CHAPTER 13
STANDARDS OF PRACTICE AND PRINCIPLES OF MEDICAL ETHICS

[Prior to 5/4/88, see 470—135.251 to 470—135.402]

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 which meets the requirements of the Poison Prevention Packaging Act of 1970, 15 U.S.C. ss. 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. ss. 301 et seq. (2001).

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

1. The name and address of the physician.
2. The name of the patient.
3. The date dispensed.
4. The directions for administering the prescription drug and any cautionary statement deemed appropriate by the physician.
5. 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) A physician shall keep a record of all prescription drugs dispensed by the physician to a patient which shall contain the information required by subrule 13.1(2) to be included on the label. Noting such information on the patient's chart or record maintained by the physician is sufficient.

This rule is intended to implement Iowa Code sections 147.55, 148.6, 272C.3 and 272C.4.

653—13.2(148,272C) Standards of practice—appropriate pain management. This rule establishes standards of practice for the management of acute and chronic pain. The board encourages the use of adjunct therapies such as acupuncture, physical therapy and massage in the treatment of acute and chronic pain. This rule focuses on prescribing and administering controlled substances to provide relief and eliminate suffering for patients with acute or chronic pain.

1. This rule is intended to encourage appropriate pain management, including the use of controlled substances for the treatment of pain, while stressing the need to establish safeguards to minimize the potential for substance abuse and drug diversion.
2. The goal of pain management is to treat each patient's pain in relation to the patient's overall health, including physical function and psychological, social and work-related factors. At the end of life, the goals may shift to palliative care.
3. The board recognizes that pain management, including the use of controlled substances, is an important part of general medical practice. Unmanaged or inappropriately treated pain impacts patients' quality of life, reduces patients' ability to be productive members of society, and increases patients' use of health care services.
4. Physicians should not fear board action for treating pain with controlled substances as long as the physicians' prescribing is consistent with appropriate pain management practices. Dosage alone is not the sole measure of determining whether a physician has complied with appropriate pain management practices. The board recognizes the complexity of treating patients with chronic pain or a substance abuse history. Generally, the board is concerned about a pattern of improper pain management or a single occurrence of willful or gross overtreatment or undertreatment of pain.
5. The board recognizes that the undertreatment of pain is a serious public health problem that results in decreases in patients' functional status and quality of life, and that adequate access by patients to proper pain treatment is an important objective of any pain management policy.
6. Inappropriate pain management may include nontreatment, undertreatment, overtreatment, and the continued use of ineffective treatments. Inappropriate pain management is a departure from the acceptable standard of practice in Iowa and may be grounds for disciplinary action.

13.2(1) *Definitions.* For the purposes of this rule, the following terms are defined as follows:

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

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

"Chronic pain" means persistent or episodic pain of a duration or intensity that adversely affects the functioning or well-being of a patient when (1) no relief or cure for the cause of pain is possible; (2) no relief or cure for the cause of pain has been found; or (3) relief or cure for the cause of pain through other medical procedures would adversely affect the well-being of the patient. If pain persists beyond the anticipated healing period of a few weeks, patients should be thoroughly evaluated for the presence of chronic pain.

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

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

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

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

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

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

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

13.2(3) *Undertreatment of pain.* The undertreatment of pain is a departure from the acceptable standard of practice in Iowa. Undertreatment may include a failure to recognize symptoms and signs of pain, a failure to treat pain within a reasonable amount of time, a failure to allow interventions, e.g., analgesia, to become effective before invasive steps are taken, a failure to address pain needs in patients with reduced cognitive status, a failure to use controlled substances for terminal pain due to the physician's concern with addicting the patient, or a failure to use an adequate level of pain management.

13.2(4) *Assessment and treatment of acute pain.* Appropriate assessment of the etiology of the pain is essential to the appropriate treatment of acute pain. Acute pain is not a diagnosis; it is a symptom. Prescribing controlled substances for the treatment of acute pain should be based on clearly diagnosed and documented pain. Appropriate management of acute 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.

