

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

657—8.1(155A) Purpose and scope. The purpose of this chapter is to establish the minimum standards 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 all pharmacies, including owners, providing the services addressed in this chapter to patients in Iowa. 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.

[ARC 3858C, IAB 6/20/18, effective 7/25/18]

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

“*Board*” means the Iowa board of pharmacy.

“*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. “Confidential information” 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 chapter 155A.

[ARC 3858C, IAB 6/20/18, effective 7/25/18]

657—8.3(155A) Responsible parties.

8.3(1) Pharmacist in charge. One professionally competent, legally qualified pharmacist in charge in each pharmacy shall work cooperatively with the pharmacy, by and through its owner or license holder, 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. A part-time pharmacist in charge has the same obligations and responsibilities as a full-time pharmacist in charge.

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. Ensuring that the pharmacy employs an adequate number of qualified personnel commensurate with the size and scope of services provided by the pharmacy.

b. Ensuring the availability of any equipment and references necessary for the particular practice of pharmacy.

c. Ensuring that there is adequate space within the prescription department or a locked room not accessible to the public for the storage of prescription drugs, including controlled substances, devices, and pharmacy records, and to support the operations of the pharmacy.

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

e. Ensuring that the pharmacy provides adequate security to prevent unauthorized access and diversion.

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. Ensuring that a pharmacist performs prospective drug use review as specified in rule 657—8.21(155A).

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

c. Dispensing drugs to patients, including the packaging, preparation, compounding, and labeling functions performed by pharmacy personnel.

d. Delivering drugs to the patient or the patient's agent.

e. Ensuring that patient medication records are maintained as specified in rule 657—6.13(155A).

f. Training and supervising pharmacist-interns, pharmacy technicians, pharmacy support persons, and other pharmacy employees.

g. Procuring and storing prescription drugs and devices and other products dispensed from the pharmacy.

h. Distributing and disposing of drugs from the pharmacy.

i. Maintaining records of all transactions of the pharmacy necessary to maintain accurate control over and accountability for all drugs as required by applicable state and federal laws, rules, and regulations.

j. Ensuring 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.

8.3(5) *Pharmacy, pharmacist in charge, and staff pharmacists.* The pharmacy, by and through its owner or license holder, the pharmacist in charge, and all staff pharmacists shall share responsibility for, at a minimum, the following:

a. Establishing and periodically reviewing (by the pharmacy and the pharmacist in charge), implementing (by the pharmacist in charge), and complying (by the pharmacist in charge and staff pharmacists) with policies and procedures for all operations of the pharmacy. The policies and procedures shall identify the frequency of review.

b. Establishing and maintaining effective controls against the theft or diversion of prescription drugs, including controlled substances, and records for such drugs.

c. Establishing (by the pharmacy and the pharmacist in charge), implementing (by the pharmacist in charge), and utilizing (by the pharmacist in charge and staff pharmacists) an ongoing, systematic program of continuous quality improvement for achieving performance enhancement and ensuring the quality of pharmaceutical services.

8.3(6) *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.

[ARC 8673B, IAB 4/7/10, effective 6/1/10; ARC 1576C, IAB 8/20/14, effective 9/24/14; ARC 1961C, IAB 4/15/15, effective 5/20/15; ARC 3858C, IAB 6/20/18, effective 7/25/18; ARC 6330C, IAB 6/1/22, effective 7/6/22]

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

8.4(1) *Display of pharmacist license.* During any period a 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

registration certificate or a copy of the registration certificate shall be readily retrievable upon request of the board or its authorized agent.

8.4(3) Identification codes. A permanent log of the initials or identification code identifying by name each 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(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(5) Identification. While on duty, pharmacy personnel shall wear visible identification that clearly identifies the person by licensed or registered title and includes at least the person's first name.

[ARC 8673B, IAB 4/7/10, effective 6/1/10; ARC 9409B, IAB 3/9/11, effective 4/13/11; ARC 3858C, IAB 6/20/18, effective 7/25/18]

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 shall be available in an amount and type to provide secure, environmentally controlled storage of drugs.

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 is maintained within a range compatible with the proper storage of drugs requiring refrigeration. If the temperature is manually or visually verified, a record of minimum daily verification shall be maintained.

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—7.5(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.

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 animal or service-animal-in-training as defined in Iowa Code section 216C.1A.

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 and the pharmacy, by and through its owner or license holder, shall share the responsibility for ensuring 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. Established policies and procedures shall include a method to calibrate and verify the accuracy of the counting device. The pharmacy shall, at least quarterly, verify the accuracy of the device and maintain a dated record identifying the individual who performed the quarterly verification.

