535:15-3-2. Pharmacy responsibilities

(a) Pharmacy staffing responsibility. Each pharmacy shall employ an adequate number of pharmacists to perform the practice of pharmacy as defined by the Oklahoma Pharmacy Act with reasonable safety.

(b) PIC. Each pharmacy, in order to obtain and maintain a pharmacy license, must have a licensed pharmacist as the PIC.

(1) A PIC is designated by his signature on the original pharmacy application or by the appropriate notification to the Board as required in 535:15-3-10 (a), and is responsible for all aspects of the operation related to the practice of pharmacy. These responsibilities include, but are not limited to the:

(A) supervision of all employees as they relate to the practice of pharmacy;
(B) establishment of policies and procedures for safekeeping of pharmaceuticals that satisfy Board requirements, including security provisions when the pharmacy is closed;
(C) proper record keeping system for the purchase, sale, delivery, possession, storage, and safekeeping of drugs;
(D) proper display of all licenses;
(E) annual controlled drug inventory; and,
(F) maintenance of prescription files;

(2) Failure of the pharmacy to have a PIC who fulfills these responsibilities is a violation of this code by both the pharmacy and PIC.

(3) No pharmacist may serve as a PIC in more than one pharmacy at a time. This requirement shall not apply to charitable pharmacies or hospital drug rooms.

(4) The PIC shall be present and practicing at the pharmacy for which he holds the PIC position no less than 20 hours per week during the pharmacy's ordinary course of business. In the event the pharmacy's normal hours of business are less than 40 hours per week the PIC shall be present and practicing at least 50 percent of the normal business hours.

(5) A PIC shall work sufficient hours in the pharmacy to exercise control and meet the responsibilities of the PIC.

(c) PIC's and pharmacy's responsibilities. The following describe responsibilities of the pharmacy and PIC.

(1) Where the actual identity of the filler of a prescription is not determinable, the PIC and the pharmacy where the prescription was filled will be the subject of any charges filed by the Board.

(2) The pharmacy and the PIC are responsible to establish and maintain effective controls against prescription errors or misfills.

(3) The pharmacy and/or PIC shall notify the Board immediately by certified mail of the separation of employment of any pharmacist, pharmacy intern, or pharmacy technician for any suspected or confirmed drug or pharmacy related violation. If the PIC is terminated for such reason, the owner or other person in charge of the pharmacy shall notify the Board by certified mail.

(4) The pharmacy, pharmacist, and/or PIC shall establish and maintain effective controls against the diversion of prescription drugs into other than legitimate medical, scientific, or industrial channels as provided by federal, state or local laws or rules.

(5) The pharmacy, pharmacist and PIC are responsible for supervision of all employees as they relate to the practice of pharmacy.

(d) Responsibility for automated pharmacy systems. This subsection describes the responsibilities of the pharmacy and the PIC for automated pharmacy systems.
(1) Prior written notice must be provided to the Board of the installation or removal of automated pharmacy systems. Such notice must include, but is not limited to the:
   (A) name and address of the pharmacy,
   (B) name of PIC,
   (C) name of the manufacturer & model of system.
(2) The system being implemented should conform to Board automated pharmacy system guidelines.
(3) The pharmacy shall monitor the automated pharmacy system with a quality assurance program.
(4) The pharmacy, pharmacist, and/or PIC shall establish and maintain effective controls against the diversion of prescription drugs into other than legitimate medical, scientific, or industrial channels as provided by federal, state or local laws or rules.
(5) The pharmacy, pharmacist and PIC are responsible for supervision of all employees as they relate to the practice of pharmacy regarding automation.

(e) **Responsibilities for personnel identification.** The PIC and the pharmacy are responsible to assure that the public is able to distinguish pharmacy technicians, auxiliary support personnel, and/or interns from any pharmacist in the pharmacy.
   (1) All pharmacy technicians, auxiliary support personnel, and/or interns must wear a designation tag and be distinctly identifiable from a practicing pharmacist.
   (2) Designation tags must be clear, readable and lettered with “Rx Tech”, “Tech”, “Clerk”, or “Intern”.
   (3) All pharmacy interns, technicians or clerks must identify themselves as such on any phone calls initiated or received while performing pharmacy functions.