13.2(5) *Effective management of chronic pain.* Prescribing controlled substances for the treatment of chronic pain should only be accomplished within an established physician-patient relationship and should be based on clearly diagnosed and documented unrelieved pain. To ensure that chronic pain is properly assessed and treated, a physician who prescribes or administers controlled substances to a

patient for the treatment of chronic pain shall exercise sound clinical judgment and establish an effective pain management plan in accordance with the following:

a. Patient evaluation. A patient evaluation that includes a physical examination and a comprehensive medical history shall be conducted prior to the initiation of treatment. The evaluation shall also include an assessment of the pain, physical and psychological function, diagnostic studies, previous interventions, including medication history, substance abuse history and any underlying or coexisting conditions. Consultation/referral to a physician with expertise in pain medicine, addiction medicine or substance abuse counseling or a physician who specializes in the treatment of the area, system, or organ perceived to be the source of the pain may be warranted depending upon the expertise of the physician and the complexity of the presenting patient. Interdisciplinary evaluation is strongly encouraged.

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

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

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

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

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

g. Pain management agreements. A physician who treats patients for chronic pain with controlled substances shall consider using a pain management agreement with each patient being treated that specifies the rules for medication use and the consequences for misuse. In determining whether to use a pain management agreement, a physician shall evaluate each patient, taking into account the risks to the patient and the potential benefits of long-term treatment with controlled substances. A physician who

prescribes controlled substances to a patient for more than 90 days for treatment of chronic pain shall utilize a pain management agreement if the physician has reason to believe a patient is at risk of drug abuse or diversion. If a physician prescribes controlled substances to a patient for more than 90 days for treatment of chronic pain and chooses not to use a pain management agreement, then the physician shall document in the patient's medical records the reason(s) why a pain management agreement was not used. Use of pain management agreements is not necessary for hospice or nursing home patients. A sample pain management agreement and prescription drug risk assessment tools may be found on the board's Web site at www.medicalboard.iowa.gov.

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

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

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

13.2(6) *Pain management for terminal illness.* The provisions of this subrule apply to patients who are at the stage in the progression of cancer or other terminal illness when the goal of pain management is comfort care. When the goal of treatment shifts to comfort care rather than cure of the underlying condition, the board recognizes that the dosage level of opiates or controlled substances to control pain may exceed dosages recommended for chronic pain and may come at the expense of patient function. The determination of such pain management should involve the patient, if possible, and others the patient has designated for assisting in end-of-life care.

13.2(7) *Prescription monitoring program.* The Iowa board of pharmacy has established a prescription monitoring program pursuant to Iowa Code sections 124.551 to 124.558 to assist prescribers and pharmacists in monitoring the prescription of controlled substances to patients. The board recommends that physicians utilize the prescription monitoring program when prescribing controlled substances to patients if the physician has reason to believe that a patient is at risk of drug abuse or diversion. A link to the prescription monitoring program may be found at the board's Web site at www.medicalboard.iowa.gov.

13.2(8) *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 Opioid Dosing for Chronic Non-cancer Pain. In March 2007, the Washington State Agency Medical Directors' Group published an educational pilot to improve care and safety of patients with chronic, noncancer pain who are treated with opioids. The guidelines include opioid dosing recommendations.

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

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

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653—13.3(147) Supervision of pharmacists who administer adult immunizations. A physician may prescribe adult immunizations via written protocol for influenza and pneumococcal vaccines for administration by an authorized pharmacist if the physician meets these requirements for supervising the pharmacist.

