Iowa Board of Pharmacy

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657 Policies and Procedures Requirement Summary

- **Chapter 3: Pharmacy Technicians**
  - **657-3.17(155A)** *Training and utilization of pharmacy technicians*. All licensed pharmacies in Iowa that use pharmacy technicians shall develop, implement, and periodically review written policies and procedures for the training and use of pharmacy techs appropriate to the practice of pharmacy. The policies and procedures shall specify the frequency of review.
- **Chapter 5: Pharmacy Support Persons**
  - **657-5.20(155A)** *Training and utilization of pharmacy support persons*. All Iowa-licensed pharmacies using pharmacy support persons shall develop, implement, and periodically review written policies and procedures for the training and utilization of pharmacy support persons. Policies shall specify the frequency of review.
- **Chapter 7: Hospital Pharmacy Practice**
  - **657-7.5(124,155A)** *Security*
    - **7.5(1)** *Pharmacy department security*. Policies and procedures shall identify measures to ensure the security of the pharmacy department, including provisions for effective control against theft of, diversion of, or unauthorized access to drugs or devices, controlled substances, records for such drugs, and patient records, including when the pharmacist is absent from the pharmacy department or absent from the facility pursuant to rule 657—7.6(155A).
    - **7.5(2)** *Security outside the pharmacy department*. Policies and procedures shall identify measures to ensure security in areas outside the pharmacy department where drugs, including controlled substances, devices, drug records, and patient records are maintained or stored, including provisions for effective control against theft of, diversion of, or unauthorized access to such drugs and records.
  - **657-7.6(155A)** *Pharmacist absence*
    - **7.6(1)** *Pharmacist absent from the pharmacy department.* A pharmacy's policies and procedures shall identify how the pharmacy will operate and be secured to prevent unauthorized access when the pharmacist may be absent from the pharmacy department but not absent from the facility. The policies and procedures shall also identify authorized activities of pharmacy staff in the pharmacy department during the absence of the pharmacist from the department in compliance with rules of the board.
    - **7.6(2)** *Pharmacy department closed*. When the pharmacist is absent from the facility, the pharmacy department shall be closed and secured to prevent unauthorized access. The pharmacist in charge shall identify in policies and procedures the facility and pharmacy staff, by title or designation, who are authorized access to the pharmacy department and the specific activities that are authorized.

- **657-7.8(124,126,155A)** *Drug Distribution and Control.* Policies and procedures governing drug distribution and control shall be established pursuant to rule 657—8.3(155A) with input from other involved hospital staff, from committees such as the pharmacy and therapeutics committee or its equivalent, and from any related patient care committee. It is essential that the pharmacist in charge or designee routinely be available to or on all patient care areas to establish rapport with the personnel and to become familiar with and contribute to medical and nursing procedures relating to drugs.
  - **7.8(1)a1** *Drug Preparation.* Established policies and procedures shall identify situations when drugs may be dispensed in other than unit dose or single unit packages outside the unit dose dispensing system.
  - **7.8(6)** *Drugs brought into the facility.* Established policies and procedures shall determine those circumstances when patient-owned drugs brought into the facility may be administered to the patient and shall identify procedures governing the use and security of drugs brought into the facility. Procedures shall address identification of the drug and methods for ensuring the integrity of the product prior to permitting its use.
  - **7.8(9)** *Hazardous drugs and chemicals*. Policies and procedures for handling drugs and chemicals that are known occupational hazards shall be established pursuant to rule 657—8.3(155A). The procedures shall maintain the integrity of the drug or chemical and protect facility personnel.
- **657-7.9(124,155A)** *Drug information.* Established policies and procedures shall include the provision to the facility's staff and patients of accurate, comprehensive information about drugs and their use.
- **657-7.10(124,155A)** *Ensuring rational drug therapy*. Policies and procedures for ensuring the quality of drug therapy shall be established pursuant to rule 657—8.3(155A). For the purpose of this rule, "professional pharmacy staff" include pharmacists, pharmacy technicians, and pharmacist-interns.
  - **7.10(2)** *Adverse drug events*. Established policies and procedures shall include a mechanism for the reporting of adverse drug events that occur in the facility which events are reviewed by the facility's established quality control committee.
- **657-7.11(124,126,155A)** *Outpatient services*
  - **7.11(2)a** *Accountabilit*y. Established policies and procedures shall include a system of drug control and accountability in the outpatient setting.
- **657-7.12(124,126,155A)** *Drug in the ED*
  - **7.12(a)** *Accountability*. Established policies and procedures shall include a system of drug control and accountability in the emergency department.
  - **7.12(3)a** *Drug dispensing-responsibility*. Pursuant to rule 657—8.3(155A), policies and procedures shall be established to ensure the accuracy and labeling of prepackaged drugs and accurate records of dispensing of drugs from the emergency department shall be maintained.

