Meeting Notice

Missouri Board of Pharmacy
Hospital Working Group

February 15, 2013 9:00 a.m. to 3:00 p.m.
Professional Registration
3605 Missouri Blvd
Jefferson City, MO 65109

Notification of special needs as addressed by the Americans with Disabilities Act should be forwarded to the Missouri Board of Pharmacy, P O Box 625, 3605 Missouri Blvd., Jefferson City, Missouri 65102, or by calling (573) 751-0091 to ensure available accommodations. The text telephone for the hearing impaired is (800) 735-2966.

If any member of the public wishes to attend the meeting, s/he should be present at the Division of Professional Registration, Main Conference Room, 3605 Missouri Blvd, Jefferson City, Missouri, at 9:00 a.m. on February 15, 2013.

Please see attached tentative agenda for this meeting.

TENTATIVE AGENDA
February 15, 2013 9:00 a.m. to 3:00 p.m.

Missouri Board of Pharmacy
Hospital Working Group Meeting

Professional Registration
3605 Missouri Blvd
Jefferson City, MO 65109
Conference Call

OPEN SESSION

1 Call to Order

2 Roll Call

3 Hospital research review

4 Adjournment

Hospital Pharmacy Statutes and Rules

Contents

- NABP Model Rules for Institutional Pharmacy
- Most commonly used rules/regulations
- Titles of all statutes and rules/regulations used, listed by state
- Full printouts of all statutes and rules relating to hospital or institutional pharmacy for each state

NABP

Model Rules for Institutional Pharmacy

Section 1. Applicability.

The following Rules are applicable to all Institutional Facilities and Institutional Pharmacies as defined in Section 2 below.

Section 2. Definitions.

(a) "Chart Order" means a lawful order entered on the chart or a medical record of an inpatient or resident of an Institutional Facility by a Practitioner or his or her designated agent for a Drug or Device and shall be considered a Prescription Drug Order provided that it contains:
- (1) the full name of the patient;
- (2) date of issuance;
- (3) name, strength, and dosage form of the Drug prescribed;
- (4) directions for use; and
- (5) if written, the prescribing Practitioner's signature or the signature of the Practitioner's agent (including the name of the prescribing Practitioner); or if electronically submitted, the prescribing Practitioner's electronic or digital signature.

(b) "Institutional Facility" means any organization whose primary purpose is to provide a physical environment for patients to obtain health care services, including but not limited to a(n):
- (1) hospital;
- (2) Long-Term Care Facility;
- (3) convalescent home;
- (4) nursing home;
- (5) extended care facility;
- (6) mental health facility;
- (7) rehabilitation center;
- (8) psychiatric center;
- (9) developmental disability center;
- (10) Drug abuse treatment center;
- (11) family planning clinic;
- (12) penal institution;
- (13) hospice;
- (14) public health facility;
- (15) athletic facility.

(c) "Institutional Pharmacy" means any place which is registered with the State Board of Pharmacy pursuant to Article V of the Pharmacy Practice Act that provides Pharmacist Care to an Institutional Facility and where Drugs, Devices, and other materials used in the diagnosis and treatment of injury, illness, and disease (hereinafter referred to as *Drugs*) are Dispensed, Compounded, and Distributed.

Section 3. Personnel.

(a) Each Institutional Pharmacy shall be directed by a Pharmacist, hereinafter referred to as the *Pharmacist-in-Charge*, who is licensed to engage in the Practice of Pharmacy in this State.

Section 4. Absence of Pharmacist.

(a) During such times as an Institutional Pharmacy may be unattended by a Pharmacist, arrangements shall be made in advance by the Pharmacist-in-Charge for provision of Drugs to the medical staff and other authorized personnel of the Institutional Facility by use of night cabinets and, in emergency circumstances, by access to the Pharmacy. A Pharmacist must be "on call" during all absences.

(b) In the absence of a Pharmacist, Drugs shall be stored in a locked cabinet or other enclosure constructed and located outside of the Pharmacy area, to which only specifically authorized personnel may obtain access by key or combination, and which is sufficiently secure to deny access to unauthorized persons. The Pharmacist-in-Charge shall, in conjunction with the appropriate committee of the Institutional Facility, develop inventory listings of those Drugs to be included in such cabinet(s) and determine who may have access, and shall ensure that:

(1) Drugs are properly Labeled;
(2) only prepackaged Drugs are available, in amounts sufficient for immediate therapeutic requirements;
(3) whenever access to the cabinet occurs, written Practitioner's orders and proofs-of-use are provided;
(4) all Drugs therein are inventoried no less than once per week;
(5) a complete audit of all activity concerning such cabinet is conducted no less than once per month; and
(6) written policies and procedures are established to implement the requirements of this Section 4.