(f) **Written drug diversion detection and prevention.** The pharmacy, pharmacist, and/or PIC shall implement and follow a written drug diversion detection policy. The policy shall be available for Board review.

(g) **Inspections.** Pharmacies are subject to inspection. The Board and/or its authorized representatives may conduct on-site periodic routine inspections and investigations during reasonable business hours.

(h) **Remodel.** The pharmacy and the PIC are responsible to notify the Board in writing in advance of any remodel in the pharmacy that would result in a change in square footage, plumbing, or additional storage areas. Such pharmacy shall be subject to inspection by the Board and shall be required to pay an inspection fee.

(i) **Closing of a Pharmacy.** The pharmacy and the PIC are responsible to notify the Board in writing within ten (10) days of the closing of a pharmacy. The notification shall include, but not be limited to:
   (1) Date of closing,
   (2) Copy of final CDS inventory,
   (3) Disposition of pharmacy records,
   (4) Disposition of prescription drugs, and
   (5) Return of pharmacy license.

(j) **Notification of Theft.** The pharmacy and the PIC shall report any theft or significant loss of any drugs to the Board. The pharmacy and the PIC must complete and submit a DEA 106 form for any theft or significant loss of controlled substances to DEA within the required time. A copy shall be sent to the Board within fourteen (14) days.

535:15-3-4. **Physical requirements for pharmacies**

The following are physical requirements for pharmacies:

(1) **Size.** The prescription department shall occupy no less than 125 square feet and shall be in a commercial location and not in a personal dwelling or residence.

(2) **Sanitary facilities.** There shall be installed the proper sanitary facilities which shall include a sink with hot (minimum 104 degrees F) and cold running water separate from the restroom facilities.
(3) **Balances.** There shall be one set of prescription balances with capacity from 1/10 grain to at least one (1) ounce. If the pharmacy proves to the Board that the practice of pharmacy at this particular site does not require weighing of drugs and/or ingredients, an exception may be made by the Executive Director of the Board to the balances requirement.

(4) **Graduates.** There shall be graduates scaled in both metric and apothecary measure sufficient in size and number to assure proper operation of the prescription department.

(5) **Spatulas.** There shall be spatulas of sufficient size and number to assure its proper operation.

(6) **Mortars and pestles.** There shall be mortars and pestles of sufficient size and number to assure its proper operation.

(7) **Library.** There shall be the necessary library which has been prescribed and standardized by the Board in Section 535:15-3-6.

(8) **Refrigeration.** There shall be sufficient refrigeration facilities to store all necessary biologicals, injectables, suppositories and other products requiring refrigeration. This refrigerator shall be entirely separate from the storage of any food products in open packages.

(9) **Exempt narcotic book.** There shall be a book suitable for the registration of all sales of exempt narcotics if such are sold or dispensed.

(10) **Poison Book.** There shall be a book suitable for the registration of all sales of poisons in accordance with applicable laws if such are sold or dispensed.

(11) **Filing.** There shall be a system of filing for all prescriptions which shall be kept for a period of not less than five (5) years.

(12) **Containers.** There shall be sufficient stock of containers suitable for the dispensing of all prescriptions both for internal and external usage.

(13) **Labels.** There shall be sufficient stock of labels both for the dispensing of prescriptions and the sale of medicines and chemicals. Label requirements are described in the Act.

(14) **E-Prescribing of Controlled Substances (EPCS).** Any pharmacy that dispenses controlled dangerous substances shall have computer software that supports EPCS by January 1, 2019.

535:15-3-9. **Non-resident pharmacies**

(a) **Definitions.** “Non-resident pharmacy” means a pharmacy, not located in Oklahoma, which transacts or does business in Oklahoma by soliciting, receiving, dispensing, and/or delivering prescription medications and devices to Oklahoma residents.

