PHARMACY BOARD[657]

Notice of Intended Action

Pursuant to the authority of Iowa Code section 147.76, the Board of Pharmacy hereby gives Notice of Intended Action to amend Chapter 8, "Universal Practice Standards," and to adopt new Chapter 39, "Expanded Practice Standards," Iowa Administrative Code.

The proposed amendments were approved at the _____, 2017 regular meeting of the Board of Pharmacy.

Pursuant to Iowa Code section 17A.7(2), the Board has engaged in a complete review of all administrative rules. The proposed action creates a new chapter for rules relating to some areas of pharmacy practice that are not required of all pharmacies, such as provision of immunizations or participation in collaborative practice agreements, but for which the Board has established minimum practice standards. The purpose of moving these rules to a separate chapter is to narrow the scope of Chapter 8 to those minimum standards that are required of every pharmacy licensed in Iowa.

The proposed amendments clarify rules where needed, reorganize rules where appropriate, remove a pharmacy's requirement to maintain a refrigerator when the pharmacy does not handle refrigerated items, incorporates language to implement two pieces of legislation from the 2017 legislative session (regarding electronic prescriptions and biological products), increases to quarterly the frequency of pharmacy review of its CQI program data, updates licensure renewal language to be consistent with other Board action, and generalizes language for collaborative practice agreements to allow for agreements with other prescribing practitioners as allowed by the prescribing practitioner's professional licensing authority.

Any interested person may present written comments, data, views, and arguments on the proposed amendments not later than 4:30 p.m. on _____, 201_. Such written materials may be sent to Terry Witkowski, Executive Officer, Iowa Board of Pharmacy, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688; or by e-mail at terry.witkowski@iowa.gov.

Requests for waiver or variance of the discretionary provisions of Board rules will be considered pursuant to 657—Chapter 34.

After review of this rulemaking, no impact on jobs is found.

These amendments are intended to implement Iowa Code sections 124.101, 124.301, 124.306, 124.308, 126.10, 126.11, 126.16, 135C.33, 147.7, 147.55, 147.72, 147.74, 147.76, 147A.18, 155A.2 through 155A.4, 155A.6, 155A.10, 155A.12 through 155A.15, 155A. 19, 155A.20, 155A.27 through 155A.29, 155A.32, 155A.33, and 155A.44.

The following amendments are proposed.

ITEM 1. Amend rule 657—8.1(155A) as follows:

657—8.1 (155A) Purpose and scope. The purpose of this chapter is to establish the minimum standard of pharmacy practice for the activities identified in this chapter. The requirements of these rules shall apply to all Iowa-licensed pharmacists, other registered pharmacy personnel, and ~~to~~ all pharmacies, including owners, providing the services addressed in this chapter to patients in Iowa. ~~and~~ These rules are in addition to rules of the board relating to specific types of pharmacy licenses issued by the board unless otherwise indicated by rule.

ITEM 2. Rescind rule 657—8.2(155A) and adopt the following **new** rule in lieu thereof:

657—8.2(155A) Definitions. For the purpose of this chapter, the following definitions shall apply:

"*Confidential information*" means information accessed or maintained by the pharmacy in the patient's or the pharmacy's records which contains personally identifiable information that could be used to identify the patient. This includes but is not limited to patient name, address, telephone number, and social security number; prescriber name and address; and prescription and drug or device information such as therapeutic effect, diagnosis, allergies, disease state, pharmaceutical services rendered, medical information, and drug interactions.

"*DEA*" means the United States Department of Justice, Drug Enforcement Administration.

"*Pharmacy support person*" or "*PSP*" means a person, other than a member of the professional pharmacy staff, registered with the board who may perform nontechnical duties assigned by a supervising pharmacist under the pharmacist's responsibility and supervision.

"*Professional pharmacy staff*" shall mean the professional employees of the pharmacy, including pharmacists, pharmacy technicians, and pharmacist-interns.

This rule is intended to implement Iowa Code 155A.

ITEM 3. Amend rule 657—8.3(155A) as follows:

657—8.3 (155A) Responsible parties.

8.3(1) No change.

8.3(2) *Pharmacy.* Each pharmacy, by and through its owner or license holder, shall work cooperatively with the pharmacist in charge and with all staff pharmacists to ensure the legal operation of the pharmacy, including meeting all inspection and other requirements of state and federal laws, rules, and regulations governing the practice of pharmacy. The pharmacy, by and through its owner or license holder, shall be responsible for employing a professionally

competent, legally qualified pharmacist in charge. The pharmacy, by and through its owner or license holder, may be held responsible for unethical conduct or practices of any of the pharmacy staff.

8.3(3) *Pharmacy and pharmacist in charge.* The pharmacist in charge and the pharmacy, by and through its owner or license holder, shall share responsibility for, at a minimum, the following:

a. to *c.* No change.

d. Ensuring that the license, registration, or certification of each professional staff member and the registration of each pharmacy support person is maintained in current and active status.

8.3(4) *Pharmacist in charge and staff pharmacists.* The pharmacist in charge and staff pharmacists shall share responsibility for, at a minimum, the following:

a. No change.

b. Ensuring that a pharmacist or pharmacist-intern provides patient counseling as specified in rule 657—6.14(155A).

c. to *j*. No change.

8.3(5) to **8.3(6)** No change.

~~**8.3(7)** *Pharmacist-documented verification.* The pharmacist shall provide, document, and retain a record of the final verification for the accuracy, validity, completeness, and appropriateness of the patient's prescription or medication order prior to the delivery of the medication to the patient or the patient's representative.~~

ITEM 4. Amend rule 657—8.4(155A) as follows:

657—8.4 (155A) Pharmacist identification and staff logs.

8.4(1) *Display of pharmacist license.* During any period the pharmacist is working in a pharmacy, each pharmacist shall display, in a position visible to the public, an original license to practice pharmacy in Iowa. A current license renewal certificate, which may be a photocopy of an original renewal certificate, shall be displayed with the original license.

8.4(2) *Registration maintained of pharmacy personnel.* Each pharmacist-intern, pharmacy technician, and pharmacy support person shall maintain current registration with the board. The certificate or a copy of the certificate shall be maintained in each pharmacy where the individual is practicing.

8.4~~(2)~~(3) *Identification codes.* A permanent log of the initials or identification codes identifying by name each ~~dispensing~~ pharmacist, pharmacist-intern, pharmacy technician, and pharmacy support person shall be maintained for a minimum of two years and shall be available for inspection and copying by the board or its representative. The initials or identification code shall be unique to the individual to ensure that each pharmacist, pharmacist-intern, pharmacy technician, and pharmacy support person can be identified.

8.4~~(3)~~(4) *Temporary or intermittent pharmacy staff.* The pharmacy shall maintain a log of all pharmacists, pharmacist-interns, pharmacy technicians, and pharmacy support persons who have worked at that pharmacy and who are not regularly staffed at that pharmacy. Such log shall include the dates and shifts worked by each pharmacist, pharmacist-intern, pharmacy technician, and pharmacy support person and shall be available for inspection and copying by the board or its representative for a minimum of two years following the date of the entry.

8.4~~(4)~~(5) *Identification badge.* ~~A pharmacist~~ Pharmacy personnel shall wear a visible identification badge while on duty that clearly identifies the person ~~as a pharmacist~~ by licensed or registered title and includes at least ~~the pharmacist's~~ the person's first name.

ITEM 5. Amend rule 657—8.5(155A) as follows:

657—8.5 (155A) Environment and equipment requirements. There shall be adequate space, equipment, and supplies for the professional and administrative functions of the pharmacy pursuant to rule 657—8.3(155A). Space and equipment in an amount and type to provide secure, environmentally controlled storage of drugs shall be available.

8.5(1) *Refrigeration.* The pharmacy shall maintain one or more refrigeration units, unless the pharmacy does not stock refrigerated items. The pharmacy shall document verification that the temperature of the refrigerator ~~shall be~~ is maintained within a range compatible with the proper storage of drugs requiring refrigeration~~, and a thermometer shall be maintained in the refrigerator to verify the temperature~~. If the temperature is manually or visually verified, a record of minimum daily verification shall be maintained.

8.5(2) No change.

