Title 10

MARYLAND DEPARTMENT OF HEALTH

Subtitle 34 BOARD OF PHARMACY

10.34.03 Institutional Pharmacy

Authority: Health Occupations Article, §12-205, Annotated Code of Maryland

.01 Scope.

This chapter applies to:

A. A permit holder that operates a pharmacy that services an inpatient setting; and
B. A person or entity that holds a pharmacy permit and operates a pharmacy in or for an institutional facility.

.02 Definitions.

A. In this chapter, the following terms have the meanings indicated.

B. Terms Defined.

(1) "Decentralized pharmacy" means an institutional pharmacy which provides services for the population of an institutional facility and is:

(a) Dependent on another institutional pharmacy for:

(i) Administrative control;

(ii) Staffing with a licensed pharmacist physically available on site in the decentralized pharmacy to supervise the performance of delegated pharmacy acts; and

(iii) Drug procurement; and

(b) Located in the same building or pavilion as the other institutional pharmacy.

(1-1) "Direct supervision" means that a licensed pharmacist is physically available to supervise the performance of delegated pharmacy acts.

(1-2) "Director of pharmacy" means a pharmacist who is responsible for the pharmacy services provided by an institutional pharmacy in compliance with appropriate State and federal laws and regulations.

(2) "Dispense" or "dispensing" means the procedure which results in the receipt of a prescription or nonprescription drug or device by a patient or the patient's agent and which entails the:

(a) Interpretation of an authorized prescriber's prescription for a drug or device;

(b) Selection and labeling of the drug or device prescribed pursuant to that prescription; and

(c) Measuring and packaging of the prescribed drug or device in accordance with State and federal laws.

(3) Distribute.

(a) “Distribute” means the process resulting in the provision of a prescription or nonprescription drug or device to a separate, intervening individual, licensed and practicing under Health Occupations Article, Title 12, Annotated Code of Maryland, prior to administration of the provided drug or device to the patient pursuant to a prescription issued by an authorized prescriber.

(b) “Distribute” does not include the operations of a person who holds a permit issued under Health Occupations Article, §12□6C□03, Annotated Code of Maryland.

(4) "Drug" means a prescription or non-prescription medication or other material used in the diagnosis or treatment of injury, illness, or disease.

(5) “Drug recall” means the recall of a drug by a manufacturer or the U.S. Food and Drug Administration (FDA) in the event that there is a reasonable possibility that the use of or exposure to an affected product may cause either:

(a) Adverse effects on health; or

(b) Death.

(6) “Emergency drug supply” means a process for supplying drugs which:

(a) May be required for the emergency need of a patient; and

(b) Is not available from an authorized source in a timely manner.

(7) "Institutional facility" or "institution" means an entity other than a comprehensive care facility, assisted living facility, developmental disabilities facility, or correctional facility whose primary purpose is to provide a physical environment for patients to obtain inpatient, outpatient, or emergency care, except for urgent care facilities that are not part of an institution.

(8) “Institutional medication protocol” means a course of therapy including drug treatment predetermined and documented by the institution and the generally accepted medical practice for proper completion of a particular therapeutic or diagnostic intervention ordered by an authorized prescriber and which allows the pharmacist to execute the protocol.

(9) "Institutional pharmacy" means a pharmacy which:

(a) Provides services to an acute care, rehabilitation, transitional care, chronic care, or mental health hospital;

(b) Engages in compounding, distributing, or dispensing of drugs;

(c) May provide nondispensing functions as described in Regulation .16 of this chapter; and

(d) Has been issued a pharmacy permit pursuant to Health Occupations Article, §§12-401 and 12-403(c), Annotated Code of Maryland.

(10) “Licensed pharmacist” means an individual who is licensed by the Board to practice pharmacy.

