CHAPTER 8
UNIVERSAL PRACTICE STANDARDS
[Prior to 2/10/88, see Pharmacy Examiners[620] Ch 6]

657—8.1(155A) Purpose and scope. The requirements of these rules apply to all Iowa-licensed pharmacists and to all pharmacies providing the services addressed in this chapter to patients in Iowa and are in addition to rules of the board relating to specific types of pharmacy licenses issued by the board.

657—8.2(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.

8.2(1) *Drug therapy problems.* In providing pharmaceutical care, the pharmacist shall strive to identify, resolve, and prevent drug therapy problems.

8.2(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 plan as appropriate.

8.2(3) *Eligibility.* Any Iowa-licensed pharmacist may practice pharmaceutical care.

657—8.3(155A) Responsibility.

8.3(1) *Pharmacy operations.* The pharmacy and the pharmacist in charge share responsibility for ensuring that all operations of the pharmacy are in compliance with federal and state laws, rules, and regulations relating to pharmacy operations and the practice of pharmacy.

8.3(2) *Practice functions.* The pharmacist is responsible for all functions performed in the practice of pharmacy. The pharmacist maintains responsibility for any and all delegated functions including functions delegated to pharmacist-interns, pharmacy technicians, and pharmacy support persons.

8.3(3) *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.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10; **ARC 1576C**, IAB 8/20/14, effective 9/24/14]

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. 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) *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) *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) *Identification badge.* A pharmacist shall wear a visible identification badge while on duty that clearly identifies the person as a pharmacist and includes at least the pharmacist's first name.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10; **ARC 9409B**, IAB 3/9/11, effective 4/13/11]

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. 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. The temperature of the refrigerator shall be 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.

8.5(2) *Sink.* The pharmacy shall have a sink with hot and cold running water located within the pharmacy department and available to all pharmacy personnel; the sink shall be maintained in a sanitary condition.

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) *Remodel or relocation—inspection.* A pharmacy planning to remodel or relocate a licensed pharmacy department on or within the premises currently occupied by the pharmacy department, or a pharmacy intending to remodel or install a sterile compounding facility or equipment, shall provide written notification to the board at least 30 days prior to commencement of the remodel, pharmacy relocation, or sterile compounding installation. The board may require on-site inspection of the facility, equipment, or pharmacy department prior to or during the pharmacy's remodel, relocation, or opening. The board may also require on-site inspection of a temporary pharmacy location intended to be utilized during the remodel, construction, or relocation of the pharmacy department.

8.5(5) *Orderly and clean.* The pharmacy shall be arranged in an orderly fashion and kept clean. All required equipment shall be in good operating condition and maintained in a sanitary manner. Animals shall not be allowed within a licensed pharmacy unless that pharmacy is exclusively providing services for the treatment of animals or unless the animal is a service dog or assistive animal as defined in Iowa Code subsection 216C.11(1).

8.5(6) *Light, ventilation, temperature, and humidity.* The pharmacy shall be properly lighted and ventilated. The temperature and humidity of the pharmacy shall be maintained within a range compatible with the proper storage of drugs.

8.5(7) *Other equipment.* The pharmacist in charge shall ensure the availability of any other equipment necessary for the particular practice of pharmacy and to meet the needs of the patients served by the pharmacy.

8.5(8) *Bulk counting machines.* Unless bar-code scanning is required and utilized to verify the identity of each stock container of drugs utilized to restock a counting machine cell or bin, a pharmacist shall verify the accuracy of the drugs to be restocked prior to filling the counting machine cell or bin. A record identifying the individual who verified the drugs to be restocked, the individual who restocked the counting machine cell or bin, and the date shall be maintained. The pharmacy shall have a method to calibrate and verify the accuracy of the counting device and shall, at least quarterly, verify

the accuracy of the device and maintain a dated record identifying the individual who performed the quarterly verification.
[**ARC 8671B**, IAB 4/7/10, effective 5/12/10; **ARC 0503C**, IAB 12/12/12, effective 1/16/13]

657—8.6(155A) Health of personnel. Only personnel authorized by the responsible pharmacist shall be in the immediate vicinity of the drug dispensing, preparation, compounding, or storage areas. Any person shown, either by medical examination or pharmacist determination, to have an apparent illness or open lesions that may adversely affect the quality or safety of a drug product or another individual shall be excluded from direct contact with components, bulk drug substances, drug product containers, closures, in-process materials, drug products, and patients until the condition is corrected or determined by competent medical personnel not to jeopardize the quality or safety of drug products or patients. All personnel who normally assist the pharmacist shall be instructed to 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.