8.5(3) *Secure barrier.* A pharmacy department shall be closed and secured in the absence of the pharmacist except as provided in rule 657—6.7(124,155A) or 657—7.6(124,155A). To ensure that secure closure, the pharmacy department shall be surrounded by a physical barrier capable of being securely locked to prevent entry when the department is closed. A secure barrier may be constructed of other than a solid material with a continuous surface if the openings in the material are not large enough to permit removal of items from the pharmacy department by any means. Any material used in the construction of the barrier shall be of sufficient strength and thickness that it cannot be readily or easily removed, penetrated, or bent. ~~The plans and specifications of the barrier shall be submitted to the board for approval at least 30 days prior to the start of construction. The pharmacy may be subject to inspection as provided in subrule 8.5(4).~~

8.5(4) to **8.5(8)** No change.

8.5(9) *Authorized collection program.* A pharmacy that is registered with the ~~United States Department of Justice, Drug Enforcement Administration,~~ DEA to administer an authorized collection program shall provide adequate space, equipment, and supplies for such collection program pursuant to 657—Chapter 10 and federal regulations for authorized collection programs, which can be found at http://deadiversion.usdoj.gov/drug_disposal/.

8.5(10) *Health of personnel.* The pharmacist in charge or supervising pharmacist shall ensure that pharmacy personnel experiencing any health condition that may have an adverse effect on drug products or pose a health or safety risk to others be prohibited from working in the pharmacy until such health condition is sufficiently resolved. All personnel who normally assist the pharmacist shall report to the pharmacist any health conditions that may have an adverse effect on drug products or may pose a health or safety risk to others.

ITEM 6. Rescind and reserve rule **657—8.6(155A)**.

ITEM 7. Amend rule 657—8.7(155A) as follows:

657—8.7 (155A) Procurement, storage, and recall of drugs and devices.

8.7(1) *Source.* Procurement of prescription drugs and devices shall be from ~~a~~ an Iowa-licensed ~~drug wholesaler licensed by the board to distribute to Iowa pharmacies~~ distributor or, on a limited basis, from another licensed pharmacy or licensed practitioner located in the United States.

8.7(2) ~~*Sufficient stock.* A pharmacy shall maintain sufficient stock of drugs and devices to fulfill the foreseeable needs of the patients served by the pharmacy.~~

~~8.7(3)~~ *Manner of storage.* Drugs and devices shall be stored in a manner to protect their identity and integrity.

8.7~~(4)~~(3) *Storage temperatures.* All drugs and devices shall be stored at the proper temperature as provided in manufacturer labeling. In the absence of a specific temperature range, ~~as defined by~~ the following terms shall be used to determine appropriate storage temperatures:

a. "*Controlled room temperature*" means temperature maintained thermostatically between ~~15~~ 20 degrees and ~~30~~ 25 degrees Celsius (~~59~~ 68 degrees and ~~86~~ 77 degrees Fahrenheit);

b. to *c.* No change

d. "*Freeze*" means temperature maintained thermostatically between ~~-20~~ -25 degrees and -10 degrees Celsius (~~-4~~ -13 degrees and 14 degrees Fahrenheit).

8.7~~(5)~~(4) No change.

8.7(5) *Outdated drugs or devices.* Any drug or device bearing an expiration date shall not be dispensed for use beyond the expiration date of the drug or device. Outdated drugs or devices shall be removed from dispensing stock and shall be quarantined until such drugs or devices are properly disposed of.

8.7(6) *Records.* All pharmacies shall maintain supplier invoices of prescription drugs and controlled substances upon which the actual date of receipt of the drugs by the pharmacist or other responsible individual is clearly recorded. All pharmacies shall maintain supplier credit memos. Pharmacy records of invoices and credit memos shall be maintained for at least two years from the date of the record. If the original supplier invoice or credit memo is received electronically, a hard copy record is not required.

ITEM 8. Rescind and reserve rule **657—8.8(124,155A)**.

ITEM 9. Amend rule 657—8.9(124,155A) as follows:

657—8.9 (124,155A) Records storage. Every ~~inventory or other~~ record required to be maintained by a pharmacy pursuant to board rules or Iowa Code chapters 124 and 155A shall be

maintained and be available for inspection and copying by the board or its representative for at least two years from the date of such ~~inventory or~~ record or the date of last activity on the record unless a longer retention period is specified for the particular record ~~or inventory~~. ~~Original hard-copy prescription and other pharmacy records more than 12 months old may be maintained in a secure storage area outside the licensed pharmacy department unless such remote storage is prohibited under federal law. A remote storage area shall be located within the same physical structure containing the licensed pharmacy department. The following records shall be maintained for at least two years.~~

8.9(1) ~~*Drug supplier invoices*~~ *Records less than 12 months old*. ~~All pharmacies shall maintain supplier invoices of prescription drugs and controlled substances upon which the actual date of receipt of the controlled substances by the pharmacist or other responsible individual is clearly recorded.~~ Records shall be maintained within the licensed pharmacy department for a minimum of 12 months, except as provided herein. Pharmacy records less than 12 months old may be stored in a secure storage area outside the licensed pharmacy department, including at a remote location, if the pharmacy has retained an electronic copy of the records in the pharmacy that is immediately available and if the original records are available within 48 hours of a request by the board or its authorized agent, unless such remote storage is prohibited under federal law.

8.9(2) ~~*Drug supplier credits*~~ *Records more than 12 months old* . ~~All pharmacies shall maintain supplier credit memos for controlled substances and prescription drugs.~~ Records more than 12 months old may be maintained in a secure storage area outside the licensed pharmacy department, including at a remote location, if the records are retrievable within 48 hours of a request by the board or its authorized agent, unless such remote storage is prohibited under federal law.

ITEM 10. Amend rule 657—8.11(147,155A) as follows:

657—8.11 (147,155A) Unethical conduct or practice. The provisions of this rule apply to licensed pharmacies, licensed pharmacists, registered pharmacy technicians, registered pharmacy support persons, and registered pharmacist-interns.

8.11(1) *Misrepresentative deeds.* A pharmacy, pharmacist, technician, support person, or pharmacist-intern shall not make any statement intended to deceive, misrepresent or mislead anyone, or be a party to or an accessory to any fraudulent or deceitful practice or transaction in pharmacy or in the operation or conduct of a pharmacy.

8.11(2) ~~*Undue influence*~~ *Unethical conduct.* A pharmacy, pharmacist, pharmacist-intern, technician, or support person shall not participate in any of the following types of unethical conduct:

a. ~~A pharmacist shall not accept professional employment or share or receive compensation in any form arising out of, or incidental to, the pharmacist's professional activities from a prescriber of prescription drugs or any other person or corporation in which one or more such prescribers have a proprietary or beneficial interest sufficient to permit them to directly or indirectly exercise supervision or control over the pharmacist in the pharmacist's professional responsibilities and duties or over the pharmacy wherein the pharmacist practices.~~ Any activity to negate a patient's freedom of choice of pharmacy services.

b. ~~A prescriber may employ a pharmacist to provide nondispensing, drug information, or other cognitive services.~~ A purchasing pharmacist or pharmacy shall not engage in any activity or include in any agreement with a selling pharmacist or pharmacy any provision that would prevent or prohibit the prior notifications required in subrule 8.35(7).

c. Providing prescription blanks or forms bearing the pharmacy's name or other means of

identification to any person authorized to prescribe, except that a hospital may make prescription blanks or forms bearing the hospital pharmacy's name or other means of identification available to hospital staff prescribers, emergency department prescribers, and prescribers granted hospital privileges for the prescribers' use during practice at or in the hospital.

d. Any financial arrangement or transaction that would violate federal healthcare fraud, waste, and abuse laws, including but not limited to the Stark Law, the False Claims Act, and the Anti-Kickback Statute.