(11) "Medication order" means a patient-specific order entered on the chart or a medical record of a patient by an authorized prescriber or the authorized prescriber’s designee for a drug or device that is transmitted in writing, verbally or by electronic means and includes the:

(a) Date ordered;

(b) Drug name;

(c) Dosage;

(d) Dosage form;

(e) Patient name with second identifier such as date of birth or medical record number;

(f) Route of administration;

(g) Administration instructions, if appropriate; and

(h) Signature, if appropriate, of an:

(i) Authorized prescriber, as defined in Health Occupations Article, §12-101(b), Annotated Code of Maryland; or

(ii) Individual permitted to practice medicine without a license as defined in Health Occupations Article, §14-302, Annotated Code of Maryland.

(12) “Order-sets” means predefined orders, including medication orders, that are based on an institutionally approved protocol.

(12-1) “Pavilion” means a detached or semidetached part of a hospital devoted to a special use.

(13) Pharmaceutical care.

(a) "Pharmaceutical care" means the provision of a patient’s drug regimen for the purpose of:

(i) Achieving definite outcomes related to the cure or prevention of a disease;

(ii) Elimination or reduction of a patient’s symptoms; or

(iii) Arresting or slowing of a disease process by identifying, resolving, or preventing actual or potential drug therapy problems.

(b) "Pharmaceutical care" may include patient counseling and providing information to licensed and certified health care providers.

(14) “Prescription Drug.

(a) “Prescription drug” means any drug required by federal law or regulation to be dispensed only by a prescription.

(b) “Prescription drug” includes:

(i) A biological product; and

(ii) Finished dosage forms and bulk drug substances subject to §503(b) of the Federal Food, Drug and Cosmetic Act.

(c) “Prescription drug” does not include blood and blood components intended for transfusion or biological products that are also medical devices.

(15) “Second identifier” means a reliable method to:

(a) Identify a patient for whom service or treatment is intended; and

(b) Match the service or treatment intended to the patient.

(16) “Verbal order” means a medication order from an authorized prescriber which is received by an authorized licensed practitioner using appropriate read back procedures that is subsequently recorded in the patient’s chart and countersigned by the prescriber within a time period required by the institution.

(17) "Written order" means a medication order that is recorded as a written document by an authorized prescriber.

.03 Issuance of Permits.

A. An institutional pharmacy shall obtain required permits in compliance with State and federal laws and regulations.

B. An institutional pharmacy shall:

(1) Staff a pharmacist at each decentralized pharmacy site within the building or pavilion in which it is located; and

(2) List decentralized pharmacy sites within the building in which it is located, on the initial application, or on the renewal application;

C. A decentralized pharmacy that meets the definition as set forth in this chapter may operate under the same permit as the institutional pharmacy located in the same building or pavilion.

D. If full service pharmacy services are provided to discharge patients, employees, clinic patients, or others, an institutional pharmacy shall obtain a full service pharmacy permit.

E. Any other pharmacy that does not meet the requirements of a decentralized pharmacy and is located on the campus or affiliated with an institutional pharmacy shall be separately licensed.

.04 Policies and Procedures.

A. The director of pharmacy shall establish and operate under a policies and procedures manual which:

(1) Complies with this chapter;

(2) Defines the scope and method of pharmacy services provided to the patients of the institutional facility;

(3) Determines when personnel may have access to the pharmacy area;

(4) Provides for the safe and efficient dispensing and delivery of pharmaceutical products as outlined in this subtitle;

(5) Includes:

(a) Labeling requirements that meet the requirements of this chapter;

(b) Distribution methods for medication that assures that a patient receives the correct dose ordered by the prescriber;

(c) Packaging methods that assure the medication is appropriately identified, designed to maintain stability until expiration and traceable throughout the distribution chain to facilitate recall;

(d) Distribution methods that provide for safe handling of medications that may be manual or computerized employing centralized, decentralized, or remote devices that meet the requirements of COMAR 10.34.28.

