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 (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, 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 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 chapters 148, 150 and 150A.