8.11(3) ~~*Lease agreements.* A pharmacist shall not lease space for a pharmacy under any of the following conditions:~~

~~*a.* to *c.* No change.~~

~~**8.11(4)** No change.~~

8.11(5) ~~*Freedom of choice/solicitation/kickbacks/fee-splitting and imprinted prescription blanks or forms.* A pharmacist or pharmacy shall not enter into any agreement which negates a patient's freedom of choice of pharmacy services. A purchasing pharmacist or pharmacy shall not engage in any activity or include in any agreement with a selling pharmacist or pharmacy any provision that would prevent or prohibit the prior notifications required in subrule 8.35(7). A pharmacist or pharmacy shall not participate in prohibited agreements with any person in exchange for recommending, promoting, accepting, or promising to accept the professional pharmaceutical services of any pharmacist or pharmacy. "Person" includes an individual, corporation, partnership, association, firm, or other entity. "Prohibited agreements" includes an agreement or arrangement that provides premiums, "kickbacks," fee-splitting, or special charges as compensation or inducement for placement of business or solicitation of patronage with any pharmacist or pharmacy. "Kickbacks" includes, but is not limited to, the provision of medication~~

~~carts, facsimile machines, any other equipment, or preprinted forms or supplies for the exclusive use of a facility or practitioner at no charge or billed below reasonable market rate. A pharmacist shall not provide, cause to be provided, or offer to provide to any person authorized to prescribe prescription blanks or forms bearing the pharmacist's or pharmacy's name, address, or other means of identification, except that a hospital may make available to hospital staff prescribers, emergency department prescribers, and prescribers granted hospital privileges for the prescribers' use during practice at or in the hospital generic prescription blanks or forms bearing the name, address, or telephone number of the hospital pharmacy.~~

~~8.11(6)~~ *Discrimination.* ~~It is unethical to unlawfully~~ A pharmacy, pharmacist, pharmacist-intern, technician, or pharmacy support person shall not discriminate between patients or groups of patients for reasons of religion, race, creed, color, gender, gender identity, sexual orientation, marital status, age, national origin, physical or mental disability, or disease state when providing pharmaceutical services.

~~8.11(7)~~ ~~*Claims of professional superiority.* A pharmacist or pharmacy shall not make a claim, assertion, or inference of professional superiority in the practice of pharmacy which cannot be substantiated, or claim an unusual, unsubstantiated capacity to supply a drug or professional service to the community.~~

8.11~~(8)~~ (4) *Unprofessional conduct or behavior.* A pharmacy, pharmacist, pharmacist-intern, technician, or pharmacy support person shall not ~~exhibit~~ engage in unprofessional behavior in connection with the practice of pharmacy~~ or refuse to provide reasonable information or answer reasonable questions for the benefit of the patient~~. Unprofessional behavior shall include, but not be limited to, the following acts: verbal abuse, coercion, intimidation, harassment, sexual advances, threats, degradation of character, indecent or obscene conduct, ~~and~~

theft, and the refusal to provide reasonable information or answer reasonable questions for the benefit of the patient.

ITEM 11. Amend rule 657—8.12(126,147) as follows:

657—8.12 (126,147) Advertising. Prescription drug ~~price and nonprice~~ information, including price, may be provided to the public by a pharmacy so long as the information is not false or misleading and is not in violation of any federal or state laws applicable to the advertisement of such articles generally and if all of the following conditions are met:

1. All charges for services to the consumer ~~must~~ shall be stated.

2. The effective dates for the prices listed shall be stated.

3. No reference shall be made to controlled substances listed in Schedules II through V of the latest revision of the Iowa uniform controlled substances Act and the rules of the Iowa board of pharmacy.

ITEM 12. Amend rule 657—8.13(135C,155A) as follows:

657—8.13 (135C,155A) Personnel histories. Pursuant to the requirements of Iowa Code section 135C.33, the provisions of this rule shall apply to any pharmacy employing any person to provide patient care services in a patient's home. For the purposes of this rule, "employed by the pharmacy" shall include any individual who is paid to provide treatment or services to any patient in the patient's home, whether the individual is paid by the pharmacy or by any other entity such as a corporation, a temporary staffing agency, or an independent contractor. Specifically excluded from the requirements of this rule are individuals such as delivery persons or couriers who do not enter the patient's home for the purpose of instructing the patient or the patient's caregiver in the use or maintenance of the equipment, device, or drug being delivered, or who do not enter the patient's home for the purpose of setting up or servicing the equipment,

device, or drug used to treat the patient in the patient's home.

8.13(1) *Applicant acknowledgment.* The pharmacy shall ask the following question of each person seeking employment in a position that will provide in-home services: "Do you have a record of founded child or dependent adult abuse or have you ever been convicted of a crime, in this state or any other state?" The applicant shall also be informed that a criminal history and child and dependent adult abuse record check will be conducted. The applicant shall indicate, by signed acknowledgment, that the applicant has been informed that such record checks will be conducted.

8.13(2) *Criminal history check.* Prior to the employment of any person to provide in-home services as described by this rule, the pharmacy shall ~~submit to~~ request that the department of public safety ~~a form specified by the department of public safety and receive the results of~~ perform a criminal history check.

8.13(3) *Abuse history checks.* Prior to the employment of any person to provide in-home services as described by this rule, the pharmacy shall ~~submit to~~ request that the department of human services ~~a form specified by the department of human services and receive the results of~~ perform a child and dependent adult abuse record check. The pharmacy may submit to the department of human services a form specified by the department of human services to request a child abuse history check.

a. to *b.* No change.

ITEM 13. Amend rule 657—8.14(155A) as follows:

657—8.14 (155A) Training and utilization of registered pharmacy ~~technicians or pharmacy support persons~~ staff. Pursuant to rule 657—8.3(155A), all Iowa-licensed pharmacies utilizing pharmacist-interns, pharmacy technicians, or pharmacy support persons shall have written

policies and procedures for the training and utilization of pharmacist-interns, pharmacy technicians, and pharmacy support persons appropriate to the practice of pharmacy at that licensed location. ~~Pharmacy technician and pharmacy support person training~~ Training shall be documented and maintained by the pharmacy for ~~the duration of employment~~ at least two years from the last date of employment or internship and shall be available for inspection by the board or its authorized agent. ~~Policies and procedures and documentation of pharmacy technician and pharmacy support person training shall be available for inspection by the board or an agent of the board.~~

ITEM 14. Amend rule 657—8.16(124,155A) as follows:

657—8.16 (124,155A) Confidential information.

8.16(1) ~~*Definition.* "Confidential information" means information accessed or maintained by the pharmacy in the patient's records which contains personally identifiable information that could be used to identify the patient. This includes but is not limited to patient name, address, telephone number, and social security number; prescriber name and address; and prescription and drug or device information such as therapeutic effect, diagnosis, allergies, disease state, pharmaceutical services rendered, medical information, and drug interactions, regardless of whether such information is communicated to or from the patient, is in the form of paper, is preserved on microfilm, or is stored on electronic media.~~

~~8.16(2)~~ *Release of confidential information.* Confidential information ~~in the patient record~~ may be released only as follows:

a. to *e.* No change.

A pharmacist shall utilize the resources available to determine, in the professional judgment of the pharmacist, that any persons requesting confidential patient information pursuant to this rule are entitled to receive that information.

8.16~~(3)~~(2) *Exceptions.* Nothing in this rule shall prohibit ~~pharmacists~~ a pharmacist from releasing confidential patient information as follows:

a. Transferring a prescription to another pharmacy upon the request of the patient or the patient's authorized representative or pursuant to subrule 8.35(7) when the pharmacy is discontinuing operations.

b. Providing a copy of a nonrefillable prescription to the ~~person for whom the prescription was issued~~ patient which nonrefillable prescription is clearly marked as a copy and not to be filled.

c. Providing drug therapy information to ~~physicians or other~~ authorized ~~prescribers~~ practitioners for their patients.

d. Disclosing information necessary for the processing of third-party payer claims ~~for payment of health care operations or services~~ on behalf of the patient.

~~*e.* Transferring, subject to the provisions of subrule 8.35(7), prescription and patient records of a pharmacy that discontinues operation as a pharmacy to another licensed pharmacy that is held to the same standards of confidentiality and that agrees to act as custodian of the transferred records.~~

~~**8.16(4)** *System security and safeguards.* To maintain the integrity and confidentiality of patient records and prescription drug orders, any system or computer utilized shall have adequate security including system safeguards designed to prevent and detect unauthorized access, modification, or manipulation of patient records and prescription drug orders.~~

8.16~~(5)~~(3) *Record disposal.* Disposal of any materials containing or including patient-specific or confidential information shall be conducted in a manner to preserve patient confidentiality.

ITEM 15. Amend rule 657—8.19(124,126,155A) as follows:

657—8.19 (124,126,155A) Manner of issuance of a prescription drug or medication order. A prescription drug order or medication order may be transmitted from a prescriber or a prescriber's agent to a pharmacy in written form, orally including telephone voice communication, by facsimile transmission as provided in rule 657—21.9(124,155A), or by electronic transmission in accordance with applicable federal and state laws, rules, and regulations. Any prescription drug order or medication order provided to a patient in written or printed form shall include the original, handwritten signature of the prescriber except as provided in rule 657—21.7(124,155A).