8.5(9) *Authorized collection program.* A pharmacy that is registered with the 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 www.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 may 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.

8.5(11) *Hazardous drugs.* The pharmacy shall ensure pharmacy personnel and patients are adequately protected from unnecessary exposure to hazardous drugs. As of December 1, 2019, the pharmacy shall be in compliance with United States Pharmacopeia (USP) General Chapter 800 for handling hazardous drugs. A pharmacy engaged in compounding of hazardous drugs may request delayed compliance for specific requirements in USP General Chapter 800 pertaining to compounding, in accordance with rule 657—20.5(126,155A).

[ARC 8671B, IAB 4/7/10, effective 5/12/10; ARC 0503C, IAB 12/12/12, effective 1/16/13; ARC 1961C, IAB 4/15/15, effective 5/20/15; ARC 2408C, IAB 2/17/16, effective 3/23/16; ARC 3858C, IAB 6/20/18, effective 7/25/18; ARC 4267C, IAB 1/30/19, effective 3/6/19; ARC 4454C, IAB 5/22/19, effective 6/26/19; ARC 5348C, IAB 12/30/20, effective 2/3/21]

657—8.6(155A) Health of personnel. Rescinded ARC 3858C, IAB 6/20/18, effective 7/25/18.

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 an Iowa-licensed distributor or, on a limited basis, from another licensed pharmacy or licensed practitioner located in the United States.

8.7(2) *Manner of storage.* Drugs and devices shall be stored in a manner to protect their identity and integrity.

8.7(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, the pharmacy shall defer to storage conditions identified in United States Pharmacopeia chapter 659.

8.7(4) *Product recall.* There shall be a system for removing from use, including unit dose, any drugs and devices subjected to a product recall.

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, hard-copy record is not required. [ARC 3858C, IAB 6/20/18, effective 7/25/18]

657—8.8(124,155A) Out-of-date drugs or devices. Rescinded ARC 3858C, IAB 6/20/18, effective 7/25/18.

657—8.9(124,155A) Records storage. Every 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 record or the date of last activity on the record unless a longer retention period is specified for the particular record.

8.9(1) Records less than 12 months old. 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 electronic copies of the records in the pharmacy that are immediately available and if the original records are available within 72 hours of a request by the board or its authorized agent, unless such remote storage is prohibited under federal law.

8.9(2) Records more than 12 months old. 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 72 hours of a request by the board or its authorized agent, unless such remote storage is prohibited under federal law.

[ARC 8539B, IAB 2/24/10, effective 4/1/10; ARC 3858C, IAB 6/20/18, effective 7/25/18; ARC 5007C, IAB 3/25/20, effective 4/29/20]

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 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) Unethical conduct.

a. A pharmacy, pharmacist, pharmacist-intern, technician, or support person shall not participate in any of the following types of unethical conduct:

(1) Any activity that negates a patient's freedom of choice of pharmacy services.

(2) 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.

(3) 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.

b. 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).

8.11(3) Discrimination. 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(4) *Unprofessional conduct or behavior.* A pharmacy, pharmacist, pharmacist-intern, technician, or pharmacy support person shall not engage in unprofessional behavior in connection with the practice of pharmacy. 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, theft, and the refusal to provide reasonable information or answer reasonable questions for the benefit of the patient.

[ARC 9526B, IAB 6/1/11, effective 7/6/11; ARC 3858C, IAB 6/20/18, effective 7/25/18]

657—8.12(126,147) Advertising. Prescription drug 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 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 board.

[ARC 3858C, IAB 6/20/18, effective 7/25/18]

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 checks 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 request that the department of public safety 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 request that the department of human services perform a child and dependent adult abuse record 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.

[ARC 3858C, IAB 6/20/18, effective 7/25/18]

657—8.14(155A) Training and utilization of registered pharmacy 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. Training shall be documented and maintained by the pharmacy for 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.

[ARC 8673B, IAB 4/7/10, effective 6/1/10; ARC 1961C, IAB 4/15/15, effective 5/20/15; ARC 3858C, IAB 6/20/18, effective 7/25/18]

657—8.15(155A) Delivery of prescription drugs and devices. A prescription order may be delivered to a patient at any location licensed as a pharmacy. Alternatively, a pharmacy may use the mail, a common carrier, or personal delivery to deliver a prescription order to any location requested by the patient. A pharmacy that delivers prescription orders by one or more alternate methods shall have policies and procedures to ensure patient confidentiality, prescription order accountability, and proper storage of prescription orders during delivery. When counseling is required pursuant to rule 657—6.14(155A), oral counseling shall be provided before the prescription order is delivered to the patient. Documentation of the delivery of prescription orders shall be maintained by the pharmacy for at least two years from the date of delivery. The term “patient” includes the patient and the patient’s authorized representatives.