(b) **Licensing requirements.** A non-resident pharmacy shall:

1. make application and receive an annual non-resident pharmacy license at a fee set by the Board;
2. maintain in good standing a pharmacy license in its resident state;
3. comply with the Oklahoma Secretary of State requirements for conducting business in this state.
4. submit on initial licensure and on renewals a written report of an inspection conducted within the previous twenty-four (24) months by the non-resident’s state or by any organization approved by the Board;
5. be in a commercial location and not a personal dwelling or residence;
6. submit on initial licensure the name and license number of an Oklahoma licensed pharmacist in charge (PIC) who is responsible for the non-resident’s pharmacy compliance with Oklahoma laws. The name of the Oklahoma licensed PIC shall be reported to the Board, in writing, with each renewal and/or within 10 days of any change of such PIC.
7. the pharmacy registrant may request, in writing, that the Board allow additional time for a new pharmacist-in-charge to get Oklahoma licensed in emergency or urgent situations. If the Board determines circumstances warrant they may grant up to a 90 day extension
(c) **Laws and regulations.** Oklahoma pharmacy laws and regulations shall apply to the practice of pharmacy for the Oklahoma portion of the nonresident pharmacy's practice or operation.

1. The pharmacist manager (also called pharmacist-in-charge (PIC)) and all other pharmacists performing pharmacist-only functions in Oklahoma licensed non-resident pharmacies must be currently licensed in the state in which they are practicing. The PIC must also be licensed by the Board.
2. The pharmacist manager (PIC) and/or pharmacy owner(s), or partners, or corporate officer(s) shall be responsible for compliance with Oklahoma laws and regulations pertaining to the provisions of receiving, dispensing, and/or delivering of prescriptions or prescription medications and devices to Oklahoma residents.

(d) **Inspections.** Non-resident pharmacies are subject to inspection and investigation. (1) The Board may conduct on-site periodic inspections and investigations during reasonable business hours.

(e) **Records.** Prescription records documenting prescriptions delivered and distributed to Oklahoma residents shall be identifiable, readily retrievable and available for Board review.

1. Records must be maintained for not less than five years.
2. Patient records shall comply with 535:15-3-14.
3. Schedule II, III, IV, and V prescription records. These records shall be sent to the Oklahoma Prescription Drug Monitoring program as set out in Title 63 of the Oklahoma Statutes.

(f) **Counseling services.** Non-resident pharmacies shall provide accessible toll-free telephone counseling by a licensed pharmacist for patient drug inquiries during regular working hours. The counseling provided shall comply with the pharmaceutical care requirements listed in OAC 535:10-9.

(g) **Prescription integrity.** A pharmacy or registrant shall not increase the quantity of a prescription without the authorization of the prescriber. Unless specified otherwise by the prescriber, a pharmacist may exercise his professional judgment to dispense up to a ninety (90) day supply for a maintenance non-controlled dangerous drugs, if sufficient quantity has been authorized by the prescriber on the original prescription, including any refills. Increasing controlled dangerous drugs or any medications that require reporting to the controlled substance database are prohibited.

(h) **Written drug diversion detection and prevention.** The pharmacy and the pharmacy manager shall implement and follow a written drug diversion detection and prevention policy and procedure. This policy and procedure shall be available for Board review.

535:15-3-10. **Inventory**

(a) **Change of ownership or pharmacy manager inventory.** When changing the owner or pharmacy manager, a controlled drug inventory must be taken and sent to the Board within ten (10) days. (It is recommended that both the out-going and in-coming managers sign the inventory). The inventory must indicate the new manager's name and registration number. The inventory should indicate the former manager's name, registration number and current employment, if known.

(b) **Inventory at renewal.** An inventory of all controlled dangerous substances (CDS) must be taken between May 1 and July 1 of each year. A copy of this inventory will be included with the pharmacy renewal application.

(c) **Board requested inventory.** In the case of suspected loss, theft, and/or diversion, a pharmacy may be requested by the Board to conduct an inventory (all, or in part), within ten (10) days and submit a copy to the Board.

