

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 other supportive personnel.

8.3(3) Pharmacist-documented verification. The pharmacist shall provide and document 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.

657—8.4(155A) Pharmacist identification.

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 codes identifying by name each dispensing pharmacist, pharmacist-intern, and pharmacy technician 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, and pharmacy technician can be identified.

8.4(3) Temporary or intermittent pharmacy staff. The pharmacy shall maintain a log of all pharmacists, pharmacist-interns, and pharmacy technicians 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, and pharmacy technician 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.

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) 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.

8.5(4) Light and ventilation. The pharmacy shall be properly lighted and ventilated.

8.5(5) Temperature and humidity. The temperature and humidity of the pharmacy shall be maintained within a range compatible with the proper storage of drugs.

8.5(6) 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.

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. 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.

657—8.10 Reserved.

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

8.11(1) *Misrepresentative deeds.* A pharmacist 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. The prohibition in paragraph “a” shall not apply until April 23, 2006, to a pharmacist who is working at a prescriber-owned pharmacy location licensed as of April 23, 1981.

c. 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 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 pharmacist shall not participate in agreements or arrangements with any person, corporation, partnership, association, firm, or others involving premiums, "kickbacks," fee-splitting, or special charges in exchange for recommending, promoting, accepting, or promising to accept the professional pharmaceutical services of any pharmacist or pharmacy as compensation or inducement for placement of business or solicitation of patronage with any pharmacist or pharmacy. "Kickbacks" include, but are not limited to, medication carts, facsimile machines, any other equipment, or preprinted forms or supplies for the exclusive use of the registrant. 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.

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.

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 examiners.

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. All Iowa-licensed pharmacies utilizing pharmacy technicians shall develop, implement, and periodically review written policies and procedures for the training and utilization of pharmacy technicians appropriate to the practice of pharmacy at that licensed location. Pharmacy policies shall specify the frequency of review. Technician training shall be documented and maintained by the pharmacy for the duration of employment. Policies and procedures and documentation of technician training shall be available for inspection by the board or an agent of the board.

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; or
- d. 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, 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).

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.

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.

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 to a pharmacy in written form, orally including telephone voice communication, or by electronic transmission in accordance with applicable federal and state laws and rules. 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.

8.19(1) *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 and rules. 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(2) *Transmitting agent.* The prescribing practitioner may authorize an agent to transmit to the pharmacy a prescription drug order or medication order orally or by electronic transmission provided that the identity of the transmitting agent is included in the order.

8.19(3) *Receiving agent.* Regardless of the means of transmission to a pharmacy, only a pharmacist, a pharmacist-intern, or a pharmacy technician shall be authorized to receive a prescription drug or medication order from a practitioner or the practitioner's agent.

8.19(4) *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.

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 8.29 Reserved.

657—8.30(126,155A) Sterile products. The requirements of this rule are in addition to the requirements of 657—Chapter 20.

8.30(1) Definitions. For the purpose of this rule, the following definitions shall apply:

“*Aseptic preparation*” means the use of procedures that are designed to preclude contamination by microorganisms during processing.

“*Batch preparation*” means the compounding or repackaging of non-patient-specific multiple units in anticipation of patient needs.

“*Class 100 condition*” means an environment in which air particle count does not exceed a total of 100 particles of 0.5 microns and larger per cubic foot.

“*Compounding*” means the constitution, reconstitution, combination, dilution, or another process causing a change in the form, composition, or strength of any ingredient or any other attribute of a product.

“*Critical area*” means the area where sterilized products or containers are exposed to the environment during aseptic preparation.

“*Hazardous drug*” means a pharmaceutical that is antineoplastic, carcinogenic, mutagenic, or teratogenic.

“*Home care patient*” means a patient in the home environment or a patient in a nursing or residential facility or institution who receives products from a pharmacy located outside the facility or institution.

“*Manipulating*” means the process of opening and closing the sterile field of a product for adjustment or attachment.

“*Repackaging*” means the subdivision or transfer of a product from a container or device into a different container or device.

“*Sterile product*” means a drug or nutritional substance that is free from living microorganisms and is compounded, manipulated, or repackaged by pharmacy personnel, using aseptic technique and other quality assurance procedures.

8.30(2) Personnel and training.

a. Pharmacist.

(1) Each pharmacy shall have a pharmacist responsible for supervising the preparation of sterile products compounded, repackaged, or manipulated within the pharmacy.