13.3(1) *Definitions.*

a. "Authorized pharmacist" means an Iowa-licensed pharmacist who has documented that the pharmacist has successfully completed an Accreditation Council for Pharmacy Education (ACPE)-approved continuing pharmaceutical education program on vaccine administration that:

(1) Requires documentation by the pharmacist of current certification in the American Heart Association or the Red Cross Basic Cardiac Life Support Protocol for health care providers;

(2) Is an evidence-based course that includes study material and hands-on training and techniques for administering vaccines, requires testing with a passing score, complies with current Centers for Disease Control and Prevention guidelines, and provides instruction and experiential training in the following content areas:

1. Standards for immunization practices;
2. Basic immunology and vaccine protection;
3. Vaccine-preventable diseases;
4. Recommended immunization schedules;
5. Vaccine storage and management;
6. Informed consent;
7. Physiology and techniques for vaccine administration;
8. Pre- and post-vaccine assessment and counseling;
9. Immunization record management; and
10. Management of adverse events, including identification, appropriate response, documentation, and reporting.

b. "Vaccine" means a specially prepared antigen which, upon administration to a person, will result in immunity and, specifically for the purposes of this rule, shall mean influenza and pneumococcal vaccines.

c. "Written protocol" means a physician's order for one or more patients that contains, at a minimum, the following:

(1) A statement identifying the individual physician authorized to prescribe drugs and responsible for the delegation of administration of adult immunizations for influenza and pneumococcus;

(2) A statement identifying the individual authorized pharmacist;

(3) A statement that forbids an authorized pharmacist from delegating the administration of adult immunizations to anyone other than another authorized pharmacist, a registered pharmacist-intern under the direct personal supervision of the authorized pharmacist, or a registered nurse;

(4) A statement identifying the vaccines that may be administered by an authorized pharmacist, the dosages, and the route of administration;

(5) A statement identifying the activities an authorized pharmacist shall follow in the course of administering adult immunizations, including:

1. Procedures for determining if a patient is eligible to receive the vaccine;
2. Procedures for determining the appropriate scheduling and frequency of drug administration in accordance with applicable guidelines;
3. Procedures for record keeping and long-term record storage including batch or identification numbers;
4. Procedures to follow in case of life-threatening reactions; and
5. Procedures for the pharmacist and patient to follow in case of reactions following administration;

(6) A statement that describes how the authorized pharmacist shall report the administration of adult immunizations, within 30 days, to the physician issuing the written protocols and to the patient's primary care physician, if one has been designated by the patient. In case of serious complications, the authorized pharmacist shall notify the physicians within 24 hours and submit a VAERS report to the bureau of immunizations, Iowa department of public health. (VAERS is the Vaccine Advisory Event Reporting System.) A serious complication is one that requires further medical or therapeutic intervention to effectively protect the patient from further risk, morbidity, or mortality.

13.3(2) *Supervision.* A physician who prescribes adult immunizations to an authorized pharmacist for administration shall adequately supervise that pharmacist. Physician supervision shall be considered adequate if the delegating physician:

a. Ensures that the authorized pharmacist is prepared as described in subrule 13.3(1), paragraph *"a"*;

b. Provides a written protocol that is updated at least annually;

c. Is available through direct telecommunication for consultation, assistance, and direction, or provides physician backup to provide these services when the physician supervisor is not available;

d. Is an Iowa-licensed physician who has a working relationship with an authorized pharmacist within the physician's local provider service area.

13.3(3) *Administration of other adult immunizations by pharmacists.* A physician may prescribe, for an individual patient by prescription or medication order, other adult immunizations to be administered by an authorized pharmacist.

This rule is intended to implement Iowa Code sections 147.76 and 272C.3.

653—13.4(148) Supervision of pharmacists engaged in collaborative drug therapy management. A supervising physician may only delegate aspects of drug therapy management to an authorized pharmacist pursuant to a written protocol with a pharmacist pursuant to the requirements of this rule. The physician is considered the supervisor and retains the ultimate responsibility for the care of the patient. The authorized pharmacist retains full responsibility for proper execution of pharmacy practice.

13.4(1) *Definitions.*

"Authorized pharmacist" means an Iowa-licensed pharmacist who meets the training requirements of the Iowa board of pharmacy (IBP) as specified in the drug therapy management criteria in 657—8.34(155A).

"Board" means the board of medicine of the state of Iowa.

"Collaborative drug therapy management" means participation by a physician and an authorized pharmacist in the management of drug therapy pursuant to a written community practice protocol or a written hospital practice protocol.