(d) **Closing Inventory.** A controlled drug inventory must be taken and a copy sent to the Board within ten (10) days of the closing of the pharmacy. No prescription drugs may be maintained in an unlicensed location.
535:15-3-11. Prescription drugs
(a) Authorization; Original and refill prescriptions. No prescription for a “dangerous drug” (as defined in 59 O.S., Section 353.1) shall be filled or refilled without the authorization of a prescriber licensed by law to prescribe within the scope of his practice.
(b) Refill time limit; Non-CDS prescriptions. Prescriptions may only be refilled as authorized by the prescriber. There shall be a maximum of one year from date of original prescription that the prescription may be refilled. After that time a new prescription shall be required.
(c) Drug expiration dating. All outdated prescription drugs shall be removed from the active inventory area upon expiration and cannot be used to fill prescriptions. The removal from the pharmacy of these expired drugs must occur within six months of expiration either by destruction or by being returned to the supplier.
(d) Prescription integrity. A pharmacy or registrant shall not increase the quantity of a prescription without the authorization of the prescriber. Unless specified otherwise by the prescriber, a pharmacist may exercise his professional judgment to dispense up to a ninety (90) day supply for a maintenance non-controlled dangerous drug, if sufficient quantity has been authorized by the prescriber on the original prescription, including any refills. Increasing controlled dangerous drugs or any medications that require reporting to the controlled substance database are prohibited.

SUBCHAPTER 5. HOSPITAL PHARMACIES

535:15-5-2. Definitions
The following words or terms, when used in this Subchapter, shall have the following meaning, unless the context clearly indicates otherwise:
"Automated dispensing systems" means a mechanical system controlled by a computer that perform operations or activities, relative to the storage, packaging, compounding, labeling, dispensing, administration, or distribution of medications, and which collects, controls, and maintains all transaction information.
"Auxiliary supportive personnel" or "auxiliary supportive person" means all persons, other than pharmacists, interns and techs, who are regularly paid employees of the hospital pharmacy and who work or perform tasks in the hospital pharmacy that do not require a permit or license (e.g. clerk, typist, delivery, or data entry person, etc.).
"Certified medication order" means a filled prescription that has been reviewed and certified by a pharmacist.
"Certified pharmacy technician" means a pharmacy technician who has a current Board approved pharmacy technician certification in addition to a current Oklahoma pharmacy technician permit.
"Director of Pharmacy" means a pharmacist licensed to engage in the practice of pharmacy in Oklahoma who is thoroughly familiar with the specialized functions of a hospital pharmacy and directs the activities of a hospital pharmacy.
"Drug room" means a secured room where drug inventories are maintained for use in a facility licensed and regulated by the Oklahoma Health Department, and which may be inspected by the Board.
"Hospital employee" means any individual employed by a hospital whose compensation for services or labor actually performed for a hospital is reflected on the payroll records of a hospital.
"Hospital" or "Hospital facility" or means hospital as defined in 59 O.S. Section 353 et seq.
"Hospital pharmacy" means the place or places in which drugs, chemicals, medicines, prescriptions, or poisons are stored, controlled and prepared for distribution and administration for the use and/or benefit of patients in a hospital facility. Hospital pharmacy shall also mean the place or places in which drugs, chemicals, medicines, prescriptions or poisons are compounded and prepared for dispensing to the members of the medical staff, hospital employees, and the members of their immediate families, patients being discharged, and for other persons in emergency situations.
"Medical staff" means a prescriber who has privileges to practice in the hospital facility.
"Medication order" means a prescription as defined in Title 59 O.S. Section 353.1.
"Pharmacist" means any person licensed to practice pharmacy by the Oklahoma Board.
"Pharmacy technician", "Tech", "Technician" or "RxTech" means a person who has been issued a permit by the Board to assist the pharmacist and performs nonjudgmental, technical, manipulative, nondiscretionary functions in the prescription department under the pharmacist's immediate supervision.
"Remote medication order processing" or "RMOP" means the processing of a medication order for a hospital facility by a pharmacist located in a remote medication order processing pharmacy site. Remote medication order processing does not include the dispensing of a drug, but may include receiving, interpreting, evaluating, clarifying and approval of medication orders. Additionally, remote medication order processing may include order entry, other data entry, performing prospective drug utilization review, interpreting clinical data, performing therapeutic interventions, and providing drug information services, and authorizing release of the medication for administration.
"Remote site" means a site located within the continental United States (US) or District of Columbia (DC) that is electronically linked to the hospital via a computer and/or other electronic communications system as defined in the operations, policies and procedures manual of a hospital pharmacy for the purposes of remote medication order processing (RMOP) of a remote medication order processing pharmacy.
"Supportive personnel" means supportive personnel as defined in 59 O.S Section 353.1 et seq.