(e) Pharmacy security methods that comply with this chapter;

(f) Conditions in which an emergency drug supply may be replenished or prepared, delivered, and stored by the institutional facility;

(g) Duties that may be performed by a licensed pharmacist, registered pharmacy technician and unlicensed personnel; and

(h) Methods for proper disposal of pharmaceuticals as required by State and federal law;

(6) Is provided to:

(a) The personnel of the pharmacy;

(b) The institutional facility; and

(c) Upon request, an agent of the Board; and

(7) Is in a form that is:

(a) Written or electronic; and

(b) Readily retrievable;

B. The director of pharmacy shall provide annual training on the policies and procedures manual to the personnel of the pharmacy.

.05 Personnel.

A. The permit holder shall appoint a licensed pharmacist as director of pharmacy who shall:

(1) Be in full and actual charge of the pharmacy and its personnel;

(2) Be responsible for the operations of the pharmacy and for compliance with the requirements of Health Occupations Article, Title 12, Annotated Code of Maryland, and the regulations promulgated under that title; and

(3) Review the policies and procedures of the pharmacy annually and revise them as necessary.

B. Staff.

(1) The pharmacy permit holder shall employ licensed pharmacists, registered pharmacy technicians, and unlicensed personnel as required to competently and safely provide pharmacy services.

(2) The director of pharmacy shall delegate responsibility for the operations of the pharmacy to a designated pharmacist when the director of pharmacy is not available.

.06 Security.

A. If a pharmacist is not present within the pharmacy, the pharmacist shall lock and secure the pharmacy and any of its decentralized areas that contain pharmaceuticals before leaving the pharmacy or the decentralized area.

B. The director of pharmacy shall establish policies and procedures for emergency access to the pharmacy or any of its decentralized areas.

C. Security Requirements. Entry into an institutional pharmacy area where prescription drugs or devices are held shall be limited to authorized personnel under a pharmacist's direct supervision.

D. An institutional pharmacy shall be equipped with:

(1) A security system to detect entry after hours, if applicable;

(2) A security system that provides additional protection against theft and diversion;

(3) Appropriate software to facilitate the identification of evidence of tampering with computers or electronic records;

(4) An inventory management and control system designed to protect against, detect, and document instances of theft, diversion, or counterfeiting;

(5) A security system designed to protect the integrity and confidentiality of data and documents;

(6) Video monitoring of entrances and exits, or alternate acceptable security; and

(7) A means to make the data and documentation required under this chapter readily available to:

(a) The Board;

(b) An agent of the Board; or

(c) Federal and State regulatory and law enforcement officials.

.07 Physical Requirements and Equipment.

A. The institutional pharmacy shall have floor space, shelving, and equipment to ensure that drugs and supplies within the institutional pharmacy are properly stored and prepared with respect to sanitation, temperature, light, ventilation, moisture control, segregation, and security.

B. The institutional pharmacy shall have professional and technical equipment, supplies, and adequate physical facilities for proper compounding, dispensing, and storage of drugs.

C. The institutional pharmacy shall have reference materials as required by COMAR 10.34.07.03 to enable personnel to prepare and dispense drugs properly and perform pharmaceutical care functions.

D. The institutional pharmacy shall store alcohol and flammables in areas that meet basic local building code requirements for the storage of volatiles and such other laws, ordinances, or regulations as may apply.

E. An institutional pharmacy that provides parenteral preparations shall comply with COMAR 10.34.19.

F. The institutional pharmacy shall dispose of hazardous materials consistent with State and federal laws and regulations;

G. The institutional pharmacy is responsible for the maintenance of the institution's automated medication systems in compliance with COMAR 10.34.28

.08 Responsibilities of Director of Pharmacy.