"Collaborative practice" means that a physician may delegate aspects of drug therapy management for the physician's patients to an authorized pharmacist through a written community practice protocol. "Collaborative practice" also means that a P&T committee may authorize hospital pharmacists to perform drug therapy management for inpatients and the hospital's clinic patients through a hospital practice protocol when the clinic and the pharmacist are under the direct authority of the hospital's P&T committee.

"Community practice protocol" means a written, executed agreement entered into voluntarily between a physician and an authorized pharmacist establishing drug therapy management for one or more of the physician's patients residing in a community setting. A community practice protocol shall comply with the requirements of subrule 13.4(2).

"Community setting" means a location outside a hospital inpatient, acute care setting or a hospital clinic setting. A community setting may include, but is not limited to, a home, group home, assisted living facility, correctional facility, hospice, or long-term care facility.

"Hospital clinic" means an outpatient care clinic operated and affiliated with a hospital and under the direct authority of the hospital's P&T committee.

"Hospital pharmacist" means an Iowa-licensed pharmacist who meets the requirements for participating in a hospital practice protocol as determined by the hospital's P&T committee.

"Hospital practice protocol" means a written plan, policy, procedure, or agreement that authorizes drug therapy management between physicians and hospital pharmacists within a hospital and its clinics as developed and determined by its P&T committee. Such a protocol may apply to all physicians and hospital pharmacists at a hospital or the hospital's clinics under the direct authority of the hospital's P&T committee or only to those physicians and pharmacists who are specifically recognized. A hospital practice protocol shall comply with the requirements of subrule 13.4(3).

"IBP" means the Iowa board of pharmacy.

"P&T committee" means a committee of the hospital composed of physicians, pharmacists, and other health professionals that evaluates the clinical use of drugs within the hospital, develops policies for managing drug use and administration in the hospital, and manages the hospital drug formulary system.

"Physician" means a person who is currently licensed in Iowa to practice medicine and surgery or osteopathic medicine and surgery. A physician who executes a written protocol with an authorized pharmacist shall supervise the pharmacist's activities involved in the overall management of patients receiving medications or disease management services under the protocol. The physician may delegate only drug therapies that are in areas common to the physician's practice.

"Therapeutic interchange" means an authorized exchange of therapeutic alternate drug products in accordance with a previously established and approved written protocol.

13.4(2) *Community practice protocol.*

a. A physician shall engage in collaborative drug therapy management with a pharmacist only under a written protocol that is identified by topic and has been submitted to the IBP or a committee authorized by the IBP. A protocol executed after July 1, 2008, will no longer be required to be submitted to the IBP; however, written protocols executed or renewed after July 1, 2008, shall be made available upon request of the board or the IBP.

b. The community practice protocol shall include:

(1) The name, signature, date and contact information for each authorized pharmacist who is a party to the protocol and is eligible to manage the drug therapy of a particular patient. If more than one authorized pharmacist is a party to the agreement, the pharmacists shall work for a single licensed pharmacy and a principal pharmacist shall be designated in the protocol.

(2) The name, signature, date and contact information for each physician who may prescribe drugs and is responsible for supervising a patient's drug therapy management. The physician who initiates a protocol shall be considered the main caregiver for the patient respective to that protocol and shall be noted in the protocol as the principal physician.

(3) The name and contact information of the principal physician and the principal authorized pharmacist who are responsible for development, training, administration, and quality assurance of the protocol.

(4) A detailed written protocol pursuant to which the authorized pharmacist will base drug therapy management decisions for patients. The protocol shall authorize one or more of the following:

1. Prescription drug orders. The protocol may authorize therapeutic interchange or modification of drug dosages based on symptoms or laboratory or physical findings defined in the protocol. The protocol shall include information specific to the dosage, frequency, duration and route of administration of the

drug authorized by the patient's physician. The protocol shall not authorize the pharmacist to change a Schedule II drug or initiate a drug not included in the established protocol.

2. Laboratory tests. The protocol may authorize the pharmacist to obtain or conduct specific laboratory tests as long as the tests relate directly to the drug therapy management.

