# 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(148,150,150A,272C) Standards of practice—prescribing or administering controlled substances for the treatment of patients with chronic, nonmalignant pain.** This rule establishes standards of practice for the management of chronic, nonmalignant pain. The purpose of the rule is to assist physicians who prescribe and administer drugs to provide relief and eliminate suffering in patients with chronic, nonmalignant pain as defined in this rule.

**13.2(1)** *Definitions.* As used in this rule:

*"Agency for Healthcare Research and Quality"* or *"AHRQ"* means the agency within the U.S. Department of Health and Human Services which is responsible for establishing Clinical Practice Guidelines on various aspects of medical practice.

*"American Academy of Pain Medicine"* or *"AAPM"* means 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.

*"American Pain Society"* or *"APS"* means 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.

*"Chronic, nonmalignant pain (i.e., not caused by cancer)"* 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.

**13.2(2)** *General provisions.* Various controlled drugs, particularly opioid analgesics, can be safely and effectively utilized to control pain in certain patients. However, inappropriate prescribing of controlled substances can lead to, or accelerate, drug abuse and diversion. Therefore, the medical management of pain shall be based on a thorough knowledge of pain assessment, pain treatment, and concern for the patient.

*a. Treatment of acute pain and cancer pain.* Physicians may refer to the Clinical Practice Guidelines published by the AHRQ for counsel on the proper treatment of acute pain and chronic pain associated with cancer. The AHRQ Clinical Practice Guidelines provide a sound, compassionate, and flexible approach to the management of pain in these patients.

*b. Treatment of chronic, nonmalignant pain.* The basic premise underlying this rule is that various drugs, particularly opioid analgesics, may be useful for treating patients with chronic, nonmalignant pain in a safe, effective, and efficient manner when other efforts, including those by other practitioners or the patient, have failed to remove or effectively treat the pain. The board strongly recommends that physicians who have reservations about the use of drugs in the treatment of chronic, nonmalignant pain consult: Definitions Related to the Use of Opioids for the Treatment of Pain, a consensus document from the American Academy of Pain Medicine (AAPM), the American Pain Society (APS), and the American Society of Addiction Medicine (ASAM) (2001). Copies of the document are available from the AAPM (http://www.painmed.org), the APS (http://www.ampainsoc.org), the ASAM (http://www.asam.org), and the office of the board at 400 S.W. 8th Street, Suite C, Des Moines, Iowa 50309-4686.

**13.2(3)** *Effective chronic, nonmalignant pain management.* To ensure that pain is properly and promptly assessed and treated, a physician who prescribes or administers controlled substances to a patient for the treatment of chronic, nonmalignant pain shall exercise sound clinical judgment by establishing 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.

*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. 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 the objectives of the treatment plan are not being met or there is evidence of diversion or a pattern of substance abuse.

*e. Consultation/referral*. The physician shall consider consultation with, or referral to, a physician with expertise in pain medicine, addiction medicine or substance abuse counseling, if the objectives of the treatment plan are not being met or there is evidence of diversion or a pattern of substance abuse.

*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. Physician-patient agreements.* Physicians treating patients at risk for substance abuse shall consider establishing physician-patient agreements that specify the rules for medication use and the consequences for misuse. In preparing agreements, a physician shall evaluate the case of each patient on its own merits, taking into account the nature of the risks to the patient and the potential benefits of treatment.

*h. Termination of care.* The physician shall consider termination of patient care if there is evidence of diversion or a repeated pattern of substance abuse.

**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 educational program meeting the training standards on vaccine administration as provided by an American Council on Pharmaceutical Education (ACPE)-approved provider of continuing pharmaceutical education 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(147) 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 examiners (IBPE) as specified in the drug therapy management criteria in 657—8.34(155A).

*"Board"* means the board of medical examiners 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).

*"IBPE"* means the Iowa board of pharmacy examiners.

*"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, osteopathic medicine and surgery, or osteopathy. 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 IBPE or a committee authorized by the IBPE. A protocol executed after July 1, 2008, will no longer be required to be submitted to the IBPE; however, written protocols executed or renewed after July 1, 2008, shall be made available upon request of the board or the IBPE.

*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 IBPE, kept on file in the pharmacy and made available to the board or IBPE upon request. A protocol executed after July 1, 2008, will no longer be required to be submitted to the IBPE; however, written protocols executed or renewed after July 1, 2008, shall be made available upon request of the board or the IBPE.

*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 IBPE. 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 IBPE 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 chapters 148, 150 and 150A.

**653—13.5(147,148,150) 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, 148, and 150.

**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 medical examiners 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 614.9.

*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** and **13.9** Reserved.

**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(147,148,150) 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, osteopathic medicine and surgery and osteopathy 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.

[Filed 2/5/79, Notice 11/29/78—published 2/21/79, effective 3/29/79]
[Filed 3/13/81, Notice 1/7/81—published 4/1/81, effective 5/6/81]
[Filed emergency 4/15/88—published 5/4/88, effective 4/15/88]
[Filed 5/11/90, Notice 3/7/90—published 5/30/90, effective 6/6/90]
[Filed 3/22/96, Notice 9/27/95—published 4/10/96, effective 6/15/96*]
[Filed 11/22/96, Notice 8/28/96—published 12/18/96, effective 1/22/97]
[Filed 5/2/97, Notice 3/26/97—published 5/21/97, effective 6/25/97]
[Filed 11/7/00, Notice 4/19/00—published 11/29/00, effective 1/3/01]
[Filed 12/1/00, Notice 10/18/00—published 12/27/00, effective 1/31/01]
[Filed 2/16/01, Notice 12/27/00—published 3/7/01, effective 4/11/01]
[Filed emergency 8/31/01 after Notice 7/25/01—published 9/19/01, effective 8/31/01]
[Filed 2/14/02, Notice 1/9/02—published 3/6/02, effective 4/10/02]
[Filed 6/6/02, Notice 5/1/02—published 6/26/02, effective 7/31/02]
[Filed 1/3/03, Notice 11/27/02—published 1/22/03, effective 2/26/03]
[Filed 12/4/03, Notice 8/20/03—published 12/24/03, effective 1/28/04]
[Filed 5/20/04, Notice 4/14/04—published 6/9/04, effective 7/14/04]
[Filed 5/3/06, Notice 2/15/06—published 5/24/06, effective 10/1/06]

*Effective date of 13.2(148,272C) delayed 70 days by the Administrative Rules Review Committee at its meeting held May 14, 1996.