535:15-5-7.4. Pharmacy technician tasks
Pharmacy technicians may perform the following tasks in a licensed hospital pharmacy facility in accordance with 535:15-5-7.2:
(1) any tasks auxiliary supportive personnel are allowed to perform;
(2) count and/or pour medications;
(3) affix the prescription label to the final container;
(4) affix auxiliary labels to the container as directed by the pharmacist;
(5) assist the pharmacist in the management of the controlled dangerous substance (CDS) inventory. The pharmacist remains responsible for completeness and accuracy;
(6) fill “Modified unit dose distribution systems”, “Automated dispensing systems” and/or “Unit dose distributions systems”;
(7) prepackage and label multi-dose and unit-dose packages of medication as directed by pharmacist established procedures for such, including selection of containers, labels and lot numbers, with provisions for the pharmacist to check the finished task prior to dispensing to the patient. (While a pharmacy technician may package and label the drug, the certification is the responsibility of the pharmacist.)
(8) perform bulk reconstitution of prefabricated non-injectable medication utilizing a pharmacist established procedure for the bulk reconstitution of prefabricated non-injectable medications.
(9) perform bulk compounding, including such items as sterile bulk solutions for small-volume injectables, sterile irrigation solutions, products prepared in relatively large volume for internal or external use by patients, and reagents or other products for other departments of the hospital facility. Such intermediate and large scale compounding may be done by a pharmacy technician through the use of a procedural manual and a system of in-process and final checks and controls developed or approved by the pharmacist and which are carefully and systematically enforced.
(10) prepare sterile compounded preparations utilizing a policy and procedure that addresses the verification of the pharmaceutical constituents, the prepared label and the final product by the pharmacist following documented training and demonstrated competency as required in OAC 535:15-10-52 (d).

(A) Pharmacy technicians may perform functions involving the:
(i) reconstitution of single dosage units that are to be administered to a given patient as a unit; and/or
(ii) addition of one manufacturer's prepared unit (whole or in part) to another manufacturer's prepared unit if the unit is to be administered as one dose to a patient.

(B) Pharmacy technicians may add a single ingredient in preparing sterile compounded preparations.

(C) Certified pharmacy technicians as defined in 535:15-5-2 may prepare chemotherapy and add multiple ingredients when preparing sterile products only following documented demonstration of appropriate competency to the Director of Pharmacy or his designated pharmacist on an annual basis.

(11) record patient or medication information for later validation by the pharmacist pursuant to procedures which prevent the information from being utilized in any way until it is validated by the pharmacist. Exempt from the necessity of pharmacist validation shall be records, such as financial, inventory control, etc., which can in no way affect the safety and accuracy of medication administration to patients.

(12) select prepackaged and pre-labeled doses of medication from storage areas and place and transport to the patient area such doses in containers bearing a patient's name in a unit dose distribution system or a modified unit dose distribution system if the pharmacist personally checks and verifies by signature or initial all patient medication before it is administered to the patient.

SUBCHAPTER 10. GOOD COMPOUNDING PRACTICES
PART 1. GOOD COMPOUNDING PRACTICES FOR NON-Sterile PRODUCTS

535:15-10-13. Compounding veterinarian preparations
(a) Prescriptions for animals may be compounded based on an order or prescription from a licensed prescriber.
(b) Compounded preparations must comply with federal statutes, rules and FDA guidances.
(c) Caution should be taken as to not violate federal patent laws by duplicating an available product in inordinate quantities.
(d) Compounding with bulk chemicals for food-producing animals is not permitted.
(e) It is acceptable for any licensed pharmacy to compound veterinary drug products to be used by veterinarians in their office for administration to clients for use in a single treatment episode, not to exceed 120 hours supply.
(f) Veterinarians may not transfer compounded medications to any other party. The transfer of compounded medications to another party is a violation of state and federal laws and rules.