8.19(1) *Requirements for a prescription.* A valid prescription drug order shall be based on a valid patient-prescriber relationship except as provided in subrule 8.19(7) for epinephrine auto-injectors and in subrule 8.19(8) for opioid antagonists.

a. *Written, electronic, or facsimile prescription.* In addition to the electronic prescription application and pharmacy prescription application requirements of this rule, a written, electronic, or facsimile prescription shall include:

(1) No change.

(2) The name and address of the patient except as provided in subrule 8.19(7) for epinephrine auto-injectors and in subrule 8.19(8) for opioid antagonists.

(3) to (5) No change.

b. to *c.* No change.

d. *Electronic prescription.* In addition to the requirements of paragraph 8.19(1)*"a,"* an electronically prepared prescription for a controlled or noncontrolled prescription drug or device that is electronically transmitted to a pharmacy shall include the prescriber's electronic signature, except as provided herein.

(1) to (3) No change.

(4) An electronic prescription for a noncontrolled prescription drug or device that is transmitted by an authorized agent shall not be required to contain the prescriber's electronic signature.

8.19(2) *Verification.* The pharmacist shall exercise professional judgment regarding the accuracy, validity, and authenticity of any prescription drug order or medication order consistent with federal and state laws, rules, and regulations. In exercising professional judgment, the ~~prescribing practitioner~~ prescriber and the pharmacist shall take adequate measures to guard against the diversion of prescription drugs and controlled substances through prescription forgeries.

8.19(3) *Transmitting agent.* The ~~prescribing practitioner~~ prescriber may authorize an agent to transmit to the pharmacy a prescription drug order or medication order orally, by facsimile transmission, or by electronic transmission provided that the first and last names and title of the transmitting agent are included in the order.

a. *New order.* A new written or electronically prepared and transmitted prescription drug or medication order shall be manually or electronically signed by the prescriber, except as provided in subrule 8.19(1), paragraph "*d*". If transmitted by the prescriber's agent, the first and last names and title of the transmitting agent shall be included in the order. If the prescription is for a controlled substance and is written or printed from an electronic prescription application,

the prescription shall be manually signed by the prescriber ~~prior to delivery of the prescription to the patient or prior to facsimile transmission of the prescription to the pharmacy~~. An electronically prepared prescription shall not be electronically transmitted to the pharmacy if the prescription has been printed prior to the electronic transmission. An electronically prepared and electronically transmitted prescription that is printed following the electronic transmission shall be clearly labeled as a copy, not valid for dispensing.

b. Refill order or renewal order. An authorization to refill a prescription drug or medication order, or to renew or continue an existing drug therapy, may be transmitted to ~~a pharmacist~~ professional pharmacy staff through oral communication, in writing, by facsimile transmission, or by electronic transmission initiated by or directed by the prescriber.

(1) to (2) No change.

8.19(4) *Receiving agent.* Regardless of the means of transmission to a pharmacy, only ~~a pharmacist, a pharmacist intern, or a certified pharmacy technician~~ professional pharmacy staff shall be authorized to receive a new prescription drug or medication order from a ~~practitioner~~ prescriber or the ~~practitioner's~~ prescriber's agent. ~~In addition to a pharmacist, a pharmacist intern, and a certified pharmacy technician, a~~ A technician trainee ~~or an uncertified pharmacy technician~~ may receive a refill or renewal order from a ~~practitioner~~ prescriber or the ~~practitioner's~~ prescriber's agent only if the technician's supervising pharmacist has authorized that function.

8.19(5) *Legitimate purpose.* The ~~pharmacist~~ pharmacy and professional pharmacy staff shall ensure that the prescription drug or medication order, regardless of the means of transmission, has been issued for a legitimate medical purpose by ~~an authorized practitioner~~ a prescriber acting in the usual course of the ~~practitioner's~~ prescriber's professional practice. A

pharmacist shall not dispense a prescription drug if the pharmacist knows or should have known that the prescription was issued solely on the basis of an Internet-based questionnaire, an Internet-based consultation, or a telephonic consultation and without a valid preexisting patient-~~practitioner~~prescriber relationship except as provided in subrule 8.19(7) for epinephrine auto-injectors and in subrule 8.19(8) for opioid antagonists.

8.19(6) to **8.19(8)** No change.

ITEM 16. Amend rule 657—8.21(155A) as follows:

657—8.21 (155A) Prospective drug use review. For purposes of promoting therapeutic appropriateness and ensuring rational drug therapy, a pharmacist shall review the patient record, information obtained from the patient, and each prescription drug or medication order to identify:

1. to 8. No change.

Upon recognizing any of the above, the pharmacist shall take appropriate steps to avoid or resolve the problem and shall, if necessary, include consultation with the prescriber. The review and assessment of patient records shall not be delegated to ~~staff assistants~~ pharmacy technicians or pharmacy support persons but may be delegated to registered pharmacist-interns under the direct supervision of the pharmacist.

ITEM 17. Adopt the following **new** rule 657—8.22(155A):

657—8.22(155A) Notification of interchangeable biological product selection. Pursuant to Iowa Code section 155A.32, when a pharmacist substitutes a biological product that is an interchangeable biological product for the biological product prescribed, the pharmacist or pharmacist's designee shall, within five business days of dispensing the biological product, communicate to the prescriber the name and manufacturer of the biological product dispensed

unless the prescription information has been entered into an electronic record system, such as an electronic medical record, electronic prescribing system, pharmacy benefit management system, or a pharmacy record to which the prescriber has access. The manner of communication to the prescriber may be via telephone, facsimile, electronic transmission, or other prevailing means.

This rule is intended to implement Iowa Code section 155A.32.

ITEM 18. Adopt the following **new** rule(s) 657—8.23(124,155A):

657—8.23(124,155A) Individuals qualified to administer. The board designates the following as qualified individuals to whom a prescriber may delegate the administration of prescription drugs. Any person specifically authorized under pertinent sections of the Iowa Code to administer prescription drugs shall construe nothing in this rule to limit that authority.

1. Persons who have successfully completed a medication administration course.
2. Licensed pharmacists.

This rule is intended to implement Iowa Code section 155A.44.

ITEM 19. Adopt the following **new** rule(s) 657—8.24(155A):

657—8.24(155A) Documented verification. The pharmacist shall provide, document, and retain a record of the final verification for the accuracy, validity, completeness, and appropriateness of the patient's prescription or medication order prior to the delivery of the medication to the patient or the patient's representative. In an approved tech-check-tech program, the checking technician shall provide, document, and retain a record of the final verification for the accuracy of the patient's prescription or medication order prior to the delivery of the medication to the patient or the patient's representative.

ITEM 20. Amend subrule 8.26(3) as follows:

8.26(3) *Policies and procedures.* Pursuant to rule 657—8.3(155A), each pharmacy shall have written policies and procedures for the operation and management of the pharmacy's CQI program. A copy of the pharmacy's CQI program description and policies and procedures shall be maintained and readily available to all pharmacy personnel. The policies and procedures shall address, at a minimum, a planned process to:

a. to *e.* No change

f. Periodically, but at least ~~annually~~ quarterly, meet with appropriate pharmacy personnel to review findings and inform personnel of changes that have been made to pharmacy policies, procedures, systems, or processes as a result of CQI program findings.

ITEM 21. Rescind and reserve rule **657—8.31(135,147A)**.

ITEM 22. Rescind and reserve rule **657—8.32(124,155A)**.

ITEM 23. Rescind and reserve rule **657—8.33(155A)**.

ITEM 24. Rescind and reserve rule **657—8.34(155A)**.

ITEM 25. Rescind rule 657—8.35(155A) and adopt the following **new** rule in lieu thereof:

657—8.35(155A) Pharmacy license. A pharmacy license issued by the board is required for all sites where prescription drugs are offered for sale or dispensed under the supervision of a pharmacist. The current pharmacy license certificate shall be displayed in a position visible to the public. The board may issue any of the following types of pharmacy licenses: a general pharmacy license, a hospital pharmacy license, a limited use pharmacy license, a telepharmacy license, or a nonresident pharmacy license. Nonresident pharmacy license applicants shall comply with board rules regarding nonresident pharmacy practice except when a waiver has been granted. Applicants for general or hospital pharmacy practice shall comply with board rules

regarding general or hospital pharmacy practice except when a waiver has been granted. Any pharmacy that dispenses controlled substances to Iowa residents must also register pursuant to 657—Chapter 10.