(c) Whenever any Drug is not available from floor supplies or night cabinets, and such Drug is required to treat the immediate needs of a patient whose health would otherwise be jeopardized, such Drug may be obtained from the Pharmacy in accordance with the requirements of this Section 4. One supervisory nurse in any given eight-hour shift is responsible for obtaining Drugs from the Pharmacy. The responsible nurse shall be designated in writing by the appropriate committee of the Institutional Facility. Removal of any Drug from the Pharmacy by an authorized nurse must be recorded on a suitable form showing the patient name, room number, name of Drug, strength, amount, date, time, and signature of nurse. The form shall be left with the container from which the Drug was removed.

(d) Emergency kit Drugs may be provided for use by authorized personnel of the Institutional Facility provided, however, such kits meet the following requirements:

(1) Emergency kit Drugs are those Drugs which may be required to meet the immediate therapeutic needs of patients and which are not available from any other authorized source in sufficient time to prevent risk of harm to patients by delay resulting from obtaining such Drugs from such other sources.
(2) All emergency kit Drugs shall be provided and sealed by a Pharmacist;
(3) The supplying Pharmacist and the medical staff of the Institutional Facility shall jointly determine the Drugs, by identity and quantity, to be included in emergency kits.
(4) Emergency kits shall be stored in secured areas to prevent unauthorized access, and to ensure a proper environment for preservation of the Drugs within them.
(5) The exterior of each emergency kit shall be labeled so as to clearly indicate that it is an emergency Drug kit and that it is for use in emergencies only. The label shall contain a listing of the Drugs contained in the kit, including name, strength, quantity, and expiration date of the contents, and the name, address(es), and telephone number(s) of the supplying Pharmacist.

(6) Drugs shall be removed from emergency kits only pursuant to a valid Chart Order.
(7) Whenever an emergency kit is opened, the supplying Pharmacist shall be notified and the Pharmacist shall restock and reseal the kit within a reasonable time so as to prevent risk of harm to patients.
(8) The expiration date of an emergency kit shall be the earliest date of expiration of any Drug supplied in the kit. Upon the occurrence of the expiration date, the supplying Pharmacist shall replace the expired Drug.

Section 5. Drug Distribution and Control.

(a) The Pharmacist-in-Charge shall establish written procedures for the safe and efficient Distribution of Drugs and for the provision of Pharmacist Care. An annual updated copy of such procedures shall be on hand for inspection by the Board of Pharmacy.

(b) Drugs brought into an Institutional Facility by a patient shall not be Administered unless they can be identified and the quality of the Drug assured. If such Drugs are not to be Administered, then the Pharmacist-in-Charge shall, according to procedures specified in writing, have them turned in to the Pharmacy, which shall package and seal them and return them to an adult member of the patient's immediate family, or store and return them to the patient upon discharge.

(c) Investigational Drugs shall be stored in and Dispensed from the Pharmacy only. All information with respect to investigational Drugs shall be maintained in the Pharmacy.

Section 6. Centralized Prescription Processing or Filling for Immediate Need.

(a) In accordance with the Model Rules for the Practice of Pharmacy and Centralized Prescription Processing and Filling, an Institutional Pharmacy may outsource services to another Pharmacy for the limited purpose of ensuring that Drugs or Devices are attainable to meet the immediate needs of patients and residents of the Institutional Facility or when the Institutional Pharmacy cannot provide services on an ongoing basis, provided that the Institutional Pharmacy:
(1) has obtained approval from the Institutional Facility to outsource Centralized Prescription Processing or Filling services for its inpatients and residents; and
(2) provides a valid Chart Order to the Pharmacy it has contracted with for the Centralized Prescription Processing or Filling services.

Comments

Section 2(a) Comment.

Chart Orders that are written by the Practitioner's agent shall be countersigned by the prescribing Practitioner within the required time period as required by state law or rule.

Section 2(b) Comment.

Although the definition of Institutional Facility is broad and may encompass an array of facilities that provide long-term medical care and services for its residents, some states may also recognize residential assisted living facilities or residential group homes as such.