The director of pharmacy or designee shall:

A. Be responsible for the safe and efficient dispensing, control, security, and accountability of drugs;

B. Work in cooperation with the other professional staff of the institutional facility with respect to the duties listed in this regulation and in ordering, administering, and controlling drug products and materials, including prescription blanks;

C. Supervise the preparation of parenteral and other medications compounded within the institutional facility;

D. Provide written policies and procedures to hospital professional and technical staff with regard to admixtures prepared within the institution outside of the institutional pharmacy including, but not limited to:

(1) Establishing policies and procedures for preparation and handling of the admixtures; and

(2) Providing incompatibility information with respect to the admixtures;

E. Recommend specifications for procurement, storage and disposal of drugs, chemicals, and biologicals administered to patients to the appropriate committee of the institutional facility as determined by the governing body;

F. Participate in the development of a formulary for the facility;

G. Establish procedures for the development of a standard format and ongoing procedures for checking the accuracy and placement of labels on medications throughout the institution;

H. Maintain and make available an inventory of antidotes and other emergency drugs, both in the pharmacy and in patient care areas, as well as:

(1) Current antidote information;

(2) Telephone numbers of a regional poison information center;

(3) Other emergency assistance organizations; and

(4) Such other materials and information as may be considered necessary by the governing body of the institutional facility;

I. Maintain records of transactions of the institutional pharmacy as may be required by applicable law and as may be necessary to maintain accurate control and accountability for pharmaceuticals;

J. Participate in those aspects of the institutional facility's quality assurance and improvement program which relate to medication safety and pharmaceutical utilization and effectiveness;

K. Participate in teaching or research programs, or both, in the institutional facility as required;

L. Implement the policies, procedures, and decisions of the governing body of the institutional facility;

M. Ensure that a system is in place that provides a safe, secure, and efficient distribution system for pharmaceutical products within the facility;

N. Ensure that the institutional pharmacy meets inspection and other requirements of Health Occupations Article, Title 12, Annotated Code of Maryland, and these regulations;

O. Develop and implement policies and procedures to ensure that discontinued and outdated drugs and drug containers with worn, illegible, or missing labels are returned to the pharmacy for proper disposition;

P. Establish policies and procedures for identification, handling, storage, and disposition of medications brought into the institution by the patients;

Q. Conduct an on-going plan for a quality assurance program that will review and evaluate pharmaceutical services and recommend improvements in these services;

R. Establish policies and procedures for identification and handling of investigational drugs that include the provision of pharmacologic and toxicologic information to the medical and nursing staff according to institutional policies ;

S. Arrange for the inspection of drug storage areas throughout the institution on a monthly basis and maintain written records of these reviews; and

T. Participate in developing and monitoring the policies and procedures pertaining to:

(1) Administration of drugs at an institutional facility to ensure that only authorized individuals administer drugs; and

(2) Self-administration of drugs not on the hospital formulary by patients to ensure that the:

(a) Administration occurs in accordance with procedures established by the appropriate committee of the institution; and

(b) That the self-administration is ordered by an authorized prescriber.

.09 Medication Packaging – Record Keeping.

A. A licensed pharmacist shall verify the selection of medication to be packaged and verify the completed packaging of medication performed by a registered pharmacy technician for the following:

(1) Accuracy;

(2) Completeness:

(3) Appropriateness; and

(4) Compliance with the U.S. Food and Drug Administration and current United States Pharmacopeia approved packaging.

B. Packaging from the Manufacturer's Original Container. The pharmacy shall use a master log with respect to drugs that are packaged within the pharmacy facility from the original manufacturer's container which includes the:

(1) Lot number assigned by the distributor or manufacturer;

(2) Manufacturer's expiration date;

(3) Manufacturer;

(4) Lot number assigned by the pharmacy;

(5) Quantity packaged;

(6) Expiration date as defined in §C of this regulations;

(7) Generic name of the drug;

(8) Strength;

(9) Date of packaging;

(10) Name of person packaging; and

(11) Initials of verifying licensed pharmacist.

C. Unless the licensed pharmacist has reason to reduce the time period, the expiration date of the medication is the lesser of:

(1) Twelve months from the date of packaging;

(2) The manufacturer's or distributor's listed expiration date; or

(3) The maximum time period allowed for the specific packaging used for the medication.