8.35(1) *Limited use pharmacy license.* A limited-use pharmacy license may be issued for nuclear pharmacy practice, correctional facility pharmacy practice, veterinary pharmacy practice, telepharmacy practice, and other limited use practice settings. Applications for a limited use pharmacy license shall be considered on a case-by-case basis.

8.35(2) *Application.* Applicants for initial licensure, license renewal, license reactivation, or license changes pursuant to subrule 8.35(6) shall complete the relevant pharmacy license application and shall include all required information and attachments. All pharmacy license applications require submission of a nonrefundable $135 license fee plus applicable penalty fees. The application shall include the signature of the pharmacy owner's authorized representative and shall require at a minimum the following:

a. Disclosure of pharmacy ownership information, including information about the pharmacy's registered agent;

b. Identification and signature of the pharmacist in charge;

c. The identification of and average number of hours worked by all pharmacists, pharmacist-interns, pharmacy technicians, and pharmacy support persons working in the pharmacy;

d. Criminal and disciplinary history information; and

e. Description of the scope of services provided by the pharmacy.

8.35(3) *License renewal.* A pharmacy license shall be renewed before January 1 of each year. An initial pharmacy license issued between November 1 and December 31 shall not require

renewal until the following calendar year. The nonrefundable fee for a timely license renewal shall be $135.

a. *Delinquent license grace period.* A pharmacy license renewal application that is postmarked or hand-delivered to the board after January 1 but prior to February 1 following expiration shall be considered delinquent and shall require the nonrefundable payment of the renewal fee plus penalty fee of $135. A pharmacy that submits a completed license renewal application, application fee, and penalty fee postmarked or delivered to the board office by January 31 shall not be subject to disciplinary action for continuing to operate in the month of January.

b. *Delinquent license reactivation beyond grace period.* If a pharmacy license is not renewed prior to the expiration of the one month grace period identified in paragraph "*a*", the pharmacy may not operate or provide pharmacy services to patients in the state of Iowa until the license is reactivated. A pharmacy without a current license may apply for license reactivation by submitting an application for reactivation and a nonrefundable $540 reactivation fee. As part of the reactivation application, the pharmacy shall disclose the prescriptions dispensed and the services, if any, that were provided to Iowa patients while the license was delinquent. A pharmacy that continues to operate or provide pharmacy services in Iowa without a current license may be subject to disciplinary sanctions.

8.35(4) *Inspection of new pharmacy location.* A new pharmacy location in Iowa shall require an on-site inspection by an authorized agent of the board. Application for pharmacy license and other required registrations shall be submitted to the board at least 14 days prior to the anticipated inspection. Any deficiencies identified during the inspection shall be corrected and verified by an authorized agent of the board prior to the issuance of the pharmacy license.

Prescription drugs, including controlled substances, may not be delivered to a new pharmacy location prior to delivery of the pharmacy license and registration certificates.

8.35(5) *Failure to complete licensure.* An application for a pharmacy license, including any other required registration applications, will become null and void if the applicant fails to complete the licensure process within six months of acceptance by the board of the required applications. The licensure process shall be complete upon the pharmacy's opening for business at the licensed location following a satisfactory inspection by an agent of the board pursuant to this rule. When an applicant fails to timely complete the licensure process, fees submitted with applications will not be transferred or refunded. If the applicant intends to proceed with a pharmacy license, a new application and fee shall be required.

8.35(6) *Pharmacy license changes.* When a pharmacy changes its name, location, ownership, or pharmacist in charge, a completed pharmacy license application with a nonrefundable $135 fee shall be submitted to the board. Upon receipt of the completed application and fee, the board shall issue an updated pharmacy license certificate unless the board identifies any ground for denial of the license. Any restrictions or disciplinary history associated with the previous pharmacy shall remain unchanged. A pharmacy wishing to disassociate itself from the previously licensed pharmacy restrictions or disciplinary history may petition the board for such disassociation. The burden is on the pharmacy to demonstrate that the current pharmacy is not associated with or responsible for the pharmacy as it previously existed. The old license certificate shall be returned to the board within ten days of receiving the updated license certificate.

a. *Name.* A change of the name under which the pharmacy is doing business shall require submission of a pharmacy license application and appropriate fee prior to the change.

b. *Location.* A change of pharmacy location shall require submission of a pharmacy license application and appropriate fee prior to the change of location. A pharmacy undergoing a change in location is required to notify patients of the change in accordance with 657—subrule 8.35(6), paragraph "*d*". A change of pharmacy location in Iowa may require an on-site inspection of the new location as provided in 657—subrule 8.35(4).

c. *Ownership.* A change in ownership of a pharmacy shall require submission of a pharmacy license application and appropriate fee prior to the change. A pharmacy undergoing a change in ownership is required to notify the pharmacist in charge and patients of the change in accordance with 657—subrule 8.35(7). If the pharmacy owner is a corporation, the sale or transfer of stock wherein the pharmacy continues to exist and the corporate owner continues to own the pharmacy does not constitute a change in ownership for the purpose of these rules. A change of ownership effectively consists of closing a pharmacy and opening a new pharmacy.

d. *Pharmacist in charge.* In addition to the requirements of this paragraph, a change of pharmacist in charge for a nonresident pharmacy shall require registration of the new permanent pharmacist in charge if the pharmacist in charge is not currently registered by the board or licensed to practice pharmacy in Iowa.

(1) If a permanent pharmacist in charge has been identified by the time of the vacancy, a pharmacy license application identifying the new pharmacist in charge, along with appropriate fee, shall be submitted to the board within ten days of the change.

(2) If a permanent pharmacist in charge has not been identified by the time of the vacancy, a temporary pharmacist in charge shall be identified. Written notification identifying the temporary pharmacist in charge shall be submitted to the board within ten days of the vacancy.

(3) If a permanent pharmacist in charge was not identified within ten days of the vacancy, the pharmacy shall, within 90 days of the vacancy, identify a permanent pharmacist in charge. A pharmacy license application identifying the permanent pharmacist in charge, along with appropriate fee, shall be submitted to the board within ten days of the appointment of a permanent pharmacist in charge and ensuring the board receives the application and fee within 90 days of the original vacancy.

8.35(7) *Closing or sale of a pharmacy.* A closing pharmacy shall ensure that all pharmacy records are transferred to another licensed pharmacy that agrees to act as custodian of the records for at least two years. A pharmacy shall not execute a sale or closing of a pharmacy unless there exists an adequate period of time prior to the pharmacy closing for delivery of the notifications to the pharmacist in charge, the board, the DEA, and pharmacy patients as required by this subrule. However, the provisions of this subrule regarding prior notifications to the board, the DEA, and patients shall not apply in the case of a board-approved emergency or unforeseeable closure, including but not limited to emergency board action, foreclosure, fire, or natural disaster.

a. *Pharmacist in charge notification.* At least 40 days prior to the effective date of the sale or closing of a pharmacy, the pharmacist in charge of the closing pharmacy shall be notified of the proposed sale or closing. Information regarding the pending sale or closure of the pharmacy may be kept confidential until public notifications are required 30 days prior to the pharmacy closing. The pharmacist in charge of the closing pharmacy shall provide input and direction to the pharmacy owner regarding the responsibilities of the closing pharmacy, including the notifications, deadlines, and time lines established by this subrule. The pharmacist

in charge of the purchasing or receiving pharmacy shall be notified of the pending transaction at least 30 days prior to the sale or closure of the pharmacy.

b. Board and DEA notifications. At least 30 days prior to the closing of a pharmacy, a written notice shall be sent to the board. Notification to the DEA shall be pursuant to federal regulation. Notification to the board shall include:

1. The anticipated date of closing or transfer of prescription drugs or records,
2. The name, address, DEA registration number, Iowa pharmacy license number, and Iowa controlled substances Act (CSA) registration number of the closing pharmacy and of the pharmacy to which prescription drugs will be transferred.
3. The name, address, DEA registration number, Iowa pharmacy license number, and CSA registration number of the location at which records will be maintained.

c. Terms of sale or purchase. If the closing is due to the sale of the pharmacy, a copy of the sale or purchase agreement, not including information regarding the monetary terms of the transaction, shall be submitted to the board upon the request of the board. The agreement shall include a written assurance from the closing pharmacy to the purchasing pharmacy that the closing pharmacy has given or will be giving notice to its patients as required by this subrule.

d. Patient notification. At least 30 days prior to closing, a closing pharmacy shall make a reasonable effort to notify all patients who had a prescription filled by the closing pharmacy within the last 18 months that the pharmacy intends to close, including the anticipated closing date.