Section 2(c) Comment.

Although traditionally characterized as being physically part of an Institutional Facility, the Model Rules recognize that an Institutional Pharmacy may or may not be physically attached to an Institutional Facility.

Section 4(d)(7) Comment.

When the Pharmacist restocks and reseals the emergency kit Drugs, it is recommended that a lock or other similar device be used to assure that unauthorized access to the kit is minimized.

Section 5(c) Comment.

Regarding the use of investigational Drugs in an institution, it is necessary that the institution ensure that such studies contain adequate safeguards for the patient, the institution, and the scientific integrity of the study. The institution must have written policies and procedures for the approval, management, and control of investigational Drug studies. All patients who participate in investigational Drug studies must freely consent, in writing, to treatment with these Drugs. The Pharmacist is responsible to the institution and to the principal investigator for seeing that procedures for the control of investigational Drug use are developed and implemented.

Section 6(a) Comment.

Although Institutional Pharmacies primarily outsource services to another Pharmacy for the purposes of meeting the immediate needs of patients and residents when the Institutional Pharmacy is closed, it is also recognized that other services may be outsourced that the Institutional Pharmacy is not able to provide on an ongoing basis.

Most Commonly Used Rules/Regulations for Hospital/Institutional Pharmacies

Definitions: 22
-AL, DE, GA, IL, IN, KY, LA, MD, MI, MN, NV, NH, NJ, NM, ND, OH, OK, OR, TX, VT, WA, WY

Absence of Pharmacist: 17
-AL, AK, DE, GA, ID, IL, IN, KY, MT, NV, NC, ND, OK, TN, VT, WA, WY

Personnel: 16
-AL, DE, GA, IN, MD, MI, MN, MT, NC, ND, OK, TN, TX, VT, WA, WY

Drug Distribution and Control: 15
-AL, AK, GA, ID, IA, KY, LA, MT, NM, NC, ND, OR, RI, TN, WA

Pharmacy Director- Minimum Responsibilities/Pharmacist in Charge; Responsibilities/Pharmacist in Charge/Responsibilities of Director of Pharmacy/Managing Pharmacist/Responsibilities of the Pharmacist-Manager/Responsible Person for an Institutional Pharmacy: 15
-ID, IN, IA, LA, MD, MI, MN, MT, NV, NJ, NC, OH, OK, VT, VA

Physical Requirements/Standards for Premises/ Environment/Minimum Standards/Pharmaceutical Service Space: 15
-GA, KY, MD, MN, NV, NH, NC, ND, OH, OK, RI, TN, VT, WA, WY

Applicability/Scope: 14
-AL, IN, IA, MD, MN, NV, NJ, ND, OK, OR, TN, VT, WA, WY

Licensure/Registration/Permits: 13
-GA, LA, MD, NV, NH, NJ, NC, ND, OK, OR, SD, WA, WY

Labeling: 12
-DE, IL, LA, MD, MI, MN, NV, NJ, OH, OK, RI, VT

Recordkeeping Requirements/Records/Recordkeeping/Records and Reports: 11
-IL, IN, IA, ME, MD, NV, NJ, OH, RI, TX, VT

Security/Storage and Security: 11
-IN, IA, ME, MD, NV, NH, NJ, OH, RI, VT, WY

Drugs from Outside Sources/ Medications from Other Sources/Patient's Own Medication/Drugs Brought into the Facility/Medications Brought into the Institution by Patients/Patient's Personal Medications: 9
-GA, IN, NJ, ND, OK, TN, RI, VT, WY

Inspections: 9
-DE, GA, IN, ME, ND, OK, TN, VT, WY

Access to Pharmacy/Withdrawal of Drugs when Facility Uses Floor Stock and Pharmacy is Closed/After Hours Access to the Institutional Pharmacy/After Hours Pharmacy Services/Access to Pharmacy-Records/Access to Pharmacy During Emergency: 8
-DE, NV, NH, NJ, RI, SD, VT, VA

Investigational Drugs: 8
-GA, NH, ND, OK, TN, VT, WA, WY

Emergency Rooms/Emergency Outpatient Medication/Emergency Outpatient Drug Delivery by Hospital Emergency Rooms/Drugs in the Emergency Department/Medication in Health Care Facility Emergency Departments: 8