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 drug wholesaler licensed by the board to distribute to Iowa pharmacies 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) *Storage temperatures.* All drugs and devices shall be stored at the proper temperature, as defined by the following terms:

a. "Controlled room temperature" means temperature maintained thermostatically between 15 degrees and 30 degrees Celsius (59 degrees and 86 degrees Fahrenheit);

b. "Cool" means temperature between 8 degrees and 15 degrees Celsius (46 degrees and 59 degrees Fahrenheit). Drugs and devices may be stored in a refrigerator unless otherwise specified on the labeling;

c. "Refrigerate" means temperature maintained thermostatically between 2 degrees and 8 degrees Celsius (36 degrees and 46 degrees Fahrenheit); and

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

8.7(5) *Product recall.* There shall be a system for removing from use, including unit dose, any drugs and devices subjected to a product recall.

657—8.8(124,155A) Out-of-date 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.

657—8.9(124,155A) Records. 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 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.* 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.

8.9(2) *Drug supplier credits.* All pharmacies shall maintain supplier credit memos for controlled substances and prescription drugs.
[**ARC 8539B**, IAB 2/24/10, effective 4/1/10]

657—8.10 Reserved.

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 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.*

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.

b. A prescriber may employ a pharmacist to provide nondispensing, drug information, or other cognitive services.

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

a. From a prescriber of prescription drugs or a group, corporation, association, or organization of such prescribers on a percentage of income basis;

b. From a group, corporation, association, or organization in which prescribers have majority control or have directly or indirectly a majority beneficial or proprietary interest on a percentage of income basis; or

c. If the rent is not reasonable according to commonly accepted standards of the community in which the pharmacy will be located.

8.11(4) *Nonconformance with law.* A pharmacist, technician, support person, or pharmacist-intern shall not knowingly serve in a pharmacy which is not operated in conformance with law, or which engages in any practice which if engaged in by a pharmacist would be unethical conduct.

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 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 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) *Unprofessional conduct or behavior.* A pharmacist shall not exhibit 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.

[**ARC 9526B**, IAB 6/1/11, effective 7/6/11]

657—8.12(126,147) Advertising. Prescription drug price and nonprice information 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 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.

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 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 the department of public safety a form specified by the department of public safety and receive the results of 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 the department of human services a form specified by the department of human services and receive the results of a 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. A person who has a criminal record, founded dependent adult abuse report, or founded child abuse report shall not be employed by a pharmacy to provide in-home services unless the department of human services has evaluated the crime or founded abuse report, has concluded that the crime or founded

abuse does not merit prohibition from such employment, and has notified the pharmacy that the person may be employed to provide in-home services.

b. The pharmacy shall keep copies of all record checks and evaluations for a minimum of two years following receipt of the record or for a minimum of two years after the individual is no longer employed by the pharmacy, whichever is greater.

657—8.14(155A) Training and utilization of pharmacy technicians or pharmacy support persons. All Iowa-licensed pharmacies utilizing pharmacy technicians or pharmacy support persons shall develop, implement, and periodically review written policies and procedures for the training and utilization of pharmacy technicians and pharmacy support persons appropriate to the practice of pharmacy at that licensed location. Pharmacy policies shall specify the frequency of review. Pharmacy technician and pharmacy support person training shall be documented and maintained by the pharmacy for the duration of employment. 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.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10]

657—8.15(155A) Delivery of prescription drugs and devices. Prescription drug orders, prescription devices, and completed prescription drug containers may be delivered, in compliance with all laws, rules, and regulations relating to the practice of pharmacy, to patients at any place of business licensed as a pharmacy.