D. The licensed pharmacist shall ensure that labeling of the medication container includes the:

(1) Generic name of the medication;

(2) Brand name of the medication, if appropriate

(3) Strength of the medication, if appropriate;

(4)Lot number of the distributor or manufacturer;

(5) Expiration date of the medication; and

(6) Beyond use date of the medication, if appropriate.

.10 Labeling for Use Outside the Institutional Facility.

A. The director of pharmacy or designee shall ensure that the labels on drugs dispensed for use outside the facility by an institutional pharmacy to clinics, ambulatory patients, or other patients about to be discharged meet the requirements of Health Occupations Article, §12-505, Annotated Code of Maryland.

B. The director of pharmacy or designee shall ensure that the labels contain other information that may be required by federal or State law or regulations including, but not limited to, cautionary information.

.11 Drug Dispensing – Emergency Supplies and Procedures.

A. The director of pharmacy shall participate in the development and maintenance of the formulary for emergency drugs and supplies that are maintained throughout the institutional facility.

B. The director of pharmacy or designee shall, in conjunction with the medical staff of the institutional facility, develop and implement written policies and procedures to ensure compliance with the provisions of this regulation.

C. The institutional pharmacy shall furnish emergency drugs and supplies only if:

(1) The emergency drugs and supplies are stored in an environment which:

(a) Maintains the integrity of the drugs; and

(b) Provides accessibility only to authorized personnel;

(2) The institution follows a policy that drugs will be dispensed from the emergency drugs and supplies formulary only upon written or verbal order by an authorized prescriber;

(3) The emergency drugs and supplies are stocked and maintained in a manner that complies with the standards of applicable State law;

(4) The emergency drugs and supplies are:

(a) Stored and secured:

(i) With a tamper evident seal; or

(ii) Via electronic means; and

(b) Kept in a secure area;

(5) The emergency drugs and supplies are labeled as follows:

(a) Clearly indicating that the emergency drugs and supplies are for use in emergencies only;

(b) Listing the expiration dates of the emergency drugs and supplies;

(c) Listing the name or initials of the pharmacist who checked the emergency drugs and supplies; and

(d) Highlighting the expiration date of the medication with the shortest expiration date;

(6) When the emergency drugs and supplies are contained within an emergency cart, the pharmacist checking the emergency cart shall ensure that the exterior of the cart is labeled with the:

(a) Contents of the emergency cart; and

(b) Name or initials of the pharmacist; and

(7) The director of pharmacy or designee shall ensure that repackaged drugs contained in emergency drugs and supplies are labeled:

(a) In accordance with Regulation .10 of this chapter; and

(b) With other information as may be required by the medical staff.

D. Upon notification that emergency drugs and supplies have been opened, a pharmacist or registered pharmacy technician shall:

(1) Restock the emergency drugs and supplies; or

(2) Provide a replacement supply.

E. The director of pharmacy or designee shall ensure:

(1) That the expiration date of emergency drugs and supplies is the earliest date of expiration of any drug supplied; and

(2) Before the expiration date, the pharmacist or designee shall replace the expired drug and relabel the emergency drugs and supplies as provided in §C(5) of this regulation.

.12 Drug Dispensing – Prescribers' Orders.

A. Drugs may be dispensed from the institutional pharmacy only in response to medication orders issued by prescribers who have been authorized to do so by law and by the governing body of the institution.

B. Documentation.

(1) Institutional Medication Protocols.

(a) The pharmacist may dispense, or make available, drugs for an approved institutional medication protocol if conditions designated by the institution are met.

(b) The director of pharmacy or designee shall assist in establishing institutional policies and procedures governing the development of order-sets for each individual situation for which institutional medication protocol orders exist.

(c) The appropriate committee of the institution shall approve any order-sets before the pharmacist may provide the medications based on the institutional medication protocol.