Chapter 8: Universal Practice Standards

- **657-8.3(155A)** *Responsible parties*
  - **8.3(5)a** *Pharmacy, pharmacist in charge, and staff pharmacists.* Establishing and periodically reviewing (by the PIC), implementing (by the PIC), and complying (by the PIC and staff pharmacists) with policies and procedures for all operations

of the pharmacy. The policies and procedures shall identify the frequency of review.

- **657-8.5(155A)** *Environment and equipment requirements*
  - **8.5(8)** *Bulk counting machines*. Established policies and procedures shall include a method to calibrate and verify the accuracy of the counting device.
- **657-8.14(155A)** *Training and utilization of registered pharmacy staff*. Pursuant to rule 657—8.3(155A), all Iowa-licensed pharmacies using pharmacist-interns, pharmacy technicians, or pharmacy support persons shall have written policies and procedures for the training and use of pharmacist-interns, pharmacy technicians, and pharmacy support persons appropriate to the practice of pharmacy at that licensed location.
- **657-8.15(155A)** *Delivery of prescription drugs and devices.* 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.
- **8.26(155A)** *Continuous quality improvement program*
  - **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. 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.

- **Chapter 10: Controlled Substances**
  - **657-10.14(124)** *Accountability of controlled substances*
    - **10.14(2)** *Policies and procedures.* The registrant shall have policies and procedures that identify, at a minimum:
      - a. Adequate storage for all controlled substances to ensure security and proper conditions with respect to temperature and humidity.
      - b. Access to controlled substances and records of controlled substances by employees of the registrant.
      - c. Proper disposition of controlled substances
- **Chapter 11: Drugs in Emergency Medical Service Programs**
  - **657-11.11(124,147A,155A)** *Policies and Procedures*
    - **11.11(1)** The service director, the medical director, and the responsible individual shall develop, implement, and adhere to written policies and procedures for the operation and management of the service program with respect to prescription

drugs and devices in accordance with these rules. The policies and procedures shall be periodically reviewed by the responsible individual, the medical director, and the service director and shall identify the frequency of the review

- **11.11(2)** The policies and procedures shall address, at a minimum, the following:
  - a. Storage of drugs at the primary program site and any program substations, including appropriate temperature controls, temperature monitoring and response when drugs are exposed to extreme temperatures pursuant to rule 657—11.13(124,147A,155A).
  - b. Storage of drugs at the primary program site and any program substations, including adequate security to prevent diversion and unauthorized access to drugs and records pursuant to rule 657—11.13(124,147A,155A).

- **657-11.13(124,147A,155A)** *Storage*
  - **11.13(2)** *Security*. Policies shall identify procedures that will utilize or require the signature of two service employees for each disbursement to ensure accountability for controlled substances.