-AK, ID, NC, RI, TN, VA, WA, WY

Emergency Drugs/Emergency Drug Access/Emergency Kits and Crash Carts/Emergency Drug Kits/Drug Dispensing-Emergency Supplies and Procedures/Emergency and Home Care Kits/Emergency Drug Carts: 8

-DE, ID, IN, LA, MD, TN, VT, WY

Reference Library/Equipment and Texts/References/Maintenance of Reference Library/Drug Information and Education/Drug Information/Reference Materials: 7

-DE, IA, NV, NJ, NM, VT, WY

Controlled Dangerous Substances/Controlled Substance Recordkeeping/Controlled Drugs/Controlled Drug Accountability: 6

-MD, NJ, OH, TN, VT, WY

Remote Processing of Medical Orders/Provision of Remote Services by Pharmacist Employed by Off-Site Pharmaceutical Service Provider/Remote Medication Order Processing Services/Remote Prescription Order Processing for Hospitals and Long Term Care Facilities: 5

-LA, NV, NC, OK, VA

Policies and Procedures Manual/Policies and Procedures/Establishment of Policies, Procedures, and Systems/Written Policies: 5

-IN, MI, MD, NV, VT

Automated Dispensing & Storage Systems/Prescriptions and Medication Orders Transmitted by Technological Devices in an Institution/Automated Dispensing Devices in Institutional Practice Sites/Automated Devices for Dispensing and Administration of Drugs/Automated Dispensing Devices: 5

-IL, NJ, TN, VA, WY

Administration of Drugs: 4

-GA, ND, OK, WA

Outpatient Orders/Outpatient Services/Outpatient Pharmacy Dispensing: 3

-DE, IA, LA

Unused Drugs, Devices, and Related Materials/Disposal of Unused Medications: 3

-MI, NJ, TN

Categories of Statutes & Rules by State

(All are Rules/Regulations unless stated that they are Statutes)

NABP: Model Rules for Institutional Pharmacy

- Applicability
- Definitions
- Personnel
- Absence of Pharmacist
- Drug Distribution and Control
- Centralized Prescription Processing or Filling for Immediate Need

Alabama (Statutes):

- Hospitals & Related Institutions

Alabama: Institutional Pharmacies

- Applicability
- Definitions
- Personnel
- Absence of Pharmacist
- Drug Distribution & Control

Alaska (Statutes):

- Pharmacists Required in Hospitals & Clinics

Alaska: Institutional Pharmacies

- Absence of a Pharmacist from an Institutional Pharmacy
- Emergency Room Outpatient Medications
    - 12 AAC 52.720 (a) "The pharmacist-in-charge of an institutional pharmacy, in cooperation with the appropriate committee of the institutional facility's medical staff, shall prepare a list of prescription drugs that may be delivered to outpatients receiving emergency treatment and shall determine appropriate quantities for unit-of-use packaging and prepackaging of the prescription drug."
- Drug Distribution & Control

Arizona (Statutes):

- Pharmacy Operated By Hospital

Arkansas (Statutes): "Hospital Pharmacies Act"

- Definitions
- Advisory Committee for Hospital Pharmacies
- Rules, Regulations, & Standards
- Hospital Pharmacy License
    - 17-92-605 (a) "All hospital pharmacies shall be licensed by the Arkansas State Board of Pharmacy as provided for by this subchapter. The hospital pharmacy license shall be issued in the name of the hospital."
- Hospital Pharmaceutical Permit
- Unlawful Activity; Construction of Provision

California (Statutes):

- Hospital Pharmacy
  - 4029 (b) "A hospital pharmacy also includes a pharmacy that may be located outside of the hospital…As a condition of licensure by the board, the pharmacy in another physical plant shall provide pharmaceutical services only to registered hospital patients who are on the premises of the same physical plant in which the pharmacy is located."
- Permitted Pharmacist Procedures in Licensed Health Care Facility
- Permitted Pharmacist Procedures in Health Care Facility; Home Health Agency or Clinic with Physician Oversight

Delaware: Hospital Pharmacy

- Definition
- Personnel
- Absence of Pharmacist
- Night Cabinets or Other Designated Areas
- Access to Pharmacy
- Emergency Drugs
- Equipment and Texts
- Drug Storage
- Labeling
- Abbreviations
- Outpatient Orders
- Suspected Adverse Drug Reaction
- Maintenance of Medication Orders. Patient Profile
- Medication Error
- Monthly Inspections

Florida (Statutes):

- Institutional Pharmacies; Permits
  - 465.019 (4) "Medicinal drugs shall be dispensed in an institutional pharmacy to outpatients only when that institution has secured a community pharmacy permit from the department. However, an individual licensed to prescribe medicinal drugs in this state may dispense up to a 24-hour supply of a medicinal drug to any patient of an emergency department of a hospital that operates a Class II institutional pharmacy, provided that the physician treating the patient in such hospital's emergency department determines that the medicinal drug is warranted and that community pharmacy services are not readily accessible, geographically or otherwise, to the patient."

