an appointment to personally examine the patient;

b. For institutional settings, including writing initial admission orders for a newly hospitalized patient;

c. Call situations in which a licensee is taking call for another licensee who has an established physician-patient relationship with the patient;

d. Cross-coverage situations in which a licensee is taking call for another licensee who has an established physician-patient relationship with the patient;

e. Situations in which the patient has been examined in person by an advanced registered nurse practitioner or a physician assistant or other licensed practitioner with whom the licensee has a supervisory or collaborative relationship;

f. Emergency situations in which the life or health of the patient is in imminent danger;

g. Emergency situations that constitute an immediate threat to the public health including, but not limited to, empiric treatment or prophylaxis to prevent or control an infectious disease outbreak;

h. Situations in which the licensee has diagnosed a sexually transmitted disease in a patient and the licensee prescribes or dispenses antibiotics to the patient's named sexual partner(s) for the treatment of the sexually transmitted disease as recommended by the U.S. Centers for Disease Control and Prevention; and

i. For licensed or certified nursing facilities, residential care facilities, intermediate care facilities, assisted living facilities and hospice settings.

13.9(21) *Prescribing based solely on an Internet request, Internet questionnaire or a telephonic evaluation—prohibited.* Prescribing to a patient based solely on an Internet request or Internet questionnaire (i.e., a static questionnaire provided to a patient, to which the patient responds with a static set of answers, in contrast to an adaptive, interactive and responsive online interview) is prohibited. Absent a valid physician-patient relationship, a licensee's prescribing to a patient based solely on a telephonic evaluation is prohibited, with the exception of the circumstances described in subrule 13.9(20).

653—13.10(135,147,148,272C,280) Standards of practice—prescribing epinephrine auto-injectors, bronchodilator canisters, bronchodilator canisters and spacers, or opioid antagonists in the name of an authorized facility.

13.10(1) Definition. For purposes of this rule:

"Authorized facility" means a facility as defined in Iowa Code section 135.185(1), a school district, or an accredited nonpublic school.

13.10(2) Notwithstanding any other provision of law to the contrary, a physician may prescribe epinephrine auto-injectors, bronchodilator canisters, bronchodilator canisters and spacers, or opioid antagonists in the name of an authorized facility to be maintained for use pursuant to Iowa Code sections 135.185, 135.190, 280.16 and 280.16A.

13.10(3) A physician who prescribes epinephrine auto-injectors, bronchodilator canisters, bronchodilator canisters and spacers, or opioid antagonists in the name of an authorized facility to be maintained for use pursuant to Iowa Code sections 135.185, 135.190, 280.16 and 280.16A, provided the physician has acted reasonably and in good faith, is not liable for any injury arising from the provision, administration, or assistance in the administration of an epinephrine auto-injector, bronchodilator canisters, bronchodilator canisters and spacers, or opioid antagonists.

653—13.11(144E,147,148,272C) Standards of practice—experimental treatments for patients with a terminal illness.

13.11(1) *Exemption from discipline.* To the extent consistent with state law, the board will not revoke, fail to renew, suspend, or take any action against a physician's license based solely on the physician's recommendations to an eligible patient regarding access to or treatment with an investigational drug, biological product, or device.

13.11(2) *Eligible patient.* A physician shall ensure that a patient meets all of the following conditions prior to the use of an investigational drug, biological product, or device pursuant to this rule:

a. The patient has a terminal illness, attested to by the patient's treating physician.

b. The patient has considered and rejected or has tried and failed to respond to all other treatment options approved by the U.S. Food and Drug Administration (FDA).

c. The patient has received a recommendation from the patient's physician for an investigational drug, biological product, or device.

d. The patient has given written informed consent for the use of the investigational drug, biological product, or device.

e. The patient has documentation from the patient's physician that the patient meets the requirements of this rule.

13.11(3) *Investigational drug, biological product, or device.* A physician may recommend access to or treatment with an investigational drug, biological product, or device that has successfully completed phase 1 of an FDA-approved clinical trial but has not yet been approved for general use by the FDA and remains under investigation in an FDA-approved clinical trial.