- **Chapter 13: Telepharmacy Practice**
  - **657-13.9(155A)** *General requirements for managing pharmacy.*
    - **13.9(2)** *Emergency Preparedness Plan*. A managing pharmacy shall develop and include in both the managing pharmacy's and the telepharmacy site's policies and procedures a plan for continuation of pharmaceutical services provided by the telepharmacy site in case of an emergency interruption of the telepharmacy site's services. The plan shall address the timely arrival at the telepharmacy site of necessary personnel or the delivery to the telepharmacy site of necessary supplies within a reasonable period of time following the identification of an emergency need.
  - **657-13.21(124,155A)** *Policies and procedures.* In addition to policies and procedures required for the specific services provided and identified in other chapters of board rules, both the managing pharmacy and the telepharmacy site shall develop, implement, and adhere to written policies and procedures for the operation and management of the specific pharmacy's operations.
    - **13.21(1)** *Minimum requirements.* Policies and procedures shall define the frequency of review, and written documentation of review by the respective pharmacist in charge shall be maintained. Policies and procedures shall address, at a minimum, the following:
      - a. Procedures ensuring that a record is made and retained identifying the pharmacist who verified the accuracy of the prescription including the accuracy of the data entry, the selection of the correct drug, the accuracy of the label affixed to the prescription container, and the appropriateness of the prescription container.
      - b. Procedures ensuring that a record is made and retained identifying the pharmacist who performed the drug utilization review as provided by rule 657—8.21(155A).
      - c. Procedures ensuring that a record is made and retained identifying the pharmacist who provided counseling to the patient or the patient's caregiver pursuant to rule 657—6.14(155A).

- d. Procedures ensuring that a record is made and retained identifying the tech who filled the prescription.
- e. Procedures ensuring adequate security to prevent unauthorized access to prescription drugs and devices and to confidential records.
- f. Procedures regarding procurement of drugs and devices, including who is authorized to order or receive drugs and devices, from whom drugs and devices may be ordered and received, and the required method for documentation of the receipt of drugs and devices.
- g. Procedures ensuring appropriate and safe storage of drugs at the telepharmacy site, including appropriate temperature controls.
- h. Procedures identifying the elements of a monthly inspection of the telepharmacy site by the pharmacist in charge or designated pharmacist, including requirements for documentation and retention of the results of each inspection.
- i. Procedures for the temporary quarantine of out-of-date and adulterated drugs from dispensing stock and the subsequent documented disposal of those drugs.
- j. Procedures and documentation required in the case of return to the telepharmacy of a drug or device.
- k. Procedures for drug and device recalls.

- **Chapter 15: Correctional Pharmacy Practice**
  - **657-15.5 (124,155A)** *Security*
    - **15.5(2)** *Access when pharmacist absent*. Pursuant to rule 657—8.3(155A), the pharmacy shall have policies and procedures for the security of the correctional pharmacy. Policies and procedures shall identify who will have access to the pharmacy, what areas may be accessed, and the procedures to be followed for obtaining drugs and chemicals when the pharmacist is absent from the pharmacy
    - **15.5(4)** *Drugs in the correctional facility.* Policies and procedures shall identify the qualified individuals who are authorized to access these drugs and the process to be followed for their removal.
  - **657-15.8(124,126,155A)** *Drug distribution and dispensing controls*
    - **15.8(4)** *Unit dose dispensing*. Policies and procedures shall be implemented that include, but are not limited to, the following:
      - a. Return and reuse of drugs;
      - b. Expiration dating;
      - c. Record keeping.

    - **15.8(5)** *Med-pak dispensing*. Policies and procedures shall be implemented that are in accordance with rule 657—22.5(155A) and include, but are not limited to, the following:
      - a. Return and reuse of containers;
      - b. Expiration dating;
      - c. Record keeping.