3. Physical findings. The protocol may authorize the pharmacist to check certain physical findings, e.g., vital signs, oximetry, or peak flows, that enable the pharmacist to assess and adjust the drug therapy, detect adverse drug reactions or determine if the patient should be referred back to the patient's physician for follow-up.

4. Patient activities. The protocol may authorize the pharmacist to monitor specific patient activities.

(5) Procedures for the physician to secure the patient's written consent. If the physician does not secure the patient's written consent, the pharmacist shall secure such and notify the patient's physician within 24 hours.

(6) Circumstances that shall cause the pharmacist to initiate communication with the physician, including but not limited to the need for new prescription orders and reports of the patient's therapeutic response or adverse reaction.

(7) A detailed statement identifying the specific drugs, laboratory tests and physical findings upon which the pharmacist shall base drug therapy management decisions.

(8) A provision for the collaborative drug therapy protocol to be reviewed, updated and reexecuted or discontinued at least every two years.

(9) A description of the method the pharmacist shall use to document the pharmacist's decisions or recommendations for the physician.

(10) A description of the types of reports the physician requires the pharmacist to provide and the schedule by which the pharmacist is to submit these reports. The schedule shall include a time frame in which a pharmacist shall report any adverse reaction to the physician.

(11) A statement of the medication categories and the type of initiation and modification of drug therapy that the physician authorizes the pharmacist to perform.

(12) A description of the procedures or plan that the pharmacist shall follow if the pharmacist modifies a drug therapy.

(13) Procedures for record keeping, record sharing and long-term record storage.

(14) Procedures to follow in emergency situations.

(15) A statement that prohibits the pharmacist from delegating drug therapy management to anyone other than another authorized pharmacist who has signed the applicable protocol.

(16) A statement that prohibits a physician from delegating collaborative drug therapy management to any unlicensed or licensed person other than another physician or authorized pharmacist.

(17) A description of the mechanism for the pharmacist and physician to communicate with each other and for documentation by the pharmacist of the implementation of collaborative drug therapy.

c. Collaborative drug therapy management is valid only when initiated by a written protocol executed by at least the patient's physician and one authorized pharmacist.

d. A collaborative drug therapy management protocol must be filed with the IBP, kept on file in the pharmacy and made available to the board or IBP upon request. A protocol executed after July 1, 2008, will no longer be required to be submitted to the IBP; however, written protocols executed or renewed after July 1, 2008, shall be made available upon request of the board or the IBP.

e. A physician may terminate or amend the collaborative drug therapy management protocol with an authorized pharmacist if the physician notifies, in writing, the pharmacist and the IBP. Notification shall include the name of the authorized pharmacist, the desired change, and the proposed effective date of the change. After July 1, 2008, the physician shall no longer be required to notify the IBP of changes in the protocol.

f. Patient consent for community practice protocols. The physician or pharmacist who initiates a protocol with a patient is responsible for securing a patient's written consent to participate in drug therapy management and for transmitting a copy of the consent to the other party within 24 hours. The consent shall indicate which protocol is involved. Any variation in the protocol for a specific patient

needs to be communicated to the other party at the time of securing the patient's consent. The patient's physician shall maintain the patient consent in the patient's medical record.

13.4(3) *Hospital practice protocol.*

a. A hospital's P&T committee shall determine the scope and extent of collaborative drug therapy management practices that may be conducted by its hospital pharmacists in the hospital and its clinics. Hospital clinics are restricted to outpatient care clinics operated and affiliated with a hospital and under the direct authority of the hospital's P&T committee.

b. Collaborative drug therapy management within a hospital setting or the hospital's clinic setting is valid only when approved by the hospital's P&T committee.

c. The hospital practice protocol shall include:

(1) The names or groups of physicians and pharmacists who are authorized by the P&T committee to participate in collaborative drug therapy management.

(2) A plan for development, training, administration, and quality assurance of the protocol.