13.11(4) *Terminal illness.* A physician shall ensure that a patient has a terminal illness prior to the use of an investigational drug, biological product, or device pursuant to this rule. A terminal illness is a progressive disease or medical or surgical condition that entails significant functional impairment and that is not considered by a treating physician to be reversible even with administration of treatments approved by the FDA and that, without life-sustaining procedures, will result in death.

13.11(5) *Written informed consent.* A physician shall obtain written informed consent prior to the use of an investigational drug, biological product, or device pursuant to this rule. Written informed consent is a written document that is signed by a patient, a parent of a minor patient, or a legal guardian or other legal representative of the patient and attested to by the patient's treating physician and a witness and that includes all of the following:

a. An explanation of the products and treatments approved by the FDA for the disease or condition from which the patient suffers.

b. An attestation that the patient concurs with the patient's treating physician in believing that all products and treatments approved by the FDA are unlikely to prolong the patient's life.

c. Clear identification of the specific proposed investigational drug, biological product, or device that the patient is seeking to use.

d. A description of the best and worst potential outcomes of using the investigational drug, biological product, or device and a realistic description of the most likely outcome. The description to include the possibility that new, unanticipated, different, or worse symptoms might result and that death could be hastened by use of the proposed investigational drug, biological product, or device. The description is based on the treating physician's knowledge of the proposed investigational drug, biological product, or device in conjunction with an awareness of the patient's condition.

e. A statement that the patient's health plan or third-party administrator and provider are not obligated to pay for any care or treatments consequent to the use of the investigational drug, biological product, or device, unless the patient's health plan or third-party administrator and provider are specifically required to do so by law or contract.

f. A statement that the patient's eligibility for hospice care may be withdrawn if the patient begins curative treatment with the investigational drug, biological product, or device and that hospice care may be reinstated if treatment ends and the patient meets hospice eligibility requirements.

g. A statement that the patient understands that the patient is liable for all expenses consequent to the use of the investigational drug, biological product, or device and that this liability extends to the patient's estate unless a contract between the patient and the manufacturer of the investigational drug, biological product, or device states otherwise.

13.11(6) *Assisting suicide.* This rule is not to be construed to allow a patient's treating physician to assist the patient in committing or attempting to commit suicide as prohibited in Iowa Code section 707A.2.

13.11(7) *Grounds for discipline.* A physician may be subject to disciplinary action for violation of this rule or 653—Chapter 23. Grounds for discipline include but are not limited to the following:

a. The physician recommends access to or treatment with an investigational drug, biological product, or device to an individual who is not an eligible patient pursuant to this rule.

b. The physician fails to obtain appropriate written informed consent prior to recommending access to or treatment with an investigational drug, biological product, or device pursuant to this rule.

c. The physician assists the patient in committing or attempting to commit suicide as prohibited in Iowa Code section 707A.2.

653—13.12(147,148,272C) Standards of practice—tick-borne disease diagnosis and treatment.

13.12(1) *Exemption from discipline.* A person licensed by the board under Iowa Code chapter 148 shall not be subject to discipline under this chapter or the board's enabling statute based solely on the physician's recommendation or provision of a treatment method for Lyme disease or other tick-borne disease if the recommendation or provision of such treatment meets all the following criteria:

a. The treatment is provided after an examination is performed and informed consent is received from the patient.

b. The physician identifies a medical reason for recommending or providing the treatment.

c. The treatment is provided after the physician informs the patient about other recognized treatment options and describes to the patient the physician's education, experience, and credentials regarding the treatment of Lyme disease or other tick-borne disease.

d. The physician uses the physician's own medical judgment based on a thorough review of all available clinical information and Lyme disease or other tick-borne disease literature to determine the best course of treatment for the individual patient.

e. The treatment will not, in the opinion of the physician, result in the direct and proximate death of or serious bodily injury to the patient.