8.15(1) *Alternative methods.* A licensed pharmacy may, by means of its employee or by use of a common carrier, pick up or deliver prescriptions to the patient or the patient's caregiver as follows:

a. At the office or home of the prescriber.

b. At the residence of the patient or caregiver.

c. At the hospital or medical care facility in which a patient is confined.

d. At an outpatient medical care facility where the patient receives treatment only pursuant to the following requirements:

(1) The pharmacy shall obtain and maintain the written authorization of the patient or patient's caregiver for receipt or delivery at the outpatient medical care facility;

(2) The prescription shall be delivered directly to or received directly from the patient, the caregiver, or an authorized agent identified in the written authorization;

(3) A prescription authorized by a prescriber not treating the patient at the outpatient medical care facility may be transmitted to the pharmacy by the authorized agent via facsimile provided that the means of transmission does not obscure or render the prescription information illegible due to security features of the paper utilized by the prescriber to prepare the prescription and provided that the original written prescription is delivered to the pharmacy prior to delivery of the filled prescription to the patient; and

(4) The outpatient medical care facility shall store the patient's filled prescriptions in a secure area pending delivery to the patient.

e. At the patient's or caregiver's place of employment only pursuant to the following requirements:

(1) The pharmacy shall obtain and maintain the written authorization of the patient or patient's caregiver for receipt or delivery at the place of employment;

(2) The prescription shall be delivered directly to or received directly from the patient, the caregiver, the prescriber, or an authorized agent identified in the written authorization; and

(3) The pharmacy shall ensure the security of confidential information as defined in subrule 8.16(1).

8.15(2) *Policies and procedures required.* Every pharmacy shipping or otherwise delivering prescription drugs or devices to Iowa patients shall develop and implement policies and procedures to ensure accountability, safe delivery, and compliance with temperature requirements as defined by subrule 8.7(4).

[**ARC 7636B**, IAB 3/11/09, effective 4/15/09]

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. Pursuant to the express written authorization of the patient or the order or direction of a court.

b. To the patient or the patient's authorized representative.

c. To the prescriber or other licensed practitioner then caring for the patient.

d. To another licensed pharmacist when the best interests of the patient require such release.

e. To the board or its representative or to such other persons or governmental agencies duly authorized by law to receive such information.

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) *Exceptions.* Nothing in this rule shall prohibit pharmacists 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.

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

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

d. Disclosing information necessary for the processing of claims for payment of health care operations or services.

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

[**ARC 9526B**, IAB 6/1/11, effective 7/6/11]

657—8.17 and **8.18** Reserved.

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.

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) The date issued.

(2) The name and address of the patient.

(3) The name, strength, and quantity of the drug or device prescribed.

(4) The name and address of the prescriber and, if the prescription is for a controlled substance, the prescriber's DEA registration number.

(5) The written or electronic signature of the prescriber.

b. Written prescription. In addition to the requirements of paragraph 8.19(1)*"a,"* a written prescription shall be manually signed, with ink or indelible pencil, by the prescriber. The requirement for manual signature shall not apply when an electronically prepared and signed prescription for a noncontrolled substance is printed on security paper as provided in 657—paragraph 21.7(3)*"b."*

c. Facsimile prescription. In addition to the requirements of paragraph 8.19(1)*"a,"* a prescription transmitted via facsimile shall include:

(1) The identification number of the facsimile machine used to transmit the prescription to the pharmacy.

(2) The time and date of transmission of the prescription.

(3) The name, address, telephone number, and facsimile number of the pharmacy to which the prescription is being transmitted.

(4) If the prescription is for a controlled substance and in compliance with DEA regulations, the manual signature of the prescriber.

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.

(1) An electronically prepared prescription for a controlled substance that is printed out or faxed by the prescriber or the prescriber's agent shall be manually signed by the prescriber.

(2) The prescriber shall ensure that the electronic prescription application used to prepare and transmit the electronic prescription complies with applicable state and federal laws, rules, and regulations regarding electronic prescriptions.