(3) A detailed written protocol pursuant to which the hospital pharmacist shall base drug therapy management decisions for patients. The protocol shall authorize one or more of the following:

1. Medication orders and prescription drug orders. The protocol may authorize therapeutic interchange or modification of drug dosages based on symptoms or laboratory or physical findings defined in the protocol. The protocol shall include information specific to the dosage, frequency, duration and route of administration of the drug authorized by the physician. The protocol shall not authorize the hospital pharmacist to change a Schedule II drug or initiate a drug not included in the established protocol.

2. Laboratory tests. The protocol may authorize the hospital pharmacist to obtain or conduct specific laboratory tests as long as the tests relate directly to the drug therapy management.

3. Physical findings. The protocol may authorize the hospital pharmacist to check certain physical findings, e.g., vital signs, oximetry, or peak flows, that enable the pharmacist to assess and adjust the drug therapy, detect adverse drug reactions or determine if the patient should be referred back to the physician for follow-up.

(4) Circumstances that shall cause the hospital pharmacist to initiate communication with the patient's physician, including but not limited to the need for new medication orders and prescription drug orders and reports of a patient's therapeutic response or adverse reaction.

(5) A statement of the medication categories and the type of initiation and modification of drug therapy that the protocol authorizes the hospital pharmacist to perform.

(6) A description of the procedures or plan that the hospital pharmacist shall follow if the hospital pharmacist modifies a drug therapy.

(7) A description of the mechanism for the hospital pharmacist and the patient's physician to communicate and for the hospital pharmacist to document implementation of the collaborative drug therapy.

This rule is intended to implement Iowa Code chapter 148.

653—13.5(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.

This rule is intended to implement Iowa Code chapters 147 and 148.

653—13.6(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 shall be

physically present to determine the accuracy and completeness of any medication that is reconstituted prior to dispensing.

13.6(1) An internal quality control assurance plan shall include the following elements:

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

b. Methods that the dispensing system employs, e.g., bar coding, 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.

13.6(2) Those dispensing systems already in place shall show evidence of a plan and testing within two months of August 31, 2001.

13.6(3) The internal quality control assurance plan shall be submitted to the board of medicine upon request.

This rule is intended to implement Iowa Code section 147.107 and 2001 Iowa Acts, House File 726, section 5(10), paragraph *"i."*

653—13.7(147,148,272C) Standards of practice—office practices.

13.7(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 shall 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.

13.7(2) *Patient referrals.* A physician shall not pay or receive compensation for patient referrals.

13.7(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.

13.7(4) *Sexual conduct.* It is unprofessional and unethical conduct, and is grounds for disciplinary action, for a physician to engage in conduct which 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.

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, regardless of whether the patient consents to that conduct.

13.7(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.

13.7(6) *Sexual harassment.* A physician shall not engage in sexual harassment. Sexual harassment is defined as verbal or physical conduct of a sexual nature which interferes with another health care worker's performance or creates an intimidating, hostile or offensive work environment.

13.7(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.

13.7(8) *Retention of medical records.* The following paragraphs become effective on January 1, 2004.

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. 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 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—13.8(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. 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.

13.8(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 which, 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.

"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; botox injections; collagen injections; and tattoo removal.

"Medical director" means a physician who assumes the role of, or holds oneself out as, medical director or a physician who serves as a medical advisor for 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 to qualified licensed or certified nonphysician persons.

"Medical spa" means any entity, however organized, which is advertised, announced, established, or maintained for the purpose of providing medical aesthetic services. Medical spa shall not include a dermatology practice which 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 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 licensing board in Iowa and qualified to perform medical aesthetic services under the supervision of a qualified physician.

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

13.8(2) *Practice of medicine.* The performance of medical aesthetic services is the practice of medicine. A medical aesthetic service shall only be performed by qualified licensed or certified nonphysician persons if the service has been delegated by the medical director who is responsible for supervision of the services performed. A medical director shall not delegate medical aesthetic services to nonphysician persons who are not appropriately licensed or certified in Iowa.

13.8(3) *Medical director.* A physician who serves as 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;

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 Web sites and signage related to the medical spa.