(2) The pharmacist shall have the responsibility for the compounding, repackaging, or manipulating of all sterile products, including education and training of all personnel concerning proper aseptic technique, incompatibility, and provision of proper incompatibility information.

(3) When any part of these processes is not under direct pharmacy supervision, the pharmacist shall have the responsibility for providing written guidelines and for approving the procedures to ensure that all pharmaceutical requirements are met.

b. Nonpharmacists.

(1) Only technical functions may be performed by nonpharmacists and only under the supervision of a pharmacist.

(2) A pharmacist shall ensure the accuracy of the sterile product prepared by a nonpharmacist prior to administration or dispensing to the patient.

c. Training. All personnel involved in compounding, repackaging, or manipulating sterile products, including pharmacists, pharmacist-interns, pharmacy technicians, and nurses, shall receive documented on-the-job training and related education commensurate with the tasks they are to perform prior to the regular performance of those tasks. Personnel shall understand and follow written policies and procedures for preparing and handling sterile products.

8.30(3) Reference requirements. References may be printed or computer-accessed. In addition to requirements set forth in rule 657—6.3(155A), 657—7.3(155A), 657—15.4(155A), or 657—16.5(155A), as appropriate, all pharmacies involved in the preparation of sterile products shall maintain a minimum of one current reference, including access to current periodic updates, from each of the following categories:

a. A general information reference such as American Hospital Formulary Service, Drug Information or comparable type reference.

b. An injectable drug compatibility reference such as Trissel's Handbook of Injectable Drugs or comparable type reference.

8.30(4) Policies and procedures. A pharmacy providing sterile products shall prepare and maintain current policies and procedures and shall ensure their ready availability to all personnel involved with sterile product preparation. Policies and procedures shall be available for inspection by the board or agents of the board and shall include, but not be limited to, the following:

a. Compounding, dispensing, and delivery of sterile products.

b. Quality assurance programs for the purpose of monitoring personnel qualifications, training, and performance.

c. Product integrity.

d. Equipment and facilities.

e. Guidelines regarding patient education.

8.30(5) Labeling requirements for patient-specific sterile products. At the time of delivery of the sterile product, the dispensing container shall bear a label with at least the following information:

a. Name and quantity of all contents.

b. Patient's name.

c. For home care patient prescriptions, unique serial number or prescription number.

d. Preparer's initials or unique identification.

e. Stability (expiration) date and time (if pertinent) as set forth in the pharmacy's policy and procedure manual.

f. The prescribed flow rate in ml/hr, if applicable.

g. Auxiliary labels as needed.

8.30(6) Labeling requirements for batch-prepared sterile products for later dispensing. Each container of a batch product prepared in anticipation of later dispensing shall bear a label with at least the following information:

a. Name and quantity of all contents.

b. Internal code to identify the date and time of preparation and the preparer's and pharmacist's initials or unique identifiers.

c. Stability (expiration) date and time (if pertinent) as set forth in the pharmacy's policy and procedure manual.

d. Auxiliary labels as needed.

8.30(7) *Space, equipment, and access.* There shall be appropriate space and equipment suitable for the preparation of sterile products and other drug compounding and packaging operations. An appropriate sterile preparation hood or room, certified annually, shall be accessible to and utilized by personnel for the preparation of IV solutions and other sterile products.

- a. The preparation area shall be structurally isolated from general work and storage areas.
- b. The preparation area shall be utilized only for the preparation of sterile products or drugs requiring aseptic preparation.
- c. The laminar airflow hood, room, or other devices used in the preparation of sterile products shall be capable of maintaining a critical area meeting Class 100 conditions during normal activity.
- d. Disposal containers for hazardous drugs and wastes, including materials from patients' homes if applicable, shall be available.
- e. Pumping devices shall be available as needed.
- f. Supplies and attire adequate to maintain an environment suitable for the aseptic preparation of sterile products shall be available and shall be appropriately utilized.
- g. A sink with hot and cold running water, with bactericidal soap available for the purpose of hand scrubs, shall be maintained convenient to the area for preparing sterile products.

8.30(8) *Drugs added to parenteral, enteral, or irrigation solutions.* Whenever drugs are added to parenteral, enteral, or irrigation solutions, whether within or outside the direct and personal supervision of a licensed pharmacist, the admixture shall be labeled with a distinctive supplementary label indicating the following information:

- a. The patient's name;
- b. The drug name, dosage, and strength per unit/volume of the drug added;
- c. The date and time of addition or dilution;
- d. The expiration date, administration time, and infusion rate when applicable; and
- e. The identity of the person adding the drug.