(3) The prescriber or the prescriber's agent shall provide verbal verification of an electronic prescription upon the request of the pharmacy.

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 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 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. 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 through oral communication, in writing, by facsimile transmission, or by electronic transmission initiated by or directed by the prescriber.

(1) If the transmission is completed by the prescriber's agent and the first and last names and title of the transmitting agent are included in the order, the prescriber's signature is not required on the fax or alternate electronic transmission.

(2) If the order differs in any manner from the original order, such as a change of the drug strength, dosage form, or directions for use, the prescriber shall sign the order as provided by paragraph 8.19(3)*"a."*

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 shall be authorized to receive a new prescription drug or medication order from a practitioner or the practitioner's agent. In addition to a pharmacist, a pharmacist-intern, and a certified pharmacy technician, a technician trainee or an uncertified pharmacy technician may receive a refill or renewal order from a practitioner or the practitioner's agent if the technician's supervising pharmacist has authorized that function.

8.19(5) *Legitimate purpose.* The pharmacist 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 acting in the usual course of the practitioner'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 relationship.

8.19(6) *Refills.* A refill is one or more dispensings of a prescription drug or device that result in the patient's receipt of the quantity authorized by the prescriber for a single fill as indicated on the prescription drug order.

a. Noncontrolled prescription drug or device. A prescription for a prescription drug or device that is not a controlled substance may authorize no more than 12 refills within 18 months following the date on which the prescription is issued.

b. Controlled substance. A prescription for a Schedule III, IV, or V controlled substance may authorize no more than 5 refills within 6 months following the date on which the prescription is issued.

[**ARC 8171B**, IAB 9/23/09, effective 10/28/09; **ARC 9912B**, IAB 12/14/11, effective 1/18/12]

657—8.20(155A) Valid prescriber/patient relationship. Prescription drug orders and medication orders shall be valid as long as a prescriber/patient relationship exists. Once the prescriber/patient relationship is broken and the prescriber is no longer available to treat the patient or oversee the patient's use of a prescription drug, the order loses its validity and the pharmacist, on becoming aware of the situation, shall cancel the order and any remaining refills. The pharmacist shall, however, exercise prudent judgment based upon individual circumstances to ensure that the patient is able to obtain a sufficient amount of the prescribed drug to continue treatment until the patient can reasonably obtain the service of another prescriber and a new order can be issued.

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. Overutilization or underutilization;
2. Therapeutic duplication;
3. Drug-disease contraindications;
4. Drug-drug interactions;
5. Incorrect drug dosage or duration of drug treatment;
6. Drug-allergy interactions;
7. Clinical abuse/misuse;
8. Drug-prescriber contraindications.

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 but may be delegated to registered pharmacist-interns under the direct supervision of the pharmacist.

657—8.22 to **8.25** Reserved.

657—8.26(155A) Continuous quality improvement program. Each pharmacy licensed to provide pharmaceutical services to patients in Iowa shall implement or participate in a continuous quality improvement program or CQI program. The CQI program is intended to be an ongoing, systematic program of standards and procedures to detect, identify, evaluate, and prevent medication errors, thereby improving medication therapy and the quality of patient care. A pharmacy that participates as an active member of a hospital or corporate CQI program that meets the objectives of this rule shall not be required to implement a new program pursuant to this rule.

8.26(1) *Reportable program events.* For purposes of this rule, a reportable program event or program event means a preventable medication error resulting in the incorrect dispensing of a prescribed drug received by or administered to the patient and includes but is not necessarily limited to:

a. An incorrect drug;

b. An incorrect drug strength;

c. An incorrect dosage form;

d. A drug received by the wrong patient;

e. Inadequate or incorrect packaging, labeling, or directions; or

f. Any incident related to a prescription dispensed to a patient that results in or has the potential to result in serious harm to the patient.

8.26(2) *Responsibility.* The pharmacist in charge is responsible for ensuring that the pharmacy utilizes a CQI program consistent with the requirements of this rule. The pharmacist in charge may delegate program administration and monitoring, but the pharmacist in charge maintains ultimate responsibility for the validity and consistency of program activities.