- **657-15.10(124,126,155A)** *Policies and procedures*. Pharmacy policies and procedures, established, implemented, and complied with pursuant to rule 657—8.3(155A), shall address, but not be limited to, the following:
  - 1. Controlled substances;
  - 2. Formulary or drug list;
  - 3. Stop orders;
  - 4. Drug sample use and distribution;
  - 5. Drug recalls;
  - 6. Outdated drugs;
  - 7. Patient records;
  - 8. Inspection of drug inventories;
  - 9. Adverse reaction reports;
  - 10. Leave and release drugs;
  - 11. Emergency/first dose drug supply;
  - 12. Drugs brought into the facility;
  - 13. Medication administration and records;
  - 14. Drug compounding;
  - 15. Sterile products;
  - 16. Access to the pharmacy in the absence of the pharmacist;
  - 17. Transfers of drugs between facilities and correctional pharmacies;
  - 18. Transfers of prescription drug orders between correctional pharmacies;
  - 19. Delivery of drugs;
  - 20. Notification when a drug or device is not available;
  - 21. Drug destruction within the pharmacy;
  - 22. Return of unused drugs.

- **Chapter 16: Nuclear Pharmacy Practice**
  - **657-16.7(155A)** *Training and utilization of pharmacy support persons.* Nuclear pharmacies utilizing pharmacy support persons shall develop, implement, and periodically review written policies and procedures for the training and utilization of pharmacy support persons. Pharmacy policies shall specify the frequency of review.
- **Chapter 17: Wholesale Distributor Licenses**
  - **657-17.8(124,155A)** *Written policies and procedures.* Wholesale distributors shall establish, maintain, and adhere to written policies and procedures that are in compliance with federal law for the receipt, security, storage, inventory, and distribution of prescription drugs, including policies and procedures for identifying, recording, and reporting losses or thefts and for correcting all errors and inaccuracies in inventories. Wholesale distributors shall also include in their written policies and procedures the following:

    - **17.8(1*)*** *Recalls and market withdrawals*. A procedure to be followed for handling recalls and withdrawals of prescription drugs.
      - a. The procedure shall be adequate to deal with recalls and withdrawals due to:
        - (1) Any action initiated at the request of the Food and Drug Administration or other federal, state, or local law enforcement agency or other government agency, including the board;

        - (2) Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or
        - (3) Any action undertaken to promote public health and safety by replacing existing merchandise with an improved product or new package design.
    - b. The requirement of this subrule shall not apply to a returns processor.
- **17.8(2)** *Emergency and disaster plan.* A procedure to ensure that wholesale distributors prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency.
- **17.8(3)** *Outdated drugs*. A procedure to ensure that any outdated prescription drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of outdated prescription drugs. The requirement of this subrule shall not apply to a returns processor.
- **17.8(4)** *Security and storage*. A procedure to ensure adequate security in accordance with rule 657—17.10(124,155A) and proper storage conditions in accordance with rule 657—17.11(155A). The requirement for proper storage conditions shall not apply to a returns processor.
- **17.8(5)** *Drugs supplied to salesperson/representative*. If supplying drugs to wholesale distributor salespersons, a procedure directing that the security, storage, and record-keeping requirements contained in these rules shall be maintained by those salespersons.
- **17.8(6)** *Personnel*. A procedure to ensure the wholesale distributor employs personnel with the education and experience appropriate to the responsibilities of the position held by the individual. Licensed wholesale distributors shall establish and maintain lists of officers, directors, managers, and other persons in charge of wholesale drug distribution, storage, and handling, including a description of their duties and a summary of their qualifications.

- **Chapter 18: Centralized Prescription Filling and Processing**
    - **657-18.10(155A)** *Policy and procedures.* Pursuant to rule 657—8.3(155A), a policy and procedure manual relating to centralized filling or centralized processing activities shall be maintained at all pharmacies involved in centralized filling or centralized processing and shall be available for inspection and copying by the board or its authorized agent. The manual shall:
        - 1. Outline the responsibilities of each of the pharmacies;
        - 2. Include a list of the names, addresses, telephone numbers, and all license and registration numbers of the pharmacies involved in centralized filling or centralized processing; and
        - 3. Include, but not necessarily be limited to, policies and procedures for:
            - Protecting the confidentiality and integrity of patient information;
            - Protecting each patient's freedom of choice of pharmacy services;
            - Maintaining appropriate records to identify the name, the initials or unique identification code, and the specific activities of each pharmacist or pharmacy technician who performed any centralized filling or centralized processing function; and

- Operating a continuous quality improvement program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems.