13.12(2) *Lyme disease treatment.* Most cases of Lyme disease can be treated successfully with a few weeks of antibiotics. Over the past several years, the International Lyme and Associated Diseases Society (ILADS) has supported longer courses of antibiotics for some patients, versus the prescribed treatment durations identified by the Infectious Diseases Society of America (IDSA) and referenced by the CDC. While IDSA has expressed concern about overtreatment, ILADS points out that treatment decisions should be based on a risk-benefit analysis. Both groups have published evidence-based guidelines.

13.12(3) *Tick-borne diseases.* According to the CDC, tick-borne diseases include:

a. Anaplasmosis is transmitted to humans by tick bites primarily from the blacklegged tick (*Ixodes scapularis*) in the northeastern and upper midwestern regions of the United States (U.S.) and the western blacklegged tick (*Ixodes pacificus*) along the Pacific coast.

b. Babesiosis is caused by microscopic parasites that infect red blood cells. Most human cases of babesiosis in the U.S. are caused by *Babesia microti*. *Babesia microti* is transmitted by the blacklegged tick (*Ixodes scapularis*) and is found primarily in the northeastern and upper midwestern regions of the U.S.

c. Borrelia mayonii infection has recently been described as a cause of illness in the upper midwestern region of the U.S. This infection has been found in blacklegged ticks (*Ixodes scapularis*) in Minnesota and Wisconsin. *Borrelia mayonii* is a new species and is the only species besides *B. burgdorferi* known to cause Lyme disease in North America.

d. Borrelia miyamotoi infection has recently been described as a cause of illness in the U.S. This infection is transmitted by the blacklegged tick (*Ixodes scapularis*) and has a geographic range similar to that of Lyme disease.

e. Bourbon virus infection has been identified in a limited number of patients in the midwestern and southern regions of the U.S. At this time, it is not known if the virus might be found in other areas of the U.S.

f. Colorado tick fever is caused by a virus transmitted by the Rocky Mountain wood tick (*Dermacentor andersoni*). Colorado tick fever occurs in the Rocky Mountain states at elevations of 4,000 to 10,500 feet.

g. Ehrlichiosis is transmitted to humans by the lone star tick (*Amblyomma americanum*), found primarily in the south central and eastern regions of the U.S.

h. *Heartland virus* cases have been identified in the midwestern and southern regions of the U.S. Studies suggest that lone star ticks (*Amblyomma americanum*) can transmit the virus. It is unknown if the virus may be found in other areas of the U.S.

i. *Lyme disease* is transmitted by the blacklegged tick (*Ixodes scapularis*) in the northeastern and upper midwestern regions of the U.S. and by the western blacklegged tick (*Ixodes pacificus*) along the Pacific coast.

j. *Powassan disease* is transmitted by the blacklegged tick (*Ixodes scapularis*) and the groundhog tick (*Ixodes cookei*). Cases have been reported primarily from northeastern states and the Great Lakes region.

k. *Rickettsia parkeri rickettsiosis* is transmitted to humans by the Gulf Coast tick (*Amblyomma maculatum*).

l. *Rocky Mountain spotted fever* is transmitted by the American dog tick (*Dermacentor variabilis*), Rocky Mountain wood tick (*Dermacentor andersoni*), and the brown dog tick (*Rhipicephalus sanguineus*) in the U.S. The brown dog tick and other tick species are associated with Rocky Mountain spotted fever in Central America and South America.

m. *Southern tick-associated rash illness* is transmitted via bites from the lone star tick (*Amblyomma americanum*) found in the southeastern and eastern regions of the U.S.

n. *Tick-borne relapsing fever* is transmitted to humans through the bite of infected soft ticks. Tick-borne relapsing fever has been reported in 15 states: Arizona, California, Colorado, Idaho, Kansas, Montana, Nevada, New Mexico, Ohio, Oklahoma, Oregon, Texas, Utah, Washington, and Wyoming and is associated with sleeping in rustic cabins and vacation homes.

o. *Tularemia* is transmitted to humans by the dog tick (*Dermacentor variabilis*), the wood tick (*Dermacentor andersoni*), and the lone star tick (*Amblyomma americanum*). Tularemia occurs throughout the U.S.

p. *364D rickettsiosis* (*Rickettsia phillipi*) is transmitted to humans by the Pacific Coast tick (*Dermacentor occidentalis*). This is a new disease that has been found in California.