If the drug is intended for addition, dilution, or reconstitution in a facility by a licensed nurse outside the direct and personal supervision of a pharmacist, specific directions for dilution, reconstitution, or addition shall accompany the drug.

8.30(9) *Additional requirements for the sterile preparation of hazardous drugs.*

- a. All hazardous drugs shall be compounded in a vertical flow biological safety cabinet. Other product preparation may not be done concurrently in this cabinet.
- b. Protective apparel, including disposable gloves and gowns with tight cuffs, shall be worn by personnel compounding hazardous drugs.
- c. Safety containment techniques for compounding hazardous drugs shall be used in conjunction with the aseptic techniques required for preparing sterile products.
- d. Disposal of hazardous waste shall comply with applicable federal and state laws and regulations.
- e. Written procedures for handling both major and minor spills of hazardous drugs shall be developed and maintained with the policies and procedures required in 8.30(4).
- f. Prepared doses of hazardous drugs shall be dispensed and labeled inside and outside with precautions and shall be distributed in a manner to minimize the risk of accidental rupture or spilling of the primary container.

8.30(10) *Additional records required.* The pharmacy shall maintain records of lot numbers of the nonsterile components used in compounding sterile products.

8.30(11) *Environmental controls for sterile products.* The pharmacy shall ensure the environmental control of all sterile products in a manner that maintains sanitation, required storage temperatures, and exposure to light at the following times:

- a. While the products are held in the pharmacy.
- b. At the time of delivery to a patient.
- c. During storage of products in the patient's home, if applicable.

8.30(12) *Quality assurance.* To monitor personnel performance, equipment, and facilities, a pharmacy shall have a documented, ongoing quality assurance control program that includes the following as a minimum:

- a. Certification of all clean rooms and laminar airflow hoods by an independent contractor for operational efficiency at least annually with records of certification to be maintained for two years.
- b. Written procedures requiring sampling if microbial contamination is suspected.
- c. End-product testing, including tests for particulate matter and testing for pyrogens, which is documented prior to the release of the product from quarantine if batch preparation of sterile products is performed using nonsterile chemicals.
- d. Written justification of the chosen expiration dates for compounded products.
- e. Documentation of quality assurance audits at planned intervals based upon the needs of individual patients, including infection control and sterile technique audits.
- f. Documentation that infusion devices provided by the pharmacy for the administration of sterile products have received biomedical maintenance to provide for proper care, cleaning, and operation of the equipment.

8.30(13) *Responsibilities for patient care.* The pharmacy and pharmacist have the following responsibilities:

- a. The pharmacist shall be knowledgeable of the roles of the physician, patient, pharmacy, and home health care provider, if applicable, related to delivery of care and the monitoring of the patient.
- b. The pharmacy shall have a pharmacist accessible at all times to respond to questions and needs of another health professional or a patient.
- c. The pharmacist shall use the clinical and laboratory data of each patient to monitor initial and ongoing drug therapy. If the pharmacist does not have access to the data, the name of the health care provider assuming responsibility for monitoring drug therapy shall be documented in the patient's profile.
- d. The pharmacist shall report to the prescribing physician any knowledge of unexpected or untoward response to drug therapy.

8.30(14) *Patient training.* If sterile products are provided to the patient in the home, the pharmacist shall verify the patient's or caregiver's training and competence in managing therapy. A pharmacist shall be involved, directly or indirectly, in training patients about drug compounding, labeling, storage, stability, or incompatibility. The pharmacist shall verify that the patient's or caregiver's competence is reassessed at intervals appropriate to the condition of the patient and type of drug therapy provided.

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(147,155A) Supervision of pharmacists who administer adult immunizations. A physician may prescribe via written protocol adult immunizations for influenza and pneumococcal vaccines for administration by an authorized pharmacist if the physician meets these requirements for supervising the pharmacist.