8.26(3) *Policies and procedures.* Each pharmacy shall develop, implement, and adhere to 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. Train all pharmacy personnel in relevant phases of the CQI program;

b. Identify and document reportable program events;

c. Minimize the impact of reportable program events on patients;

d. Analyze data collected to assess the causes and any contributing factors relating to reportable program events;

e. Use the findings to formulate an appropriate response and to develop pharmacy systems and workflow processes designed to prevent and reduce reportable program events; and

f. Periodically, but at least annually, 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.

8.26(4) *Event discovery and notification.* As provided by the procedures of the CQI program, the pharmacist in charge or appropriate designee shall be informed of and review all reported and documented program events. All pharmacy personnel shall be trained to immediately inform the pharmacist on duty of any discovered or suspected program event. When the pharmacist on duty determines that a reportable program event has occurred, the pharmacist shall ensure that all reasonably necessary steps are taken to remedy any problems or potential problems for the patient and that those steps are documented. Necessary steps include, but are not limited to, the following:

a. Notifying the patient or the patient's caregiver and the prescriber or other members of the patient's health care team as warranted;

b. Identifying and communicating directions or processes for correcting the error; and

c. Communicating instructions for minimizing any negative impact on the patient.

8.26(5) *CQI program records.* All CQI program records shall be maintained on site at the pharmacy or shall be accessible at the pharmacy and be available for inspection and copying by the board or its representative for at least two years from the date of the record. When a reportable program event occurs or is suspected to have occurred, the program event shall be documented in a written or electronic storage record created solely for that purpose. Records of program events shall be maintained in an orderly manner and shall be filed chronologically by date of discovery.

a. The program event shall initially be documented as soon as practicable by the staff member who discovers the event or is informed of the event.

b. Program event documentation shall include a description of the event that provides sufficient information to permit categorization and analysis of the event and shall include:

(1) The date and time the program event was discovered and the name of the staff person who discovered the event; and

(2) The names of the individuals recording and reviewing or analyzing the program event information.

8.26(6) *Program event analysis and response.* The pharmacist in charge or designee shall review each reportable program event and determine if follow-up is necessary. When appropriate, information and data collected and documented shall be analyzed, individually and collectively, to assess the cause and any factors contributing to the program event. The analysis may include, but is not limited to, the following:

a. A consideration of the effects on the quality of the pharmacy system related to workflow processes, technology utilization and support, personnel training, and both professional and technical staffing levels;

b. Any recommendations for remedial changes to pharmacy policies, procedures, systems, or processes; and

c. The development of a set of indicators that a pharmacy will utilize to measure its program standards over a designated period of time.

657—8.27 to **8.29** Reserved.

657—8.30(126,155A) Sterile products. Rescinded IAB 6/6/07, effective 7/11/07.

657—8.31 Reserved.

657—8.32(124,155A) Individuals qualified to administer. The board designates the following as qualified individuals to whom a practitioner 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.

657—8.33(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.

8.33(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 8.33(2).

"Authorized pharmacist-intern" means an Iowa-registered pharmacist-intern who has met the requirements for an authorized pharmacist identified in paragraphs 8.33(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.

8.33(2) *Authorized pharmacist training and continuing education.* An authorized pharmacist shall document successful completion of the requirements in paragraph 8.33(2)*"a"* and shall maintain competency by completing and maintaining documentation of the continuing education requirements in paragraph 8.33(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.

8.33(3) *Protocol requirements.* A pharmacist may administer vaccines pursuant to CDC protocols. A protocol shall be unique to a pharmacy. 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. Links to CDC protocols shall be provided on the board's Web site at www.iowa.gov/ibpe. 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.

8.33(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.

8.33(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.

8.33(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.

8.33(7) *Verification and reporting.* The requirements of this subrule do not apply to influenza and other emergency vaccines administered via protocol pursuant to subrule 8.33(4). An authorized pharmacist shall:

a. Prior to administering a vaccine identified in subrule 8.33(5) or subrule 8.33(6), consult the statewide immunization registry or health information network.

b. Within 30 days following administration of a vaccine identified in subrule 8.33(5) or subrule 8.33(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.