PART 3. GOOD COMPOUNDING PRACTICES FOR STERILE PRODUCTS

535:15-10-64.1. Compounding veterinarian sterile preparations
(a) Prescriptions for animals may be compounded based on an order or prescription from a licensed prescriber.
(b) Compounded preparations must comply with federal statutes, rules and FDA guidances.
(c) Caution should be taken as to not violate federal patent laws by duplicating an available product in inordinate quantities.
(d) Compounding with bulk chemicals for food-producing animals is not permitted.
(e) It is acceptable for any licensed pharmacy to compound veterinary drug products to be used by veterinarians in their office for administration to clients for use in a single treatment episode, not to exceed 120 hours supply.
(f) Veterinarians may not transfer compounded medications to any other party. The transfer of compounded medications to another party is a violation of state and federal laws and rules.

**SUBCHAPTER 18. CUSTOMIZED ADHERENCE MEDICATION PACKAGE (CAMP) [NEW]**

535:15-18-1. Purpose

The rules of this Subchapter are to provide standards for the preparation and labeling of customized adherence medication packaging by licensed pharmacies, pursuant to orders or prescriptions. Pharmacists, the pharmacy manager and pharmacies are responsible for meeting the requirements of this subchapter.

535:15-18-2. Definitions

The following words or terms, when used in this Subchapter, shall have the following meaning, unless the content clearly indicates otherwise:

"Customized Adherence Medication Package" or "CAMP" means packaging for dispensed drugs that is comprised of units containing two or more medications and designed to assist the user in administering or self-administering the drugs in accordance with directions for use.

"USER" means patient or caregiver.

535:15-18-3. Packaging Requirements

Pharmacists, the pharmacy manager and pharmacies are responsible for meeting the following requirements:

(1) In place of dispensing two or more prescribed drug products in separate containers, a pharmacist may, with the consent of the patient, the patient’s caregiver, or a prescriber, provide a CAMP. The CAMP is designed and labeled to indicate the day and time or period of time that the contents within each CAMP are to be taken. The dispensing pharmacy shall instruct the patient or caregiver on the use of the CAMP.

(2) In the absence of more stringent packaging requirements for any of the drug products contained in the CAMP, each CAMP shall be in compliance with the United States Pharmacopeia (USP) and National Formulary (NF). Each container shall be designed as to show evidence of tampering. CAMP packaging shall comply with all provisions of the poison prevention packaging act.

(3) When preparing a CAMP, the dispenser shall take into account any applicable USP Compendial requirements or guidelines, the physical and chemical compatibility of the dosage forms placed within each container, and any therapeutic incompatibilities that may affect the simultaneous administration of the medications. Medications shall not be dispensed in CAMP in any of the following situations:

   (A) The USP monograph or official labeling of a medication requires dispensing in the original container.
   (B) The drugs or dosage forms are incompatible with packaging components or each other.
   (C) The drugs are therapeutically incompatible when administered simultaneously.

(4) If two medications have physical characteristics that make them indistinguishable from each other, then the medication shall not be packaged together in the same CAMP.

(5) Medications that have been dispensed in CAMP may not be returned to stock or dispensed to another patient when returned to the pharmacy for any reason. If a prescription for any drug contained in the CAMP is changed, then a new appropriately labeled CAMP may be prepared for the patient. Medications that have been dispensed in CAMP are not eligible for donation under the Utilization of Unused Prescription Medications Act.
535:15-18-4. Labeling
(a) Packaging must bear, at a minimum, the labeling requirements as stated in Title 59, Section 353.20.1 (B); and,
   (1) Physical description of medication (i.e. imprint, description) or be separately packaged;
   (2) Expiration date;
   (3) Lot number(s), if required;
   (4) Date and time to be given
(b) If packaging is detachable into individual units of administration time, each individual unit must bear:
   (1) The name of patient;
   (2) The name and strength of the medication(s); and
   (3) Date and time to be given.
(c) If packaging is detachable, (a)(4) of this section does not apply.

SUBCHAPTER 19. AUTOMATION RULES [NEW]

535:15-19-1. Purpose
These rules of this Subchapter are to establish standards for automated dispensing systems by licensed pharmacies. Pharmacists, the pharmacy manager and pharmacies are responsible for meeting the rules of this subchapter.