13.12(4) *Grounds for discipline.* A physician may be subject to disciplinary action for violation of these rules or the rules found in 653—Chapter 23. Grounds for discipline include, but are not limited to, the following:

a. The physician fails to perform and document an appropriate examination or fails to obtain and document appropriate informed consent from the patient.

b. The physician fails to identify and document a medical reason for recommending or providing the treatment.

c. The physician fails to inform the patient about other recognized treatment options or fails to describe to the patient the physician's education, experience, and credentials regarding the treatment of Lyme disease or other tick-borne diseases.

d. The physician fails to use the physician's own medical judgment based on a thorough review of all available clinical information and Lyme disease or other tick-borne disease literature to determine the best course of treatment for the individual patient.

e. The treatment provided, in the opinion of the physician, will likely result in the direct and proximate death of or serious bodily injury to the patient.

653—13.13(124E,147,148,272C) Standards of practice—medical cannabidiol.

13.13(1) *Definitions.* For purposes of this rule:

"Bordering state" means the same as defined in Iowa Code section 331.910.

"Debilitating medical condition" means any of the following:

1. Cancer, if the underlying condition or treatment produces one or more of the following:
- Severe or chronic pain.
- Nausea or severe vomiting.
- Cachexia or severe wasting.

2. Multiple sclerosis with severe and persistent muscle spasms.

3. Seizures, including those characteristic of epilepsy.
4. AIDS or HIV as defined in Iowa Code section 141A.1.
5. Crohn's disease.
6. Amyotrophic lateral sclerosis.
7. Any terminal illness, with a probable life expectancy of under one year, if the illness or its treatment produces one or more of the following:

- Severe or chronic pain.
- Nausea or severe vomiting.
- Cachexia or severe wasting.

8. Parkinson's disease.
9. Chronic pain.
10. Ulcerative colitis.
11. Severe, intractable autism with self-injurious or aggressive behaviors.
12. Corticobasal degeneration.
13. Post-traumatic stress disorder.

"Department" means the Iowa department of public health.

"Form and quantity" means the types and amounts of medical cannabidiol allowed to be dispensed to a patient or primary caregiver as approved by the department subject to recommendation by the medical cannabidiol board and approval by the board of medicine.

"Medical cannabidiol" means any pharmaceutical grade cannabinoid found in the plant *Cannabis sativa* L. or *Cannabis indica* or any other preparation thereof that is delivered in a form recommended by the medical cannabidiol board, approved by the board of medicine, and adopted by the department pursuant to rule.

"Medical cannabidiol board" means the board established pursuant to Iowa Code section 124E.5.

"Primary caregiver" means a person who is a resident of this state or a bordering state, including but not limited to a parent or legal guardian, at least 18 years of age, who has been designated by a patient's health care practitioner as a necessary caretaker taking responsibility for managing the well-being of the patient with respect to the use of medical cannabidiol pursuant to the provisions of this chapter.

"Untreatable pain" means any pain whose cause cannot be removed and, according to generally accepted medical practice, the full range of pain management modalities appropriate for the patient has been used without adequate result or with intolerable side effects.

"Written certification" means a document signed by a physician licensed pursuant to Iowa Code chapter 148 with whom the patient has established a patient-physician relationship and who is the patient's primary care provider that states that the patient has a debilitating medical condition and identifies that condition and provides any other relevant information.