- **Chapter 19: Nonresident Pharmacies**
  - **657-19.7(155A)** *Confidential data*. Pursuant to rule 657—8.3(155A), each nonresident pharmacy shall have policies and procedures to ensure patient confidentiality and to protect patient identity and patient-specific information from inappropriate or nonessential access, use, or distribution pursuant to the requirements of rule 657—8.16(124,155A).
  - **657-19.8(124,155A)** *Storage and shipment of drugs and devices*. Pursuant to rule 657—8.3(155A), each nonresident pharmacy shall have policies and procedures to ensure compliance with rules 657—8.7(155A) and 657—8.15(155A). Policies and procedures shall provide for the shipment of controlled substances via a secure and traceable method.
  - **657-19.9(155A)** *Patient record system, prospective drug use review, and patient counseling*
    - **19.9(3)** *Patient counseling*. Pursuant to rule 657—8.3(155A), each nonresident pharmacy shall have policies and procedures to ensure that Iowa patients receive appropriate counseling pursuant to the requirements of rule 657—6.14(155A).
- **Chapter 21: Electronic Data and Automated Systems in Pharmacy Practice**
  - **657-21.20(124,155A)** *Automated medication distribution system (AMDS)*
    - **21.10(1)** *Policies and procedures*. Pursuant to the requirements regarding policies and procedures in 657—subrule 8.3(5), each pharmacy utilizing an AMDS shall have policies and procedures that address all aspects of the operation of the AMDS to include, at a minimum:
      - a. Access to drugs and patient information,
      - b. Pharmacy personnel training in the proper operation of the AMDS,
      - c. Methods to ensure accurate stocking of the AMDS pursuant to subrule 21.10(2),
      - d. Confidentiality of patient information,
      - e. Routine and preventative maintenance of the AMDS according to manufacturer recommendations,
      - f. Packaging and labeling of prescription drugs loaded into or dispensed from the AMDS that is in compliance with federal and state laws, rules, and regulations, and
      - g. Security and control of the prescription drugs maintained and utilized in the AMDS to include:
        - (1) Drug loading, storage, and records.
        - (2) Drugs removed from system components but not used.
        - (3) Inventory.
        - (4) Cross contamination.
        - (5) Lot number control.
        - (6) Wasted or discarded drugs.
        - (7) Controlled substances.
- **Chapter 22: Unit Dose, Alternative Packaging, and Emergency Boxes**
  - **657-22.1(155A)** *Unit dose dispensing system*