8.33(1) Definitions.

a. *“Authorized pharmacist”* means an Iowa-licensed pharmacist who has documented that the pharmacist has successfully completed an educational program meeting the training standards on vaccine administration as provided by an American Council on Pharmaceutical Education (ACPE)-approved provider of continuing pharmaceutical education that:

(1) Requires documentation by the pharmacist of current certification in the American Heart Association or the Red Cross Basic Cardiac Life Support Protocol for health care providers;

(2) Is an evidence-based course that includes study material and hands-on training and techniques for administering vaccines, requires testing with a passing score, complies with current Centers for Disease Control and Prevention guidelines, and provides instruction and experiential training in the following content areas:

1. Standards for immunization practices;
2. Basic immunology and vaccine protection;
3. Vaccine-preventable diseases;
4. Recommended immunization schedules;
5. Vaccine storage and management;
6. Informed consent;
7. Physiology and techniques for vaccine administration;
8. Pre- and post-vaccine assessment and counseling;
9. Immunization record management; and
10. Management of adverse events, including identification, appropriate response, documentation, and reporting.

b. *“Vaccine”* means a specially prepared antigen which, upon administration to a person, will result in immunity and, specifically for the purposes of this rule, shall mean influenza and pneumococcal vaccines.

c. *“Written protocol”* means a physician’s order for one or more patients that contains, at a minimum, the following:

(1) A statement identifying the individual physician authorized to prescribe drugs and responsible for the delegation of administration of adult immunizations for influenza and pneumococcus;

(2) A statement identifying the individual authorized pharmacists;

(3) A statement that forbids an authorized pharmacist from delegating the administration of adult immunizations to anyone other than another authorized pharmacist or a registered nurse;

(4) A statement identifying the vaccines that may be administered by an authorized pharmacist, the dosages, and the route of administration;

(5) A statement identifying the activities an authorized pharmacist shall follow in the course of administering adult immunizations, including:

1. Procedures for determining if a patient is eligible to receive the vaccine;
2. Procedures for determining the appropriate scheduling and frequency of drug administration in accordance with applicable guidelines;
3. Procedures for record keeping and long-term record storage including batch or identification numbers;
4. Procedures to follow in case of life-threatening reactions; and
5. Procedures for the pharmacist and patient to follow in case of reactions following administration.

(6) A statement that describes how the authorized pharmacist shall report the administration of adult immunizations, within 30 days, to the physician issuing the written protocols and to the patient's primary care physician if one has been designated by the patient. In case of serious complications, the authorized pharmacist shall notify the physicians within 24 hours and submit a VAERS report to the bureau of immunizations, Iowa department of public health. (VAERS is the Vaccine Advisory Event Reporting System.) A serious complication is one that requires further medical or therapeutic intervention to effectively protect the patient from further risk, morbidity, or mortality.

8.33(2) Supervision. A physician who prescribes adult immunizations to an authorized pharmacist for administration shall adequately supervise that pharmacist. Physician supervision shall be considered adequate if the delegating physician:

- a. Ensures that the authorized pharmacist is prepared as described in subrule 8.33(1), paragraph "a";
- b. Provides a written protocol that is updated at least annually;
- c. Is available through direct telecommunication for consultation, assistance, and direction, or provides physician backup to provide these services when the physician supervisor is not available;
- d. Is an Iowa-licensed physician who has a working relationship with an authorized pharmacist within the physician's local provider service area.

8.33(3) Administration of other adult immunizations by pharmacists. A physician may prescribe, for an individual patient by prescription or medication order, other adult immunizations to be administered by an authorized pharmacist.

This rule is intended to implement Iowa Code sections 147.76, 155A.3, 155A.4, and 272C.3.

657—8.34 Reserved.

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 working in the pharmacy, and the average number of hours worked by each pharmacist and each pharmacy technician 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 \$100.

a. Late payment penalty. Failure to renew the pharmacy license before January 1 following expiration shall require a renewal fee of \$200. Failure to renew the license before February 1 following expiration shall require a renewal fee of \$300. Failure to renew the license before March 1 following expiration shall require a renewal fee of \$400. Failure to renew the license before April 1 following expiration shall require a renewal fee of \$500 and may require an appearance before the board. In no event shall the fee for late renewal of a pharmacy license exceed \$500.

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 \$100 license fee 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. 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. 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 sub-rule 8.35(5). A new pharmacy license is required as provided above. 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 following the stock sale or transfer.

c. A change of pharmacist in charge shall require completion and submission of the application and fee for new pharmacy license within 90 days following the vacancy.

8.35(7) Pharmacy closing. At least two weeks prior to the closing 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 sell the pharmacy including the anticipated date of sale or closing.

a. Prior notification 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. Notification 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.

b. 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).

c. The license certificate and CSA 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.

d. 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.

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.

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