13.13(2) *Written certification.* A physician who is a patient's primary care provider may provide the patient a written certification of diagnosis if, after examining and treating the patient, the physician determines, in the physician's medical judgment, that the patient suffers from a debilitating medical condition that qualifies for the use of medical cannabidiol pursuant to Iowa Code chapter 124E.

a. The physician shall provide explanatory information as provided by the department to the patient about the therapeutic use of medical cannabidiol and the possible risks, benefits, and side effects of the proposed treatment.

b. Subsequently, the physician shall do the following:

(1) Determine, on an annual basis, if the patient continues to suffer from a debilitating medical condition and, if so, may issue the patient a new written certification of that diagnosis.

(2) Otherwise comply with all requirements established by the department pursuant to rule.

c. A physician may provide, but has no duty to provide, a written certification pursuant to this rule.

13.13(3) *Adding or removing debilitating medical conditions and amending form and quantity of medical cannabidiol.* Recommendations made by the medical cannabidiol board pursuant to Iowa

Code section 124E.5 relating to the addition or removal of allowable debilitating medical conditions for which the medical use of cannabidiol would be medically beneficial or to the amendment of the form and quantity of allowable medical uses of cannabidiol shall be made to the board of medicine for consideration. The medical cannabidiol board shall submit a written recommendation, a copy of the petition and all other information received during consideration of the petition. The board of medicine shall consider the information received from the medical cannabidiol board and may seek information from other sources if it is deemed relevant by the board of medicine. The decision regarding a recommendation by the medical cannabidiol board is at the sole discretion of the board of medicine. The board of medicine shall make its decision within 180 days of receipt of the recommendation from the medical cannabidiol board. If the recommendation is approved by the board of medicine, it shall be adopted by rule.

13.13(4) *Financial interests.* A physician shall not share office space with, accept referrals from, or have any financial relationship with a medical cannabidiol manufacturer or dispensary.

13.13(5) *Criminal prosecution.* A physician, including any authorized agent or employee thereof, shall not be subject to prosecution for the unlawful certification, possession, or administration of marijuana under the laws of this state for activities arising directly out of or directly related to the certification or use of medical cannabidiol in the treatment of a patient diagnosed with a debilitating medical condition as authorized by Iowa Code chapter 124E.

13.13(6) *Civil or disciplinary penalties.* A physician, including any authorized agent or employee thereof, shall not be subject to any civil or disciplinary penalties by the board of medicine or any business, occupational, or professional licensing board or entity, solely for activities conducted relating to a patient's possession or use of medical cannabidiol as authorized by Iowa Code chapter 124E. Nothing in this rule prevents the board of medicine from taking action in response to violations of any other sections of law or rule.

13.13(7) *Grounds for discipline.* A physician may be subject to disciplinary action for violation of these rules or the rules found in 653—Chapter 23. Grounds for discipline include but are not limited to the following:

a. The physician provides an individual a written certification without establishing a patient-physician relationship, including examining and treating the individual, or without being the individual's primary care provider.

b. The physician provides a patient a written certification without determining, in the physician's medical judgment, that the patient suffers from a debilitating medical condition that qualifies for the use of medical cannabidiol pursuant to Iowa Code chapter 124E.

c. The physician provides a patient a written certification without providing explanatory information as provided by the department to the patient about the therapeutic use of medical cannabidiol and the possible risks, benefits, and side effects of the proposed treatment.

d. The physician provides an individual a new written certification without determining, on an annual basis, that the patient continues to suffer from a debilitating medical condition.

e. The physician shares office space with, accepts referrals from, or has a financial relationship with a medical cannabidiol manufacturer or dispensary.

653—13.14(146A) Abortion prerequisites.

13.14(1) *Written certification.* At least 24 hours prior to performing an abortion, a physician shall obtain written certification from the pregnant woman of each prerequisite as required in Iowa Code sections 146A.1(1)*"a"* through 146A.1(1)*"d"*(1). The written certification shall list each required prerequisite separately and shall include a line for date and signature of the pregnant woman. The physician shall maintain a copy of the certification as part of the pregnant woman's medical records.

13.14(2) *Exceptions.* This rule shall not apply to abortions performed in a medical emergency, as provided in Iowa Code section 146A.1(2).