(2) A pharmacist may provide medications based on orders which do not contain unapproved abbreviations as published by the appropriate committee of the institutional facility.

(3) The director of pharmacy or designee shall ensure that authorized personnel have access to patient information necessary for drug monitoring including the patient's:

(a) Sex;

(b) Age;

(c) Weight;

(d) Height;

(e) Diagnosis;

(f) Medication and food allergies;

(g) Pregnancy and lactation status;

(h) Vaccination status; and

(i) Name.

.13 Controlled Dangerous Substances.

A. Drug Accountability.

(1) The director of pharmacy is responsible for establishing procedures and maintaining adequate written or electronic records regarding dispensing and accountability of controlled dangerous substances which specify at least the following:

(a) Name and strength of the drug;

(b) Dose;

(c) Dosage form;

(d) Prescriber;

(e) Patient name with second identifier;

(f) Date and time of administration; and

(g) Individual administering the drug;

(2) The director of pharmacy shall be responsible for establishing and maintaining adequate procedures for documentation of:

(a) Recording of receipt of delivery to the pharmacy;

(b) Entering into pharmacy inventory;

(c) Receiving into Schedule II inventory; and

(d) Dispensing of controlled dangerous substances, Schedule II — Schedule V.

(3) The director of pharmacy or designee shall be responsible for establishing and maintaining adequate procedures for documenting partially administered controlled dangerous substances:

(a) For disposal by hospital policy; and

(b) Return of unused drugs to the pharmacy.

(4) The director of pharmacy or designee shall establish procedures to ensure that controlled dangerous substance records include the handwritten or electronic signature of the individual authorized:

(a) By the institution to dispose of drugs or to return them to the pharmacy; and

(b) To witness the disposal, as defined by the institution's policies and procedures.

B. Storage and Security in the Institutional pharmacy.

(1) On at least a monthly basis, a pharmacist or registered pharmacy technician shall perform a physical count of each Schedule II controlled dangerous substance in the pharmacy and shall then compare that count with the perpetual inventory maintained by the pharmacy with reference to each drug;

(2) On at least a monthly basis, the director of pharmacy or designee shall:

(a) Investigate discrepancies within the pharmacy;

(b) Report losses as required by law; and

(c) Take appropriate action; and

(3) The director of pharmacy or designee shall establish a procedure by which previously dispensed controlled dangerous substances that are no longer necessary for medical reasons are returned to the pharmacy.

C. Storage and Security in the Institution. The director of pharmacy shall develop policies that only permit the dispensing of controlled dangerous substances when the following security precautions exist in the institution and the pharmacy:

(1) Access to controlled dangerous substances outside the pharmacy is restricted to authorized personnel approved by institutional policy;

(2) Controlled dangerous substances stored outside the pharmacy are accounted for at least at the change of each shift by licensed personnel authorized by the institution, unless a controlled access automated dispensing system provides an on-demand report of a perpetual inventory; and

(3) A pharmacist reviews the discrepancies in counts of controlled dangerous substances previously reported by other professional personnel.

.14 Drug Recalls.

A. The director of pharmacy or designee shall develop and implement a drug recall procedure that can be readily activated to assure that drugs which have been recalled are returned to the pharmacy for proper disposition.

B. If a recall has been initiated for a drug that has been purchased by the institution, the director of pharmacy or designee shall issue a notice in a timely manner informing affected departments of the institution that the drug shall be returned to the pharmacy for proper return or disposal.

C. The institutional pharmacy is responsible for the timely retrieval of affected drugs.

.15 Adverse Drug Events.

A. The director of pharmacy or designee shall participate in the appropriate committee or committees to establish procedures to report and record adverse drug events including medication errors and adverse drug reactions.

B. The director of pharmacy or designee shall immediately report adverse drug events to the prescriber, or the prescriber's designee, and make a written or electronic report to the appropriate committee or committees, as determined by the governing body of the institutional facility.