[ARC 5007C, IAB 3/25/20, effective 4/29/20]

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

8.16(1) Release of confidential information. Confidential information 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(2) Exceptions. Nothing in this rule shall prohibit 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 the patient with a copy of a nonrefillable prescription that is clearly marked as a copy and not to be filled.
- c. Providing drug therapy information to authorized practitioners for their patients.
- d. Disclosing information necessary for the processing of third-party payer claims on behalf of the patient.

8.16(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.

[ARC 9526B, IAB 6/1/11, effective 7/6/11; ARC 3858C, IAB 6/20/18, effective 7/25/18]

657—8.17 Reserved.

657—8.18(124,155A) Electronic prescription mandate. Beginning January 1, 2020, all prescriptions shall be transmitted electronically to a pharmacy pursuant to rule 657—21.6(124,155A), except as provided in rule 657—21.8(124,155A). A pharmacist who receives a written, oral, or facsimile prescription shall not be required to verify that the prescription is subject to an exception provided in

rule 657—21.8(124,155A) and may dispense a prescription drug pursuant to an otherwise valid written, oral, or facsimile prescription pursuant to rule 657—8.19(124,126,155A).
[ARC 4580C, IAB 7/31/19, effective 9/4/19]

657—8.19(124,126,155A) Manner of issuance of a prescription drug or medication order. A prescription drug order or medication order that is issued prior to January 1, 2020, or that is exempt from the electronic prescription mandate pursuant to rule 657—21.8(124,155A) 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—21.7(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—21.6(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) The date issued.
- (2) The name and address of the patient except as provided in subrule 8.19(7) for epinephrine auto-injectors, subrule 8.19(8) for opioid antagonists, or subrule 8.19(9) for expedited partner therapy.
- (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 21.6(2)“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, except as provided herein.

- (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.
- (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 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 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 paragraph 8.19(1) "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. 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 professional pharmacy staff 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 professional pharmacy staff shall be authorized to receive a new prescription drug or medication order from a prescriber or the prescriber's agent. A technician trainee may receive a refill or renewal order from a prescriber or the prescriber's agent only if the technician's supervising pharmacist has authorized that function.

8.19(5) Legitimate purpose. The 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 a prescriber acting in the usual course of the 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.

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.

8.19(7) Epinephrine auto-injector prescription issued to school or facility. A physician, an advanced registered nurse practitioner, or a physician assistant may issue a prescription for one or more epinephrine auto-injectors in the name of a facility as defined in Iowa Code subsection 135.185(1), a school district, or an accredited nonpublic school. The prescription shall comply with all requirements of subrule 8.19(1) as applicable to the form of the prescription except that the prescription shall be issued in the name and address of the facility, the school district, or the accredited nonpublic school in lieu of the name and

address of a patient. Provisions requiring a preexisting patient-prescriber relationship shall not apply to a prescription issued pursuant to this subrule.

a. The pharmacy's patient profile and record of dispensing of a prescription issued pursuant to this subrule shall be maintained in the name of the facility, school district, or accredited nonpublic school to which the prescription was issued and the drug was dispensed.

b. The label affixed to an epinephrine auto-injector dispensed pursuant to this subrule shall identify the name of the facility, school district, or accredited nonpublic school to which the prescription is dispensed.

8.19(8) Opioid antagonist prescription issued to law enforcement, fire department, or service program. A physician, an advanced registered nurse practitioner, or a physician assistant may issue a prescription for one or more opioid antagonists in the name of a law enforcement agency, fire department, or service program pursuant to Iowa Code section 147A.18 and rule 657—39.7(135,147A). The prescription shall comply with all requirements of subrule 8.19(1) as applicable to the form of the prescription except that the prescription shall be issued in the name and address of the law enforcement agency, fire department, or service program in lieu of the name and address of a patient. Provisions requiring a preexisting patient-prescriber relationship shall not apply to a prescription issued pursuant to this subrule.

a. The pharmacy's patient profile and record of dispensing of an opioid antagonist pursuant to this subrule shall be maintained in the name of the law enforcement agency, fire department, or service program to which the prescription was issued and the drug was dispensed.

b. The label affixed to an opioid antagonist dispensed pursuant to this subrule shall identify the name of the law enforcement agency, fire department, or service program to which the prescription is dispensed and shall be affixed such that the expiration date of the drug is not rendered illegible.