13.14(3) *Discipline.* Failure to comply with this rule or the requirements of Iowa Code section 146A.1 may constitute grounds for discipline.

653—13.15(135L,146A,146E,147,148,272C) Standards of practice for physicians who perform or induce abortions—definitions—detection of fetal heartbeat—fetal heartbeat exceptions—discipline.

13.15(1) *Standards of practice.* This rule sets forth the standards of practice for physicians who perform or induce abortions. More information is contained in Iowa Code section 146E.2(5).

13.15(2) *Definitions.* As used in this rule or in Iowa Code chapter 146E:

"Private health agency" means any establishment, facility, organization, or other entity that is not owned by a federal, state, or local government that either is a health care provider or employs or provides the services of a health care provider. Establishments, facilities, organizations, or other entities that are health care providers include the following:

1. A hospital as defined in Iowa Code section 135B.1;
2. A health care facility as defined in Iowa Code section 135C.1;
3. A health facility as defined in Iowa Code section 135P.1; or
4. A similar entity that either is a health care provider or employs or provides the services of a health care provider.

"Public health agency" means any establishment; facility; organization; administrative division; or entity that is owned by a federal, state, or local government that either is a health care provider or employs or provides the services of a health care provider. Establishments, facilities, organizations, administrative divisions, or other entities that are health care providers include the following:

1. A hospital as defined in Iowa Code section 135B.1;
2. A health care facility as defined in Iowa Code section 135C.1;
3. A health facility as defined in Iowa Code section 135P.1; or
4. A similar entity that either is a health care provider or employs or provides the services of a health care provider.

"Standard medical practice" means the degree of skill, care, and diligence that a physician of the same medical specialty would employ in like circumstances. As applied to the method used to determine the presence of a fetal heartbeat for purposes of Iowa Code chapter 146E and this rule, "standard medical practice" includes employing the appropriate means of detection depending on the estimated gestational age of the unborn child and the condition of the woman and her pregnancy.

"The pregnancy is the result of a rape" means a circumstance in which the pregnancy is the result of conduct that would constitute an offense under Iowa Code section 709.2, 709.3, 709.4, or 709.4A when perpetrated against a female, regardless of where the conduct occurred.

"The pregnancy is the result of incest" means a circumstance in which a sex act occurs between closely related persons that involves a vaginal penetration that causes a pregnancy. The closely related persons must be related, either legitimately or illegitimately, as an ancestor, descendant, brother or sister of the whole or half blood, aunt, uncle, niece, or nephew. For purposes of this rule, a closely related person includes a stepparent, stepchild, or stepsibling, including siblings through adoption.

"Unborn child" means an individual organism of the species *Homo sapiens* from fertilization to live birth—that is, at all stages of development, including embryo and fetus.

"Woman" means a female individual regardless of her age.

13.15(3) *Detection of fetal heartbeat.* A physician who intends to perform or induce an abortion must determine via ultrasound whether the woman is carrying an unborn child with a detectable fetal heartbeat.

a. Obligation. The obligation under this rule requires a bona fide effort to detect a fetal heartbeat in the unborn child. This effort must be made in good faith and according to standard medical practice and reasonable medical judgment.

b. Method. The physician shall perform a transabdominal pelvic ultrasound on the woman to determine whether the unborn child has a detectable fetal heartbeat. This shall be performed in a

manner consistent with standard medical practice, with real-time ultrasound equipment with a transducer of appropriate frequency. The equipment must be properly maintained and in proper functioning order.

13.15(4) *Fetal heartbeat exceptions.* The following applies to a physician who intends to perform or induce an abortion under a fetal heartbeat exception as defined in Iowa Code chapter 146E and this rule:

a. Incest or rape. For purposes of this rule, a pregnancy resulting from incest or rape may be reported within the appropriate time frame to a licensed physician whose services are retained for an abortion procedure.