535:15-19-2. Definitions
The following words or terms, when used in this Subchapter, shall have the following meaning, unless the content clearly indicates otherwise:

"Automated dispensing system" means an automated system used by a pharmacy licensed by the state of Oklahoma to assist in dispensing a prescription drug order by selecting, labeling, filling, or sealing medication for dispensing. An “automated dispensing system” does not include automated devices used solely to count medication that is then subject to final product check by a pharmacist prior to dispensing, vacuum tube drug delivery systems, or automated dispensing and storage systems used to dispense medication directly to a patient or to an authorized health care practitioner for immediate distribution or administration to the patient.

"Electronic verification system" means an electronic verification, bar code verification, weight verification, radio frequency identification (RFID), or similar electronic process or system that accurately verifies medication has been properly dispensed and labeled by, or loaded into, an automated dispensing system.

"Manufacturer’s unit of use package" means a drug dispensed in the manufacturer’s original and sealed packaging, or in the original and sealed packaging of a repackager, without additional manipulation or preparation by the pharmacy, except for application of the pharmacy label.

"Prepacked" for the purposes of this chapter means any drug that has been removed from the original packaging of the manufacturer or an FDA repackager and is placed in a properly labeled dispensing container by a pharmacy for the purpose of dispensing to the ultimate user from the pharmacy in which the prepacking occurred.

535:15-9-3. Medication Stocking
Automated dispensing systems may be stocked or loaded by a pharmacist, or by an intern or pharmacy technician under the direct supervision of a pharmacist.
535:15-9-4. Pharmacist Verification

A licensed pharmacist shall inspect and verify the accuracy of the contents of any final dispensing container filled or packaged by an automated dispensing system, and any label affixed thereto, prior to dispensing.


(a) Written policies and procedures shall be established by and reviewed annually by the pharmacist-in-charge, be maintained in the pharmacy, and be available for review upon inspection.

(b) At a minimum, the pharmacy and pharmacy personnel shall establish and follow policies and procedures for the following:

1. accurate filling, loading, and stocking of the system;
2. sanitary operations of the system and preventing cross-contamination of cells, cartridges, containers, cassettes, or packages;
3. investigating and addressing dispensing errors and system malfunctions;
4. tracking and documenting prescription errors related to the system that are not corrected prior to dispensing to the patient;
5. testing the proper function of the system and any accompanying electronic verification system; at a minimum, the system and electronic verification system shall be tested before the first use of the system or restarting the system and upon any modification to the system or electronic verification system that changes or alters the dispensing or electronic verification process;
6. written documentation of training persons authorized to access, stock, or load the system in equipment use and operations which shall be maintained in the pharmacy and be available for inspection;
7. preventing unauthorized access to the system, including, assigning, discontinuing, or changing security access;
8. identifying and recording persons responsible for stocking, loading, and filling the system
9. conducting routine and preventive maintenance and, if applicable, calibration;
10. removing expired, adulterated, misbranded, or recalled drugs;
11. ensuring proper drug storage within the system, consistent with the manufacturer’s specifications and the USP;
12. maintaining an ongoing quality assurance program that monitors performance of the system and any electronic verification system to ensure proper and accurate functioning; and
13. ensuring compliance with state and federal law, including, all applicable labeling, storage, and security requirements.

535:15-19-6. Recordkeeping

Records and documentation required by this chapter shall be maintained in the pharmacy’s records electronically or in writing for a minimum of two (2) years. Records shall be made readily available for inspection and produced to the board inspector upon request.


A pharmacist, or an intern or pharmacy technician under the direct supervision of a licensed pharmacist, may prepack drugs for other than immediate dispensing purposes provided that the following conditions are met:

1. prepacking occurs at the licensed pharmacy utilizing the system;
2. only products which will be dispensed directly to the patient may be prepacked;
(3) containers utilized for prepacking shall meet standards specified by the USP, which has been incorporated herein by reference (e.g. preservation, packaging, storage and labeling section of the general notices and requirements); and where needed, light resistant containers shall be used;

(4) any prepacked drug must have a label affixed to it which contains, at a minimum, the name and strength of the drug, quantity, NDC number, the expiration date and lot number, and the date prepacked; and

(5) a record of drugs prepacked must be kept, and include the following: the name and strength of the drug, lot number, NDC number, expiration date, date of prepacking, total number of dosage units (tabs, caps) prepacked, quantity per prepacked container, initials of prepacker and of pharmacist performing verification of prepack.