8.19(9) Expedited partner therapy. Pursuant to Iowa Code section 139A.41, a physician, physician assistant, or advanced registered nurse practitioner may issue a prescription to one or more sexual partners of an infected patient for an oral antibiotic intended to treat a sexually transmitted chlamydia or gonorrhea infection. The prescription shall comply with all requirements of subrule 8.19(1) as applicable to the form of the prescription except that the prescription shall not be required to contain the patient name and address. The prescription shall indicate the antibiotic is being issued for the purpose of expedited partner therapy. Provisions requiring a preexisting patient-prescriber relationship shall not apply to a prescription issued pursuant to this subrule.

[ARC 8171B, IAB 9/23/09, effective 10/28/09; ARC 9912B, IAB 12/14/11, effective 1/18/12; ARC 2414C, IAB 2/17/16, effective 3/23/16; ARC 2827C, IAB 11/23/16, effective 11/3/16; ARC 3858C, IAB 6/20/18, effective 7/25/18; ARC 4580C, IAB 7/31/19, effective 9/4/19; ARC 4903C, IAB 2/12/20, effective 3/18/20]

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, any remaining prescription refills may be dispensed at the discretion of the pharmacist for a suitable amount of time so that the patient can establish care with a new provider and a new order can be issued. In determining the duration of which prescriptions may be dispensed, the pharmacist shall consider the patient's health care status and access to health care services.

[ARC 3639C, IAB 2/14/18, effective 3/21/18]

657—8.21(155A) Prospective drug use review.

8.21(1) 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:

- a.* Overutilization or underutilization;
- b.* Therapeutic duplication;
- c.* Drug-disease contraindications;
- d.* Drug-drug interactions;
- e.* Incorrect drug dosage or duration of drug treatment;

- f. Drug-allergy interactions;
- g. Clinical abuse/misuse;
- h. 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. Information that shall be obtained for the purpose of drug utilization review includes, but is not limited to, a complete list of prescription and nonprescription medications being used by the patient, patient allergies, and patient disease states. The collection of patient information to be used for drug utilization review may be delegated to a pharmacy technician or pharmacist-intern. The review and assessment of patient records shall not be delegated to pharmacy technicians or pharmacy support persons but may be delegated to registered pharmacist-interns under the direct supervision of the pharmacist.

8.21(2) A pharmacist shall be exempt from the requirements of subrule 8.21(1) when dispensing a prescription issued to an unnamed patient for an oral antibiotic pursuant to Iowa Code section 139A.41. [ARC 3858C, IAB 6/20/18, effective 7/25/18; ARC 4903C, IAB 2/12/20, effective 3/18/20; ARC 5350C, IAB 12/30/20, effective 2/3/21]

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.
[ARC 3858C, IAB 6/20/18, effective 7/25/18]

657—8.23(124,155A) Individuals qualified to administer. Rescinded ARC 6076C, IAB 12/15/21, effective 1/19/22.

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 technician product verification 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.

[ARC 3858C, IAB 6/20/18, effective 7/25/18; ARC 5007C, IAB 3/25/20, effective 4/29/20]

657—8.25 Reserved.

657—8.26(155A) Continuous quality improvement program. Pursuant to rule 657—8.3(155A), each pharmacy licensed to provide pharmaceutical services to patients in Iowa shall implement or participate in a continuous quality improvement program (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 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. 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. 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 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.

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 but no more than three days following discovery of the event 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.

[ARC 1961C, IAB 4/15/15, effective 5/20/15; ARC 2413C, IAB 2/17/16, effective 3/23/16; ARC 3858C, IAB 6/20/18, effective 7/25/18]

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(135,147A) Opioid antagonist dispensing by pharmacists by standing order. Rescinded ARC 3858C, IAB 6/20/18, effective 7/25/18.

657—8.32(124,155A) Individuals qualified to administer. Rescinded ARC 3858C, IAB 6/20/18, effective 7/25/18.

657—8.33(155A) Vaccine administration by pharmacists. Rescinded ARC 3858C, IAB 6/20/18, effective 7/25/18.

657—8.34(155A) Collaborative drug therapy management. Rescinded ARC 3858C, IAB 6/20/18, effective 7/25/18.

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, 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;
- e. Description of the scope of services provided by the pharmacy; and
- f. If the pharmacy is located outside of Iowa, identification of a registered agent located in Iowa.

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 a 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 8.35(3) "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 pharmacy location.

a. A new pharmacy location in Iowa shall require an on-site inspection by an authorized agent of the board. Application for a 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 the delivery of the pharmacy license and registration certificates.

b. A pharmacy location in Iowa which is applying for a different license type than previously held may be subject to an inspection prior to the issuance of the new license.