(1) Written notification shall identify the pharmacy that will be receiving the patient's records. The notification shall advise patients that all patient records will be transferred to the identified pharmacy and that patients may contact the closing pharmacy to request the transfer of

remaining refills to a pharmacy of the patient's choice. The notification shall also advise patients that after the date of closing patients may contact the pharmacy to which the records have been transferred.

(2) Written notification shall be delivered to each patient at the patient's last address on file with the closing pharmacy by direct mail or personal delivery. A pharmacy shall not be required to provide written notice to more than one patient within the same household.

(3) Public notice shall be provided in a location and manner clearly visible to patients in the pharmacy pickup locations including drive-through prescription pickup lanes, on pharmacy or retail store entry and exit doors, and at pharmacy prescription counters.

e. Patient communication by receiving pharmacy. A pharmacy receiving the patient records of another pharmacy shall not contact the patients of the closing pharmacy until after the transfer of those patient records from the closing pharmacy to the receiving pharmacy and after the closure of the closing pharmacy.

f. Prescription drug inventory. A complete inventory of all prescription drugs being transferred shall be taken as of the close of business. The inventory shall serve as the ending inventory for the closing pharmacy as well as a record of additional or starting inventory for the pharmacy to which the drugs are transferred. A copy of the inventory shall be maintained in the records of the purchasing pharmacy for at least two years.

(1) DEA Form 222 is required for transfer of Schedule II controlled substances.

(2) The inventory of controlled substances shall be completed pursuant to the requirements in rule 657—10.19(124,155A).

(3) The inventory of all noncontrolled prescription drugs shall include the name, strength, dosage form, and quantity, which may be estimated.

(4) Controlled substances and prescription drugs requiring destruction or other disposal shall be transferred in the same manner as all other drugs. The new owner is responsible for the disposal of these drugs.

g. Return of certificates and forms. The pharmacy license certificate and CSA registration certificate of the closing or selling pharmacy shall be returned to the board within ten days of closing or sale. The pharmacy shall be responsible for complying with federal DEA regulations for the cancellation and return of DEA forms and certificates.

h. Signs at closed pharmacy location. A location that no longer houses a licensed pharmacy shall not display any sign, placard, or other notification, visible to the public, which identifies the location as a pharmacy. A sign or other public notification that cannot feasibly be removed shall be covered so as to conceal the identification as a pharmacy. Nothing in this paragraph shall prohibit the display of a public notice to patients, as required in paragraph 8.35(7)*"d,"* for a reasonable period not to exceed six months following the pharmacy closing.

8.35(8) *Reporting discipline and criminal convictions.* A pharmacy shall, no later than 30 days after the final action, provide written notice to the board of any discipline imposed by any licensing authority on any license or registration held by the pharmacy. Discipline may include, but is not limited to, fine or civil penalty, citation or reprimand, probationary period, suspension, revocation, or voluntary surrender. A pharmacy shall, no later than 30 days after a conviction, provide written notice to the board of any criminal conviction of the pharmacy or of any pharmacy owner when that conviction is related to prescription drugs or to the operation of the pharmacy. The term criminal conviction includes instances when the judgment of conviction or sentence is deferred.

ITEM 26. Rescind and reserve rule **657—8.40(155A,84GA,ch63)**.

ITEM 27. Amend **657—Chapter 8**, implementation sentence, as follows:

These rules are intended to implement Iowa Code sections 124.101, 124.301, 124.306, 124.308, 126.10, 126.11, 126.16, 135C.33, 147.7, 147.55, 147.72, 147.74, 147.76, 155A.2 through 155A.4, 155A.6, 155A.10, 155A.12 through 155A.15, 155A.19, 155A.20, 155A.27 through 155A.29, 155A.31 through ~~155A.32, and 155A.33~~ 155A.35, and ~~2013 Iowa Acts, Senate File 353~~ 155A.41.

ITEM 28. Adopt the following **new** 657—Chapter 39:

CHAPTER 39

EXPANDED PRACTICE STANDARDS

657—39.1(155A) Purpose and scope. The purpose of this chapter is to establish the minimum standards for the programs and activities identified in this chapter. These rules shall apply to all licensed pharmacists, other registered pharmacy personnel, and all pharmacies, including owners, engaged in the programs and activities identified in this chapter in the state of Iowa. These rules are in addition to rules of the board relating to the practice of pharmacy unless otherwise indicated by rule.

657—39.2 and **39.3** Reserved.

657—39.4(155A) Pharmaceutical care. Pharmaceutical care is a comprehensive, patient-centered, outcomes-oriented pharmacy practice in which the pharmacist accepts responsibility for assisting the prescriber and the patient in optimizing the patient's drug therapy plan and works to promote health, to prevent disease, and to optimize drug therapy. Pharmaceutical care does not include the prescribing of drugs without the consent of the ~~prescribing practitioner~~ prescriber.

39.4(1) *Drug therapy problems.* In providing pharmaceutical care, the pharmacist shall strive to identify, resolve, and prevent drug therapy problems.

39.4(2) *Drug therapy plan.* In providing pharmaceutical care, the pharmacist shall access and evaluate patient-specific information, identify drug therapy problems, and utilize that information in a documented plan of therapy that assists the patient or the patient's caregiver in achieving optimal drug therapy. In concert with the patient, the patient's prescribing practitioner, and the patient's other health care providers, the pharmacist shall assess, monitor, and suggest modifications of the drug therapy plan as appropriate.

657—39.5 and **39.6** Reserved.

657—39.7(135,147A) Opioid antagonist dispensing by pharmacist -- standing order. An authorized pharmacist may dispense an opioid antagonist pursuant to a standing order established by the department, which standing order can be found via the board's Web site, or pursuant to a standing order authorized by an individual licensed health care professional in compliance with the requirements of this rule. An authorized pharmacist may only delegate the dispensing of an opioid antagonist to an authorized pharmacist-intern under the direct supervision of an authorized pharmacist. Nothing in this rule prohibits a prescriber or facility from establishing and implementing standing orders or protocols under the authority granted to the prescriber or facility.

39.7(1) *Definitions.* For the purposes of this rule, the following definitions shall apply:

"*Authorized pharmacist*" means an Iowa-licensed pharmacist who has completed the training requirements of this rule. "Authorized pharmacist" also includes an Iowa-registered pharmacist-intern who has completed the training requirements of this rule and is working under the direct supervision of an authorized Iowa-licensed pharmacist.

"*Department"* means the Iowa department of public health.

"*First responder"* means an emergency medical care provider, a registered nurse staffing an authorized service program under Iowa Code section 147A.12, a physician assistant staffing an authorized service program under Iowa Code section 147A.13, a fire fighter, or a peace officer as defined in Iowa Code section 801.4 who is trained and authorized to administer an opioid antagonist.

"*Licensed health care professional"* means a person licensed under Iowa Code chapter 148 to practice medicine and surgery or osteopathic medicine and surgery, an advanced registered nurse practitioner licensed under Iowa Code chapter 152 or 152E and registered with the board of nursing, or a physician assistant licensed to practice under the supervision of a physician as authorized in Iowa Code chapters 147 and 148C.

"*Opioid antagonist"* means the same as defined in Iowa Code section 147A.1.

"*Opioid-related overdose"* means the same as defined in Iowa Code section 147A.1.

"*Person in a position to assist"* means a family member, friend, caregiver, health care provider, employee of a substance abuse treatment facility, or other person who may be in a position to render aid to a person at risk of experiencing an opioid-related overdose.

"*Recipient"* means an individual at risk of an opioid-related overdose or a person in a position to assist an individual at risk of an opioid-related overdose.

"*Standing order"* means a preauthorized medication order with specific instructions from the licensed health care professional to dispense a medication under clearly defined circumstances.

39.7(2) *Authorized pharmacist training.* An authorized pharmacist shall document successful completion of an ACPE-approved continuing education program of at least one-hour

duration related to opioid antagonist utilization prior to dispensing opioid antagonists pursuant to a standing order.