[**ARC 1030C**, IAB 9/18/13, effective 9/1/13; **ARC 1786C**, IAB 12/10/14, effective 1/14/15]

657—8.34(155A) Collaborative drug therapy management. An authorized pharmacist may only perform collaborative drug therapy management pursuant to protocol with a physician pursuant to the requirements of this rule. The physician 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.

8.34(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.

"Board" means the board of pharmacy.

"Collaborative drug therapy management" means participation by an authorized pharmacist and a physician 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 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 a physician establishing drug therapy management for one or more of the pharmacist's and physician's patients residing in a community setting. A community practice protocol shall comply with the requirements of subrule 8.34(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 physicians 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 physicians at a hospital or the hospital's clinics or only to those pharmacists and physicians who are specifically recognized. A hospital practice protocol shall comply with the requirements of subrule 8.34(3).

"IBM" means the Iowa board of medicine.

"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.

8.34(2) *Community practice protocol.*

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

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 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 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 physician 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 physician, the authorized pharmacist shall secure such and notify the patient's physician within 24 hours.

(6) Circumstances that shall cause the authorized 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 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 physician.

(10) A description of the types of reports the authorized pharmacist is to provide to the physician 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 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 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 a physician from delegating collaborative drug therapy management to any unlicensed or licensed person other than another physician or an authorized pharmacist.

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

d. The collaborative drug therapy protocol must be filed with the board, kept on file in the pharmacy, and be made available upon request of the board or the IBM. After July 1, 2008, protocols shall no longer be filed with the board but shall be maintained in the pharmacy and made available to the board and the IBM upon request.

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 board. 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 board of changes in a protocol but the written notification shall be maintained in the pharmacy and made available upon request of the board or the IBM.

f. 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 shall 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.

8.34(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 physicians 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 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 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 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 physician to communicate and for the hospital pharmacist to document implementation of the collaborative drug therapy.

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. A pharmacy license issued by the board is also required for all sites where drug information or other cognitive pharmacy services, including but not limited to drug use review and patient counseling, are provided by a pharmacist. The board may issue any of the following types of pharmacy licenses: a general pharmacy license, a hospital pharmacy license, a special or limited use pharmacy license, or a nonresident pharmacy license. Nonresident pharmacy license applicants shall comply with board rules regarding nonresident pharmacy practice except when specific exemptions have been granted. Applicants for general or hospital pharmacy practice shall comply with board rules regarding general or hospital pharmacy practice except when specific exemptions have been granted. Any pharmacy located within Iowa that dispenses controlled substances must also register pursuant to 657—Chapter 10.

8.35(1) *Exemptions.* Applicants who are granted exemptions shall be issued a "general pharmacy license with exemption," a "hospital pharmacy license with exemption," a "nonresident pharmacy license with exemption," or a "limited use pharmacy license with exemption" and shall comply with the provisions set forth by that exemption. A written petition for exemption from certain licensure requirements shall be submitted pursuant to the procedures and requirements of 657—Chapter 34 and will be determined on a case-by-case basis.

8.35(2) *Limited use pharmacy license.* Limited use pharmacy license may be issued for nuclear pharmacy practice, correctional facility pharmacy practice, and veterinary pharmacy practice. Applications for limited use pharmacy license for these and other limited use practice settings shall be determined on a case-by-case basis.

8.35(3) *Application form.* Application for licensure and license renewal shall be on forms provided by the board. The application for a pharmacy license shall require an indication of the pharmacy ownership classification. If the owner is a sole proprietorship (100 percent ownership), the name and address of the owner shall be indicated. If the owner is a partnership or limited partnership, the names and addresses of all partners shall be listed or attached. If the owner is a corporation, the names and addresses of the officers and directors of the corporation shall be listed or attached. Any other pharmacy ownership classification shall be further identified and explained on the application. The application form shall require the name, signature, and license number of the pharmacist in charge. The names and license numbers of all pharmacists engaged in practice in the pharmacy, the names and registration numbers of all pharmacy technicians and pharmacy support persons working in the pharmacy, and the average number of hours worked by each pharmacist, pharmacy technician, and pharmacy support person shall be listed or attached. Additional information may be required of specific types of pharmacy license applicants. The application shall be signed by the pharmacy owner or the owner's, partnership's, or corporation's authorized representative.