13.8(4) *Delegated medical aesthetic service.* When a medical director delegates a medical aesthetic service to qualified licensed or certified nonphysician persons, 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.

13.8(5) *Supervision.* A medical director who delegates performance of a medical aesthetic service to qualified licensed or certified nonphysician persons is responsible for providing appropriate supervision. The medical director shall:

a. Ensure that all licensed or certified nonphysician persons are qualified and competent to safely perform each 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 which are beyond the scope of that person's license or certification unless the person is supervised by a qualified supervising physician;

c. Ensure that all qualified licensed or certified nonphysician persons receive direct, in-person, on-site supervision from the medical director or other qualified licensed physician 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 each week and review at least 10 percent of patient charts for medical aesthetic services performed by qualified licensed or certified nonphysician persons;

e. Be physically located, at all times, within 60 miles of the location where qualified licensed or certified nonphysician persons perform medical aesthetic services;

f. Be available, in person or electronically, at all times, to consult with qualified licensed or certified nonphysician persons who perform 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 who perform medical aesthetic services;

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

i. Ensure that all qualified licensed or certified nonphysician persons maintain accurate and timely medical records for the 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 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 licensed or certified nonphysician persons are visibly displayed at each medical spa 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 who perform medical aesthetic services at a medical spa, within 14 days of a request by the board.

13.8(6) *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.

13.8(7) *Physician assistants.* Nothing in these rules shall be interpreted to contradict or supersede the rules established in 645—Chapters 326 and 327.

[**ARC 9088B**, IAB 9/22/10, effective 10/27/10]

653—13.9(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.

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

"Interventional chronic pain management" means the diagnosis and treatment of pain-related disorders with the application of interventional techniques in managing subacute, chronic, persistent, and intractable pain. Interventional techniques include percutaneous (through the skin) needle placement to inject drugs in targeted areas. Interventional techniques also include nerve ablation (excision or amputation) and certain surgical procedures. Interventional techniques often involve injection of steroids, analgesics, and anesthetics and include: lumbar, thoracic, and cervical spine injections, intra-articular injections, intrathecal injections, epidural injections (both regular and transforaminal), facet injections, discography, nerve destruction, occipital nerve blocks, lumbar sympathetic blocks and vertebroplasty, and kyphoplasty. Interventional chronic pain management includes the use of fluoroscopy when it is used to assess the cause of a patient's chronic pain or when it is used to identify anatomic landmarks during interventional techniques. Specific interventional techniques include: SI joint injections; spinal punctures; epidural blood patches; epidural injections; epidural/spinal injections; lumbar injections; epidural/subarachnoid catheters; occipital nerve blocks; axillary nerve blocks; intercostals nerve blocks; multiple intercostals nerve blocks; ilioinguinal nerve blocks; peripheral nerve

blocks; facet joint injections; cervical/thoracic facet joint injections; lumbar facet injections; multiple lumbar facet injections; transforaminal epidural steroid injections; transforaminal cervical steroid injections; sphenopalatine ganglion blocks; paravertebral sympathetic blocks; neurolysis of the lumbar facet nerve; neurolysis of the cervical facet nerve; and destruction of the peripheral nerve.

13.9(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.

13.9(3) *Practice of medicine.* Interventional chronic pain management is the practice of medicine.
[**ARC 8918B**, IAB 6/30/10, effective 8/4/10]

653—13.10(17A,147,148,272C) Waiver or variance prohibited. Renumbered as 653—13.21(17A,147,148,272C), IAB 12/24/03, effective 1/28/04.

653—13.11 to **13.19** Reserved.

653—13.20(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 shall be utilized by the board as guiding principles in the practice of medicine and surgery and osteopathic medicine and surgery in this state.

13.20(1) *Conflict of interest.* A physician should not provide medical services under terms or conditions which 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.

13.20(2) *Fees.* Any fee charged by a physician shall be reasonable.

653—13.21(17A,147,148,272C) Waiver or variance prohibited. Rules in this chapter are not subject to waiver or variance pursuant to 653—Chapter 3 or any other provision of law.

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