Georgia: Hospital Pharmacy Regulations

- Definitions
- Licensure and Registration
  - 480-13-02 "All hospital pharmacies shall renew biennially by June 30th of each odd-numbered year with the Georgia State Board of Pharmacy…"
- Personnel
- Absence of Pharmacist
- Physical Requirements
- Drug Distribution & Control
  - 480-13-.06 (11) "Emergency room dispensing. An authorized practitioner may, when drugs or controlled substances are not otherwise available from a licensed pharmacy, dispense an emergency amount of medication, but only sufficient quantities until such time as medication can be obtained from a pharmacy licensed as a retail pharmacy."
- Administration of Drugs

- Drugs from Outside Sources
- Investigational Drugs
- Inspections

Idaho: Institutional Facility

- Institutional Facility with Onsite Pharmacy-Minimum Responsibilities
- Institutional Pharmacy Director – Minimum Responsibilities
- Institutional Facility – General Standards for Administration and Control of Drugs & Devices
    - 630.02 "Drugs and Devices Dispensed for Administration or Use Outside an Institutional Facility. A drug or device prepared for self-administration or use by patient while outside the confines of the institutional facility must comply with the standard prescription drug labeling requirements."
- Institutional Facility – Emergency Drug Access and Pharmacist Absence
- Institutional Facility – Emergency Drug Supply Preparation and Monitoring
- Institutional Facility – Emergency Kits and Crash Carts – General Rules
- Institutional Facility – Nursing Home Emergency Kits
- Home Health or Hospice Emergency Kits
- Institutional Facility – Hospital Floor Stock
- Institutional Facility – Emergency Outpatient Drug Delivery by Hospital Emergency Rooms
    - 637. "A limited supply of drugs, not including Schedule II controlled substances, may be approved for delivery to outpatients receiving hospital emergency room treatment if stored in the emergency room pursuant to applicable law and these rules pertaining to emergency drug product storage and if accessed and delivered as permitted or restricted by this rule."
- Institutional Facility – Offsite Pharmacy Practice Standards
- Institutional Facility – Offsite Services – First Dose Pharmacy
- Institutional Facility – Centralized Pharmacy Services
- Institutional Facility – Practice of Telepharmacy

Illinois: Offsite Institutional Pharmacy Services, Onsite Institutional Pharmacy Services

- Offsite Institutional Pharmacy Services
    - Definition
    - Recordkeeping Requirements for Dispensing Prescriptions or Orders
    - Changing Pharmacy Provider Services
    - Staffing of the Pharmacy
    - Labeling Requirements
    - Sterile Products
- Onsite Institutional Pharmacy Services
    - Definition
    - Recordkeeping Requirements
    - Labeling Requirements
    - Staffing of the Pharmacy
    - Medication Dispensing in the Absence of a Pharmacist
    - Sterile Products
    - Automated Dispensing & Storage Systems

Indiana: Hospital Pharmacies

- Definitions
- Purpose
- Applicability
- Pharmacist in Charge; Responsibilities
- Policies and Procedures Manual

- Personnel
- Pharmacist's Duties
- Absence of Pharmacist
- Emergency Drug Kits from Type III and Type IV pharmacies
- Security
- Performance Improvement Events, Sentinel Events, Corrective and Avoidance Measures, Review, Records, and Documentation
- Drug Distribution, Storage, and Accountability
- Drug Self-Administration
- Patient's Own Medication
- Inspections

Iowa: Hospital Pharmacy Practice

- Purpose and Scope
- Pharmacist in Charge
- Reference Library
- Security
- Verification by Pharmacist when Pharmacy is Closed
- Drug Distribution and Control
- Drug Information
- Ensuring Rational Drug Therapy
- Outpatient Services
- Drugs in the Emergency Department
- Records