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, pharmacist in charge, or license type, a completed pharmacy license application with a nonrefundable \$135 fee shall be submitted to the board pursuant to subrule 8.35(2). Upon receipt of the completed application and fee, the board shall issue an updated pharmacy license certificate, pending any necessary inspection pursuant to paragraph 8.35(4) "b," 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 of name.

b. *Location.* Except as provided in subrule 8.35(10) for a temporary relocation due to an exceptional circumstance, 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 paragraph 8.35(7)“d.” A change of pharmacy location in Iowa may require an on-site inspection of the new location as provided in 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 in ownership. A change of ownership occurs when the owner listed on the pharmacy’s most recent application changes. A pharmacy undergoing a change in ownership is required to notify the pharmacist in charge and patients of the change in accordance with subrule 8.35(7). 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 the 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. The pharmacy license application and the pharmacist in charge registration application, if needed, including appropriate fees, shall be received by the board within 90 days of the original vacancy of the permanent pharmacist in charge position.

(4) If a permanent pharmacist in charge is out of the pharmacy for an extended leave of absence of no more than 120 days, the pharmacy may identify an interim pharmacist in charge and provide notice of such to the board on forms provided by the board. Identification of an interim pharmacist in charge shall not require submission of a new pharmacy license application and shall not result in a permanent change in pharmacist in charge on the pharmacy license. If a permanent pharmacist in charge is out of the pharmacy for an extended leave of absence greater than 120 days, the pharmacy shall initiate a change of pharmacist in charge in accordance with this rule.

e. License type. A change in pharmacy license type shall require submission of a pharmacy license application and appropriate fee prior to the change in license type. A pharmacy changing license type shall notify the pharmacist in charge and patients of the change in accordance with subrule 8.35(7).

f. License change application submission. An application for license change shall be timely submitted pursuant to this subrule. A licensed pharmacy that has timely submitted an application for license change and fee may continue to service Iowa patients while the license change is pending final approval. An applicant who has submitted an application for license change after the required date of submission pursuant to this subrule but within 30 days of the required date of submission shall be assessed a nonrefundable late penalty fee of \$135 in addition to the license fee. An applicant who has submitted an application for license change 31 days or later following the required date of submission pursuant to this subrule shall be assessed a nonrefundable late penalty fee of \$540.

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’s closing for delivery of the notifications to the pharmacist in charge, the board, the DEA, and pharmacy patients as required by this subrule. The executive director may exempt a pharmacy from one or more of the notification requirements in the event of an unforeseeable closure.

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, which are required 30 days prior to the pharmacy's closing, are made. 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 timelines 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).
- (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’s 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.

8.35(9) License verification fee. The board may require a nonrefundable fee of \$15 for completion of a request for written license verification of any pharmacy license.

8.35(10) Emergency temporary location changes. In response to a proclamation of disaster emergency or in the event of a natural or man-made disaster, fire, or other occurrence which results in sufficient damage to a pharmacy location as to render it unsafe to operate, a pharmacy may relocate to a temporary or mobile location only as provided herein.

a. Within one business day of the damage to the pharmacy rendering it unsafe, the pharmacy shall provide notice to the board of its intent to temporarily relocate pharmacy operations and provide the address of the temporary or mobile location.

b. A board compliance officer shall conduct an on-site inspection of the temporary or mobile location within five business days of the relocation.

c. A pharmacy may operate from the temporary or mobile location for no more than six months. If the pharmacy is not able to return to the original location within six months, the pharmacy shall submit an application and fee pursuant to paragraph 8.35(6) “b” prior to the expiration of the six-month temporary relocation period.

d. A pharmacy shall notify the board of its intent to return pharmacy operations to the original location at least five business days in advance of its return.

e. A board compliance officer shall conduct an on-site inspection of the original location prior to the return of pharmacy operations.

[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; ARC 1962C, IAB 4/15/15, effective 5/20/15; ARC 3236C, IAB 8/2/17, effective 9/6/17; ARC 3345C, IAB 9/27/17, effective 11/1/17; ARC 3858C, IAB 6/20/18, effective 7/25/18; ARC 4268C, IAB 1/30/19, effective 3/6/19; ARC 5007C, IAB 3/25/20, effective 4/29/20; ARC 6073C, IAB 12/15/21, effective 1/19/22; ARC 6417C, IAB 7/27/22, effective 8/31/22]

657—8.36 to 8.39 Reserved.

657—8.40(155A,84GA,ch63) Pharmacy pilot or demonstration research projects. Rescinded ARC 3858C, IAB 6/20/18, effective 7/25/18.

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.35, and 155A.41.

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⁰ Two or more ARCs

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