39.7(3) *Additional supply.* Notwithstanding a standing order to the contrary, an authorized pharmacist shall only dispense an opioid antagonist after completing an eligibility assessment and providing training and education to the recipient.

39.7(4) *Assessment.* An authorized pharmacist shall assess an individual for eligibility to receive an opioid antagonist pursuant to a standing order. In addition to the criteria identified in a standing order, an authorized pharmacist shall also take into consideration the following criteria to determine the eligibility of the recipient to receive and possess an opioid antagonist:

a. The person at risk of an opioid-related overdose for which the opioid antagonist is intended to be administered has no known sensitivity or allergy to naloxone, unless the person at risk is not known to the recipient, including but not limited to a first responder or member of law enforcement.

b. The recipient is oriented to person, place, and time and able to understand and learn the essential components of opioid-related overdose, appropriate response, and opioid antagonist administration.

39.7(5) *Recipient training and education.* Upon assessment and determination that an individual is eligible to receive and possess an opioid antagonist pursuant to a standing order, an authorized pharmacist shall, prior to dispensing an opioid antagonist pursuant to a standing order, provide training and education to the recipient that includes, but is not limited to, the information identified in this subrule. An authorized pharmacist shall require the recipient to attest that, if the product will be accessible to any other individual for administration, the recipient will make available to such individual all received training and education materials. An

authorized pharmacist may provide to the recipient written materials that include, but may not be limited to, the information identified in this subrule, but it shall not be in lieu of direct pharmacist consultation with the recipient.

a. The signs and symptoms of opioid-related overdose as described in the standing order.

b. The importance of calling 911 as soon as possible and the potential need for rescue breathing.

c. The appropriate use and directions for administration of the opioid antagonist to be dispensed pursuant to the standing order.

d. Adverse reactions of the opioid antagonist as well as reactions resulting from opioid withdrawal following administration.

e. The proper storage conditions, including temperature excursions, of the opioid antagonist being dispensed.

f. The expiration date of the opioid antagonist being dispensed and the appropriate disposal of the opioid antagonist upon expiration.

g. The prohibition of the recipient from further distributing the opioid antagonist to another individual, unless that individual has received appropriate training and education.

h. Information about substance abuse or behavioral health treatment programs.

39.7(6) *Labeling.* Upon the determination that a recipient is eligible to receive and possess an opioid antagonist, an authorized pharmacist shall label the product pursuant to rule 657—6.10(126,155A) and 657—subrule 8.19(8). An authorized pharmacist shall ensure that the labeling does not render the expiration date of the product illegible. The medication shall be dispensed in the name of the eligible recipient.

39.7(7) *Reporting.* A copy of the assessment form shall be submitted to the department as provided on the assessment form within seven days of the dispensing of the opioid antagonist or within seven days of a denial of eligibility.

39.7(8) *Records.* An authorized pharmacist shall create and maintain an original record of each individual assessment on forms provided by the board, regardless of the eligibility determination following assessment, and dispensing of opioid antagonists pursuant to a standing order. These records shall be available for inspection and copying by the board or its authorized agent for at least two years.

657—39.8 and **39.9** Reserved.

657—39.10(155A) Vaccine administration by pharmacists. An authorized pharmacist may administer vaccines pursuant to protocols established by the CDC in compliance with the requirements of this rule. An authorized pharmacist may only delegate the administration of a vaccine to an authorized pharmacist-intern under the direct supervision of the authorized pharmacist.

39.10(1) *Definitions.* For the purposes of this rule, the following definitions shall apply:

"*ACIP*" means the CDC Advisory Committee on Immunization Practices.

"*ACPE*" means the Accreditation Council for Pharmacy Education.

"*Authorized pharmacist*" means an Iowa-licensed pharmacist who has met the requirements identified in subrule 39.10(2).

"*Authorized pharmacist-intern*" means an Iowa-registered pharmacist-intern who has met the requirements for an authorized pharmacist identified in paragraphs 39.10(2)"*a*" and "*c.*"

"*CDC*" means the United States Centers for Disease Control and Prevention.

"*Immunization"* shall have the same meaning as, and shall be interchangeable with, the term "vaccine."

"*Protocol"* means a standing order for a vaccine to be administered by an authorized pharmacist.

"*Vaccine"* means a specially prepared antigen administered to a person for the purpose of providing immunity.

39.10(2) *Authorized pharmacist training and continuing education.* An authorized pharmacist shall document successful completion of the requirements in paragraph 39.10(2)*"a"* and shall maintain competency by completing and maintaining documentation of the continuing education requirements in paragraph 39.10(2)*"b."*

a. Initial qualification. An authorized pharmacist shall have successfully completed an organized course of study in a college or school of pharmacy or an ACPE-accredited continuing 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 CDC 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, counseling, and identification of contraindications to the vaccine;

9. Immunization record management; and

10. Management of adverse events, including identification, appropriate response, documentation, and reporting.

b. Continuing education. During any pharmacist license renewal period, an authorized pharmacist who engages in the administration of vaccines shall complete and document at least one hour of continuing education related to vaccines.

c. Certification maintained. During any period within which the pharmacist may engage in the administration of vaccines, the pharmacist shall maintain current certification in the American Heart Association or the Red Cross basic cardiac life support protocol for health care providers.

39.10(3) *Protocol requirements.* A pharmacist may administer vaccines pursuant to a protocol based on CDC recommendations. A protocol shall be unique to a pharmacy. The pharmacy shall comply with the parameters of the protocol. The prescriber who signs a protocol shall identify within the protocol, by name or category, those pharmacists or other qualified health professionals that the prescriber is authorizing to administer vaccines pursuant to the protocol. A protocol:

a. Shall be signed by a licensed Iowa prescriber practicing in Iowa.

b. Shall expire no later than one year from the effective date of the signed protocol.

c. Shall be effective for patients who wish to receive a vaccine administered by an authorized pharmacist, who meet the CDC recommended criteria, and who have no contraindications as published by the CDC.

d. Shall require the authorized pharmacist to notify the prescriber who signed the protocol within 24 hours of a serious complication and shall submit a Vaccine Advisory Event Reporting System (VAERS) report.

e. Shall specifically indicate whether the authorizing prescriber agrees that the administration of vaccines may be delegated by the authorized pharmacist to an authorized pharmacist-intern under the direct supervision of the authorized pharmacist.

39.10(4) *Influenza and other emergency vaccines.* An authorized pharmacist shall only administer via protocol, to patients six years of age and older, influenza vaccines and other emergency vaccines in response to a public health emergency.

39.10(5) *Other adult vaccines.* An authorized pharmacist shall only administer via protocol, to patients 18 years of age and older, the following vaccines:

a. A vaccine on the ACIP-approved adult vaccination schedule.

b. A vaccine recommended by the CDC for international travel.

39.10(6) *Vaccines administered via prescription.* An authorized pharmacist may administer any vaccine pursuant to a prescription or medication order for an individual patient. In case of serious complications, the authorized pharmacist shall notify the prescriber who authorized the prescription within 24 hours and shall submit a VAERS report.

39.10(7) *Verification and reporting.* The requirements of this subrule do not apply to influenza and other emergency vaccines administered via protocol pursuant to subrule 39.10(4). An authorized pharmacist shall:

a. Prior to administering a vaccine identified in subrule 39.10(5) or subrule 39.10(6), consult the statewide immunization registry or health information network.

b. Within 30 days following administration of a vaccine identified in subrule 39.10(5) or subrule 39.10(6), report the vaccine administration to the statewide immunization registry or health information network and to the patient's primary health care provider, if known.

657—39.11 and **39.12** Reserved.

657—39.13(155A) Collaborative drug therapy management. An authorized pharmacist may only perform collaborative drug therapy management pursuant to protocol with an authorized provider pursuant to the requirements of this rule. The authorized provider retains the ultimate responsibility for the care of the patient. The pharmacist is responsible for all aspects of drug therapy management performed by the pharmacist.

39.13(1) *Definitions.*

"Authorized pharmacist" means an Iowa-licensed pharmacist whose license is in good standing and who meets the drug therapy management criteria defined in this rule.

"Authorized provider" means an Iowa-licensed prescribing practitioner who is authorized by the practitioner's professional licensing authority to participate in a collaborative practice agreement with an authorized pharmacist pursuant to these rules and the rules of the practitioner's professional licensing authority. An authorized provider 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 authorized provider may delegate only drug therapies that are in areas common to the authorized provider's practice.