8.35(4) *License expiration and renewal.* General pharmacy licenses, hospital pharmacy licenses, special or limited use pharmacy licenses, and nonresident pharmacy licenses shall be renewed before January 1 of each year. The fee for a new or renewal license shall be $135.

a. Late payment penalty. Failure to renew the pharmacy license before January 1 following expiration shall require payment of the renewal fee and a penalty fee of $135. Failure to renew the license before February 1 following expiration shall require payment of the renewal fee and a penalty fee of $225. Failure to renew the license before March 1 following expiration shall require payment of the renewal fee and a penalty fee of $315. Failure to renew the license before April 1 following expiration shall require payment of the renewal fee and a penalty fee of $405 and may require an appearance before the board. In no event shall the combined renewal fee and penalty fee for late renewal of a pharmacy license exceed $540.

b. Delinquent license. If a license is not renewed before its expiration date, the license is delinquent and the licensee may not operate or provide pharmacy services to patients in the state of Iowa until the licensee renews the delinquent license. A pharmacy that continues to operate in Iowa without a current license may be subject to disciplinary sanctions pursuant to the provisions of 657—subrule 36.1(4).

8.35(5) *Inspection of new pharmacy location.* If the new pharmacy location within Iowa was not a licensed pharmacy immediately prior to the proposed opening of the new pharmacy, the pharmacy location shall require an on-site inspection by a pharmacy board inspector prior to the issuance of the pharmacy license. The purpose of the inspection is to determine compliance with requirements pertaining to space, library, equipment, security, temperature control, and drug storage safeguards. Inspection may be scheduled anytime following submission of necessary license and registration applications and prior to opening for business as a pharmacy. Prescription drugs, including controlled substances, may not be delivered to a new pharmacy location prior to satisfactory completion of the opening inspection.

8.35(6) *Pharmacy license changes.* When a pharmacy changes its name, location, ownership, or pharmacist in charge, a new pharmacy license application with a license fee as provided in subrule 8.35(4) shall be submitted to the board office. Upon receipt of the fee and properly completed application, the board will issue a new pharmacy license certificate. The old license certificate shall be returned to the board office within ten days of the change of name, location, ownership, or pharmacist in charge.

a. Location. A change of pharmacy location in Iowa shall require an on-site inspection of the new location as provided in subrule 8.35(5) if the new location was not a licensed pharmacy immediately prior to the relocation.

b. Ownership. A change of ownership of a currently licensed Iowa pharmacy, or a change of pharmacy location to another existing Iowa pharmacy location, shall not require on-site inspection

pursuant to subrule 8.35(5). A new pharmacy license is required as provided in this subrule. A change of ownership effectively consists of a closing pharmacy, which is subject to the requirements for a closing pharmacy, and of a new pharmacy, which is subject to the requirements of a new pharmacy, with the possible exception of the on-site inspection as provided by this paragraph. In those cases in which the pharmacy is owned by a corporation, the sale or transfer of all stock of the corporation does not constitute a change of ownership provided the corporation that owns the pharmacy continues to exist and continues to own the pharmacy following the stock sale or transfer.

c. Pharmacist in charge. A change of pharmacist in charge shall require completion and submission of the application and fee for new pharmacy license.

(1) 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, signed by the pharmacy owner or corporate officer and the temporary pharmacist in charge, shall be submitted to the board within 10 days following the vacancy.

(2) Within 90 days following the vacancy, a permanent pharmacist in charge shall be identified, and an application for pharmacy license, including the license fee as provided in subrule 8.35(4), shall be submitted to the board office.