Kansas (Statutes):

- Institutional Drug Rooms; Supervision and Record-Keeping; Rules and Regulations

Kentucky: Pharmacy Services in Hospitals or Other Organized Health Care Facilities

- Definitions
- Pharmacy Administration
- Physical Facility
- Drug Distribution and Control
- Assuring Rational Drug Therapy

Louisiana: Hospital Pharmacy

- Hospital Pharmacy
  - Cross References
  - Definitions
  - Hospital Pharmacy Permit
  - Pharmacist-in-Charge
  - Drug Distribution Control
  - Prescription Drug Orders
  - Labeling
  - Ambulance Service Drugs
  - Pharmacist Absence/Drug Cabinet
  - Drug Returns
  - Off-Site Pharmacy Services
  - Outpatient Pharmacy Dispensing
    - 1523A. "Hospital outpatient dispensing shall require a separate pharmacy permit for the specialty classification(s) under these regulations."
  - Remote Processing of Medical Orders
- Institutional Pharmacy

- General Requirements
  - Cross References
  - Definitions
  - Institutional Pharmacy Permit
  - Drug Cabinet
- Emergency Drug Kits
  - Definitions
  - Emergency Drug Kit Permit
  - Emergency Drug Kit Requirements
- Drug Abuse Treatment Center Pharmacies
  - Purpose
  - Cross References
  - Definitions
  - Drug Abuse Treatment Center Pharmacy Permit
  - Minimum Security Controls for Drug Abuse Treatment Centers
  - Records and Reports of Drug Abuse Treatment Centers
- Drug Donations to Pharmacies in Penal Institutions
  - Medication Transfers

Maine: Pharmacy Services at Rural Health Centers

- Consulting Pharmacist; Monthly Inspection
- Limitation on Prescription Authority
- Recordkeeping
- Storage and Security
- Freedom of Choice

Maryland: Inpatient Institutional Pharmacy

- Scope
- Definitions
- Issuance of Permits
- Policies and Procedures
- Personnel
- Security
- Physical Requirements and Equipment
- Responsibilities of Director of Pharmacy
- Medication Packaging – Record Keeping
- Labeling for Use Outside the Institutional Facility
- Drug Dispensing – Emergency Supplies and Procedures
- Drug Dispensing – Prescribers' Orders
- Controlled Dangerous Substances
- Drug Recalls
- Adverse Drug Events
- Pharmaceutical Care Functions of the Pharmacist

Michigan: Pharmacy Services in Medical Institutions (No titles, just the descriptions)

- Definitions
- Licensed Pharmacist
- Personnel
- Responsibilities of Pharmacist-In-Charge
- Adopting Written Policies & Procedures to Promote Safe Medication Practice
- Labeling
- Unused Prescription Medication
- Policies Available to the Board of Pharmacy

Minnesota: Operations in Hospitals

- Definitions
- Scope
- Pharmacists and Support Personnel
- Hospital Pharmacist-In-Charge
- Patient Care
- Pharmaceutical Service Policies
- Maintaining Security and Emergency Access
- Drug Handling and Storage
- Pharmaceutical Service Space
- Prescription Labeling
- Extension of Pharmacy Services Under License

Mississippi: Institutional/Long Term Care Facilities (LTCF)

- Consulting Pharmacists to Institutional (LTC) Facilities
- Unit Dose Dispensing Systems for (LTCF)
- Return of Medications from an institutional Facility to the Provider Pharmacy

Montana: Institutional Pharmacies

- Personnel
- Institution Pharmacist and Pharmacist-In-Charge Responsibility
- Absence of Pharmacist in Institutional Settings
- Drug Distribution and Control in an Institutional Facility
- Use of Emergency Drug Kits in Certain Institutional Facilities
- Sterile Products
- Outpatient Centers for Surgical Services
    - 24.174.1122 (1) "The board shall annually register and inspect all outpatient centers for surgical services in Montana, regardless of pharmacy status."
- Return of Medication from Long Term Care Facilities – Donated Drug Program