"Board" means the board of pharmacy.

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

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

"*Community practice protocol"* means a written, executed agreement entered into voluntarily between an authorized pharmacist and an authorized provider establishing drug therapy management for one or more of the pharmacist's and authorized provider's patients residing in a community setting. A community practice protocol shall comply with the requirements of subrule 39.13(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.

"*Drug therapy management criteria"* means one or more of the following:

1. Graduation from a recognized school or college of pharmacy with a doctor of pharmacy (Pharm.D.) degree;

2. Certification by the Board of Pharmaceutical Specialties (BPS);

3. Certification by the Commission for Certification in Geriatric Pharmacy (CCGP);

4. Successful completion of a National Institute for Standards in Pharmacist Credentialing (NISPC) disease state management examination and credentialing by the NISPC;

5. Successful completion of a pharmacy residency program accredited by the American Society of Health-System Pharmacists (ASHP); or

6. Approval by the board of pharmacy.

"*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 hospital pharmacists and authorized providers within a hospital and the hospital's clinics as developed and determined by the hospital's P&T committee. Such a protocol may apply to all pharmacists and authorized providers at a hospital or the hospital's clinics or only to those pharmacists and authorized providers who are specifically recognized. A hospital practice protocol shall comply with the requirements of subrule 39.13(3).

"*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.

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

39.13(2) *Community practice protocol.*

a. An authorized pharmacist shall engage in collaborative drug therapy management with an authorized provider only under a written protocol that has been identified by topic. Protocols shall be made available upon request of the board or the licensing board of the authorized provider.

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 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 authorized pharmacist shall be designated in the protocol.

(2) The name, signature, date, and contact information for each authorized provider who may prescribe drugs and is responsible for supervising a patient's drug therapy management. The authorized provider 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 authorized provider.

(3) The name and contact information of the principal authorized provider 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 authorized provider. The protocol shall not authorize the pharmacist to change a Schedule II drug or to initiate a drug not included in the established protocol.

2. Laboratory tests. The protocol may authorize the pharmacist to obtain or to 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 authorized provider for follow-up.

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

(5) Procedures for securing the patient's written consent. If the patient's consent is not secured by the authorized provider, the authorized pharmacist shall secure such and notify the patient's authorized provider within 24 hours.

(6) Circumstances that shall cause the authorized pharmacist to initiate communication with the authorized provider 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 authorized pharmacist shall base drug therapy management decisions.

(8) A provision for the collaborative drug therapy management 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 authorized provider.

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

(11) A statement of the medication categories and the type of initiation and modification of drug therapy that the provider 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 authorized pharmacist from delegating drug therapy management to anyone other than another authorized pharmacist who has signed the applicable protocol.

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

(17) A description of the mechanism for the pharmacist and the authorized provider 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 one authorized pharmacist and at least one authorized provider.

d. The collaborative drug therapy protocol shall be kept on file in the pharmacy and be made available upon request of the board the licensing board of the authorized provider.

e. An authorized provider may terminate or amend the collaborative drug therapy management protocol with an authorized pharmacist if the authorized provider notifies the pharmacist in writing. Notification shall include the name of the authorized pharmacist, the desired change, and the proposed effective date of the change. Written notification shall be maintained in the pharmacy and be made available upon request of the board the licensing board of the authorized provider.

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

39.13(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 the hospital's pharmacists.

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 pharmacists and providers 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 authorized provider. The protocol shall not authorize the hospital pharmacist to change a Schedule II drug or to initiate a drug not included in the established protocol.

2. Laboratory tests. The protocol may authorize the hospital pharmacist to obtain or to 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 authorized provider for follow-up.

(4) Circumstances that shall cause the hospital pharmacist to initiate communication with the patient’s authorized provider 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 P&T committee 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 authorized provider to communicate and for the hospital pharmacist to document implementation of the collaborative drug therapy.

657—39.14 and **657—39.15** Reserved.

657—39.16(155A) Pharmacy pilot or demonstration research projects. The purpose of this rule is to specify the procedures to be followed in applying for approval of a pilot or demonstration research project for innovative applications in the practice of pharmacy as authorized by 2011 Iowa Acts, chapter 63, section 36, as amended by 2012 Iowa Acts, chapter 1113, section 31 and 2013 Iowa Acts, chapter 138, section 128. In reviewing projects, the board will consider only projects that expand pharmaceutical care services that contribute to positive patient outcomes. The board will not consider any project intended only to provide a competitive advantage to a single applicant or group of applicants.

39.16(1) *Definitions.* For the purposes of this rule, the following definitions shall apply:

"*Act*" means Iowa Code chapter 155A, the Iowa pharmacy practice Act.

"*Board*" means the Iowa board of pharmacy.

"*Practice of pharmacy"* means the practice of pharmacy as defined in Iowa Code section 155A.3(34).

"*Project"* means a pilot or demonstration research project as described in this rule.

39.16(2) *Scope of project.* A project may not expand the definition of the practice of pharmacy. A project may include therapeutic substitution or substitution of medical devices used in patient care if such substitution is included under a collaborative drug therapy management protocol established pursuant to rule 657—39.13(155A).

39.16(3) *Board approval of a project.* Board approval of a project may include the grant of an exception to or a waiver of rules adopted under the Act or under any law relating to the authority of prescription verification and the ability of a pharmacist to provide enhanced patient care in the practice of pharmacy. Project approval, including exception to or waiver of board rules, shall initially be for a specified period of time not exceeding 18 months from commencement of the project. The board may approve the extension or renewal of a project following consideration of a petition that clearly identifies the project, that includes a report similar to the final project report described in paragraph 39.16(6)*"a,"* that describes and explains any proposed changes to the originally approved and implemented project, and that justifies the need for extending or renewing the term of the project.

39.16(4) *Applying for approval of a project.* A person who wishes the board to consider approval of a project shall submit to the board a petition for approval that contains at least the following information:

a. Responsible pharmacist. Name, address, telephone number, and pharmacist license number of each pharmacist responsible for overseeing the project.

b. *Location of project.* Name, address, and telephone number of each specific location and, if a location is a pharmacy, the pharmacy license number where the proposed project will be conducted.

c. *Project summary.* A detailed summary of the proposed project that includes at least the following information:

(1) The goals, hypothesis, and objectives of the proposed project.

(2) A full explanation of the project and how it will be conducted.

(3) The time frame for the project including the proposed start date and length of study. The time frame may not exceed 18 months from the proposed start date of the project.

(4) Background information or literature review to support the proposed project.

(5) The rule or rules to be waived in order to complete the project and a request to waive the rule or rules.

(6) Procedures to be used during the project to ensure that the public health and safety are not compromised as a result of the waiver.

39.16(5) *Review and approval or denial of a proposed project.*

a. *Staff review.* Upon receipt of a petition for approval of a project, board staff shall initially review the petition for completeness and appropriateness. If the petition is incomplete or inappropriate for board consideration, board staff shall return the petition to the requestor with a letter explaining the reason the petition is being returned. A petition that has been returned pursuant to this paragraph may be amended or supplemented as necessary and submitted for reconsideration.

b. *Board review.* Upon review by the board of a petition for approval of a project, the board shall either approve or deny the petition. If the board approves the petition, the approval:

(1) Shall be specific for the project requested;

(2) Shall approve the project for a specific time period; and

(3) May include conditions or qualifications applicable to the project.

c. *Inspection.* The project site and project documentation shall be available for inspection and review by the board or its representative at any time during the project review and the approval or denial processes and, if a project is approved, throughout the approved term of the project.

d. *Documentation maintained.* Project documentation shall be maintained and available for inspection, review, and copying by the board or its representative for at least two years following completion or termination of the project.

39.16(6) *Presentation of reports.* The pharmacist responsible for overseeing a project shall be responsible for submitting to the board any reports required as a condition of a project, including the final project report.

a. *Final project report.* The final project report shall include a written summary of the results of the project and the conclusions drawn from those results. The final project report shall be submitted to the board within three months after completion or termination of the project.

b. *Board review.* The board shall receive and review any report regarding the progress of a project and the final project report at a regularly scheduled meeting of the board. The report shall be an item on the open session agenda for the meeting.

These rules are intended to implement Iowa Code sections 135.190, 147.76, 147A.18, 155A.2, 155A.3, 155A.13, 155A.33, 155A.44, and 2011 Iowa Acts, chapter 63, section 36, as amended.