8.35(7) *Closing pharmacy.* A closing pharmacy shall ensure that all patient and prescription records are transferred to another pharmacy that is held to the same standards of confidentiality as the closing pharmacy and that agrees to act as custodian of the records for the appropriate retention period for each record type as required by federal or state laws, rules, or regulations. 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 Drug Enforcement Administration (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 of a pharmacy, the pharmacist in charge of the closing pharmacy, if that individual is not an owner of the closing pharmacy, shall be notified of the proposed sale. The owner of the closing pharmacy may direct the pharmacist in charge to maintain information regarding the pending closure of the pharmacy 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 closing pharmacy shall prepare patient notifications pursuant to paragraph 8.35(7)*"d."* At least 30 days prior to the effective date of the sale of a pharmacy, the pharmacist in charge of the purchasing or receiving pharmacy, if that individual is not an owner of the pharmacy, shall be notified of the pending transaction.

b. Board and DEA notifications. At least 30 days prior to the closing of a pharmacy, including a closing by sale of a pharmacy, a written notice shall be sent to the board and to the Drug Enforcement Administration (DEA) notifying those agencies of the intent to discontinue business or to sell the pharmacy and including the anticipated date of closing. These prior notifications shall include 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. Notifications shall also include the name, address, DEA registration number, Iowa pharmacy license number, and CSA registration number of the location at which prescription files, patient profiles, and controlled substance receipt and disbursement 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 prescriptions and records. The notification shall advise patients that if they have any questions regarding their prescriptions and records that they may contact the closing pharmacy. If the closing pharmacy receives no contact from the patient within the 30-day notification period prior to the pharmacy closing, all patient information will be transferred to the receiving pharmacy. The notification shall also advise patients that after the date of closing patients may contact the pharmacy to which the prescriptions and 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 and also by public notice. Public notice refers to the display, in a location and manner clearly visible to patients, of signs in pharmacy pickup locations including drive-through prescription pickup lanes, on pharmacy or retail store entry and exit doors, or at pharmacy prescription counters. In addition, notice may be posted on the pharmacy's Web site, displayed on a marquee or electronic sign, communicated via automated message on the pharmacy's telephone system, or published in one or more local newspapers or area shopper publications.

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 included in the records of each licensee.

(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 657—10.35(124,155A).

(3) The inventory of all noncontrolled prescription drugs may be estimated.

(4) The inventory shall include the name, strength, dosage form, and quantity of all prescription drugs transferred.

(5) Controlled substances 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 substances as provided in rule 657—10.18(124).

g. Surrender of certificates and forms. The pharmacy license certificate and CSA registration certificate of the closing or selling pharmacy shall be returned to the board office within ten days of closing or sale. The DEA registration certificate and all unused DEA Forms 222 shall be returned to the DEA within ten days of closing. All authorizations to utilize the DEA's online controlled substances ordering system (CSOS) and all digital certificates issued for the purpose of ordering controlled substances for the closing pharmacy shall be canceled or revoked within ten days of closing.

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) *Failure to complete licensure.* An application for a pharmacy license, including an application for registration pursuant to 657—Chapter 10, if applicable, will become null and void if the applicant fails to complete the licensure process within six months of receipt 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 an inspection rated as satisfactory by an agent of the board

if such an inspection is required pursuant to this rule. When an applicant fails to timely complete the licensure process, fees submitted with applications will not be transferred or refunded.
[**ARC 8673B**, IAB 4/7/10, effective 6/1/10; **ARC 9526B**, IAB 6/1/11, effective 7/6/11 (See Delay note at end of chapter); **ARC 9693B**, IAB 9/7/11, effective 8/11/11; **ARC 0504C**, IAB 12/12/12, effective 1/16/13]

657—8.36 to **8.39** Reserved.

657—8.40(155A,84GA,ch63) 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, House File 2464, section 31. 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.

8.40(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.

8.40(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—8.34(155A).

8.40(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 8.40(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.

8.40(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.

8.40(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.

8.40(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.

[**ARC 0393C**, IAB 10/17/12, effective 11/21/12; **ARC 1032C**, IAB 9/18/13, effective 10/23/13]

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.32, and 155A.33 and 2013 Iowa Acts, Senate File 353.

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