        - **22.1(4)d** *Expiration dating*. Drugs or dosage forms having known stability problems are assigned an expiration date of less than 90 days or are not repackaged as determined by policies developed by the pharmacy.
        - **22.1(6)e** *Return of drugs*. The pharmacy includes in written policies and procedures the manner in which returned drugs will be recorded or identified.
    - **657-22.7(124,155A)** *Emergency/first dose drug supply.*
        - **22.7(6)** *Notifications*. Whenever an emergency/first dose drug supply is opened or has expired, the provider pharmacy shall be notified, and the pharmacist shall be responsible for replacing the drug within 72 hours to prevent risk of harm to patients. Pursuant to rule 657—8.3(155A), established policies and procedures shall address notification, record keeping, and documentation procedures for use of the supply.
        - **22.7(7)** *Procedures*.
            - a. The pharmacy, in communication with the director of nursing of the facility and the medical director of the facility, or their respective designees, and as provided in rule 657—8.3(155A), shall have written policies and procedures to ensure compliance with this rule.
    - **657-22.9(155A)** *Home health agency/hospice emergency drugs.*
        - **22.9(6)** *Policies and procedures*. The pharmacy, pursuant to rule 657—8.3(155A) and in coordination with the home health agency or hospice, shall have policies and procedures to address storage conditions and security for drugs and kit maintenance. Outdated, expired drugs shall be properly disposed of by the pharmacy.
- **Chapter 23: Care Facility Pharmacy Practice**
    - **657-23.7(124,155A)** *Policies and procedures*. Pursuant to rule 657—8.3(155A), each pharmacy shall have policies and procedures related to all aspects of the pharmacy's packaging and dispensing responsibilities to the residents of a care facility. The policies and procedures shall be maintained at the provider pharmacy and shall be available to the facility and the consultant pharmacist. Policies and procedures shall include, at a minimum:
        - 1. Methods used to dispense and deliver drugs and devices to the facility in a timely fashion.
        - 2. Proper notification to the facility when a drug or device is not readily available.
        - 3. Proper labeling requirements to meet the needs of the facility and which are consistent with state and federal laws and regulations.
        - 4. Appropriate drug destruction or return of unused drugs, or both, consistent with state and federal laws and regulations.
        - 5. An automatic stop order policy to ensure that drug orders are not continued inappropriately.
        - 6. Methods to ensure that all discontinued, outdated, deteriorated, or improperly labeled drugs and all containers with worn, illegible or missing labels are disposed of so as to render them unusable and protected from unauthorized possession or use
- **Chapter 40: Technology-Assisted Technician Product Verification Programs**

- **657-40.7(155A)** *Policies and procedures*. Policies and procedures shall be developed and adhered to in a TPV program. Policies and procedures for a TPV program shall include, at a minimum, the following:
  - 1. A program to train certified pharmacy technicians to be checking technicians pursuant to subrule 40.4(2), including but not limited to training in the scanning technology to be utilized in the TPV program, limitations of the scanning technology, and strategies to compensate for these limitations.
  - 2. A procedure to identify a representative sample to complete a quarterly quality assurance double check of prescriptions verified by each checking technician.
  - 3. Redirection of pharmacist hours to clinical pharmacy services.
  - 4. Identification of drug products for which authorized checking technicians will be prohibited from performing final drug product verification during the prescription-filling or medication distribution process.

- **Chapter 42: Limited Distributor License**
  - **657-42.7(155A)** *Policies and Procedures*
    - **42.7(1)** Distributors shall have for all aspects of the distributor's operation policies and procedures that, at a minimum, address the rules in this chapter and any other applicable federal, state, and local laws, rules, and regulations.
    - **42.7(2)** The policies shall address, at a minimum:
      - a. Security of the facility and of patient information;
      - b. Storage of products, including proper storage conditions and handling of outdated, recalled, and returned products;
      - c. Records, including the retention period for all required records;
      - d. Security, storage and records for products in the possession of a distributor's authorized representative; and
      - e. Employment of personnel with education and experience appropriate to the responsibilities of the position held.
- **Chapter 43: Third Party Logistics Provider License**
  - **657-43.6(155A)** *Policies and procedures*. A licensed 3PL shall establish, maintain, and adhere to written policies and procedures that are in compliance with standards established pursuant to federal and Iowa law and which address, at a minimum, the following:
    - 1. Storage practices;
    - 2. Maintaining adequate security;
    - 3. Receipt, inventory, shipment, and distribution of product;
    - 4. Theft or loss;
    - 5. Inventory errors and inaccuracies;
    - 6. Manufacturer recalls and withdrawals;
    - 7. Emergency and disaster plan;
    - 8. Records, including the retention period for all required records;
    - 9. Drug diversion detection and prevention; and
    - 10. Outdated, adulterated, or suspect products.