C. The director of pharmacy shall participate in the deliberations of the institutional committee charged with the development of the programmatic and operational changes that result from the analysis of medication errors or other adverse events.

D. The director of pharmacy, in collaboration with the medical staff and other appropriate departments and services, shall develop and maintain a process for training staff regarding detecting and reporting medication errors to prevent future occurrences.

E. The director of pharmacy or designee shall make further reports of adverse reactions as required by federal or State law.

.16 Pharmaceutical Care Functions of the Pharmacist.

The pharmacist shall be available as necessary to provide pharmaceutical care to individual patients including, but not limited to:

A. Participating in decisions about medication use for patients including decisions not to use medication therapy as well as judgments about:

(1) Medication selection;

(2) Dosages;

(3) Routes and methods of administration;

(4) Medication therapy monitoring; and

(5) The provision of medication-related information and counseling to individual patients;

B. Cooperating directly with health care professionals and the patient in designing, implementing, and monitoring a therapeutic outcome.

C. Providing care directly to the patient to improve a patient's quality of life through achieving definite and predefined, medication-related therapeutic outcomes such as:

(1) Curing the disease;

(2) Eliminating or reducing a symptomatology;

(3) Arresting or slowing a disease process;

(4) Preventing a disease or symptomatology; and

(5) Improving patient's quality of life.

D. Identifying potential and actual medication-related problems, resolving actual medication-related problems, and preventing potential medication-related problems caused by:

(1) Untreated indications;

(2) Improper drug selection;

(3) Sub-therapeutic dosage;

(4) Failure to received medication;

(5) Over dosage;

(6) Adverse drug reactions;

(7) Drug interactions, including drug-drug, drug-food, drug-laboratory test interactions; and

(8) Medication use without appropriate indication.

.17 Requirements for a Decentralized Pharmacy.

A. A decentralized pharmacy is subject to:

(1) Health Occupations Article, Title 12, Annotated Code of Maryland;

(2) This subtitle; and

(3) Other applicable State and federal laws and regulations.

B. A decentralized pharmacy shall ensure that a licensed pharmacist is immediately available on the premises of the decentralized pharmacy to:

(1) Supervise pharmacy operations; and

(2) Provide the final check for preparing medication orders for administration in the institutional facility.

C. Notwithstanding §B of this regulation, a pharmacist assigned to a decentralized pharmacy may leave the decentralized pharmacy for a short period of time to perform pharmaceutical care functions in the institutional facility.

D. A director of pharmacy of the institutional pharmacy shall be responsible for pharmacy operations involving a decentralized pharmacy, including direct supervision of decentralized pharmacy personnel by a pharmacist and compliance with this chapter.

E. A pharmacy department may store prescription medications and over the counter medications that are approved for use by the institutional pharmacy as required for the treatment of patients in the nursing unit served by the decentralized pharmacy.

F. An institutional pharmacy and the decentralized pharmacy shall have shared common electronic files or appropriate technology to allow access to sufficient information necessary or required to process functions required for the care of patients within the service area of the decentralized pharmacy.

G. A decentralized pharmacy shall have a pharmacist physically located at the decentralized pharmacy to directly supervise pharmacy technicians and pharmacy technician trainees during hours of operation.

H. An institutional pharmacy shall notify the Board in writing within 14 days of a change of location, discontinuance of service, or closure of a decentralized pharmacy.

I. Security.

(1) In addition to the security requirements outlined in COMAR 10.34.05, a decentralized pharmacy shall have adequate security and procedures to:

(a) Prohibit unauthorized access;

(b) Comply with federal and State regulations; and

(c) Maintain patient confidentiality.

(2) Access to the decentralized pharmacy shall be limited to pharmacists, pharmacy technicians, and pharmacy technician trainees employed by the institutional pharmacy, and other personnel authorized by the director of pharmacy.