(1) To determine whether the pregnancy is the result of incest, a physician who intends to perform or induce an abortion must use the following information:

1. Whether the sex act occurred between the woman and a closely related person, meaning, either legitimately or illegitimately, an ancestor, descendant, brother or sister of the whole or half blood, aunt, uncle, niece, or nephew, including a stepparent, stepchild, or stepsibling to include an adopted sibling.
2. The date the act occurred.
3. If initial reporting was to someone other than the physician who intends to perform or induce an abortion, the date the act was reported to a law enforcement agency, public health agency, private health agency, or family physician.

The physician who intends to perform or induce an abortion shall use this information to determine whether the fetal heartbeat exception for incest applies. This information does not prescribe the manner in which the physician is to obtain this information. This information and its source shall be documented in the woman's medical records.

The physician who intends to perform or induce an abortion may rely on the information received upon a good-faith assessment that the information is true. The physician who intends to perform or induce an abortion may require the person providing the information to sign a certification form attesting that the information is true.

(2) To determine whether the pregnancy is the result of a rape, a physician who intends to perform or induce an abortion must use the following information:

1. The date the sex act that caused the pregnancy occurred.
2. The age of the woman seeking an abortion at the time of that sex act.
3. Whether the sex act constituted a rape.
4. Whether the rape was perpetrated against the woman seeking an abortion.
5. If initial reporting was to someone other than the physician who intends to perform or induce an abortion, the date the rape was reported to a law enforcement agency, public health agency, private health agency, or family physician.

The physician who intends to perform or induce an abortion shall use this information to determine whether the fetal heartbeat exception for rape applies. This rule does not prescribe the manner in which the physician is to obtain this information. This information and its source shall be documented in the woman's medical records.

The physician who intends to perform or induce an abortion may rely on the information received upon a good-faith assessment that the information is true. The physician who intends to perform or induce an abortion may require the person providing the information to sign a certification form attesting that the information is true.

b. Fetal abnormality. A certification from an attending physician that a fetus has a fetal abnormality that in the attending physician's reasonable medical judgment is incompatible with life must contain the following information:

(1) The diagnosis of the abnormality;

(2) The basis for the diagnosis, including the tests and procedures performed, the results of those tests and procedures, and why those results support the diagnosis; and

(3) A description of why the abnormality is incompatible with life.

The diagnosis and the attending physician's conclusion must be reached in good faith following a bona fide effort, consistent with standard medical practice and reasonable medical judgment, to determine the health of the fetus. The certification must be signed by the attending physician. A physician who intends to perform or induce an abortion may rely in good faith on a certification from an attending physician if the physician who intends to perform or induce an abortion has a copy of the certification. The certification must be included in the woman's medical records by the physician who intends to perform or induce an abortion.

13.15(5) *Discipline.* Failure to comply with this rule or the requirements of Iowa Code chapter 146E may constitute grounds for discipline.

653—13.16(147,148) Principles of medical ethics. The Code of Medical Ethics (2002-2003) prepared and approved by the American Medical Association and the Code of Ethics (2002-2003) prepared and approved by the American Osteopathic Association is utilized by the board as guiding principles in the practice of medicine and surgery and osteopathic medicine and surgery in this state.

13.16(1) *Conflict of interest.* A physician should not provide medical services under terms or conditions that tend to interfere with or impair the free and complete exercise of the physician's medical judgment and skill or tend to cause a deterioration of the quality of medical care.

13.16(2) *Fees.* Any fee charged by a physician shall be reasonable.

653—13.17(147A) Emergency medical care provider. A physician with a license in good standing may be staffed on an authorized emergency medical services (EMS) program provided the physician can document equivalency through education and additional skills training essential in the delivery of out-of-hospital emergency care. The equivalency shall be accepted when documentation has been reviewed and approved at the local level by the medical director of the authorized EMS service program and the department of health and human services bureau of emergency medical and trauma services in accordance with the form adopted by the department of health and human services.

These rules are intended to implement Iowa Code chapters 124, 124E, 144E, 146E, 148 and 272C and sections 147.55, 148.6, 147.107, 272C.3 and 272C.4.