Nevada: Medical Facilities and Correctional Institutions

- General Provisions
    - Definitions
    - Licensing
    - Biennial Registration
    - Change of Ownership
- Standards of Operation
    - Scope of Services in Hospital or Correctional Institution
    - Maintenance of Registration Certificates Required
    - Managing Pharmacist
    - Consultant Pharmacist
    - Staff Pharmacist
    - Establishment of Policies, Procedures, and Systems
    - Handling of Medications in Correctional Institutions without Pharmacies
    - Standards for Premises
    - Security of Premises
    - Maintenance of Reference Library
    - Procurement and Storage of Drugs
    - Development and Use of Formulary
    - Preparation and labeling of admixtures
    - Prepackaging of Drugs
    - Policies and Procedures for Distribution of Drugs
    - Limitations on Distribution of Drugs
    - Withdrawal of Drugs when Full-Time Pharmacist is Absent

    - Withdrawal of Drugs when Part-Time or Consultant Pharmacist is Absent
    - Withdrawal of Drugs when Facility Uses Floor Stock and Pharmacy is Closed
- Records
    - Maintenance and Availability of Records
    - Statutes Applicable to Maintenance of Records
    - Contents and Maintenance of Chart Orders
    - Maintenance of Records for Controlled Substances
    - Maintenance of Records of Controlled Substances Administered from Floor Stock
    - Maintenance of Additional Records
    - Maintenance of Records for Distribution of Controlled Substances to Another Pharmacy or Practitioner
    - Separation of Certain Records
    - Permission to Use Centralized System for Keeping Records
- Chart Order Processing Services
    - Definitions
    - Provision of Services by Pharmacies within Certain Hospitals and Correctional Institutions
    - Provision of Remote Services by Pharmacist Employed by Off-Site Pharmaceutical Service Provider
    - Policies and Procedures of Off-Site Pharmaceutical Service Providers

New Hampshire: Institutional Practices

- Definitions
- Licensing and Practice Standards
- Environment
- Drug Security
- Dispensing Practices
- Access to the Pharmacy
- Drug Control in Ambulatory Patient Treatment Areas
- Investigational Drugs
- Purchase of Drugs

New Jersey: Pharmaceutical Services for Health Care Facilities

- Purpose and Scope
- Definitions
- Licensure of Institutional Pharmacies
- Contract Pharmaceutical Services; Institutional Permit Required
- Advisory Committees
- Pharmacy and Therapeutics Committee; Applicability; Policies and Procedures
- Control of Health Care Pharmaceutical Services; Responsibilities of the Pharmacist-in-Charge of the Provider Pharmacy
- Pharmaceuticals; Drug Supply; Investigational Drugs; Controlled Dangerous Substances
- Drug Disbursement; Written Orders
- Drug Disbursement; Oral Orders
- Monitoring of Patient Drug Therapy
- Medication Not Dispensed in Finished Form
- Drug Labeling
- Use of Patient’s Own Medication
- Drug-Dispensing Devices
- Disposal of Unused Medications
- Records and Reports
- Drug Information and Education
- After Hours Access to the Institutional Pharmacy

- Pharmacy Facilities; Space
- Storage and Security
- Equipment
- Institutional Decentralized Pharmacies
- Valid Medication Orders; Out-Of-State Medication Orders
- Prescriptions and Medication Orders Transmitted by Technological Devices in an Institution

New Mexico: Hospital Pharmacies

- Definitions
- Leadership
- Facilities
- Pharmacy Service Unit
- Drug Distribution and Control
- Drug Information
- Assuring Rational Drug Therapy
- Research
- In-House Clinics
- Application of Regulation

North Carolina: Hospitals: Other Health Facilities

- Registration and Permits
- Supervision of Drugs in Areas Outside of Pharmacy
- Institutional Pharmacy Drug Inventories and Emergency Kits
- Medication In Institutional Emergency Departments
- Standards for Pharmacy Service
- Automatic Stop Orders
- Institutional Formulary
- Institutional Discharge Medication Option
- Research Participation
- Personnel
- Responsibilities of the Pharmacist-Manager
- Physical Requirements
- Absence of Pharmacist
- Drug Distribution and Control
- Medication in Health Care Facility Emergency Departments
    - 21 NCAC 46.1415 (a) "In those health care facilities having 24 hour outpatient pharmacy service, all drugs dispensed to outpatients including emergency department patients must be dispensed by a pharmacist."
- Repackaging
- Remote Medication Order Processing Services
- Supervision of Unit Dose Medication Systems

North Dakota: Hospital Pharmacy

- Definitions
- Applicability
- Registration
- Personnel
- Absence of Pharmacist
- Physical Requirements
- Drug Distribution and Control
- Nondistributive Roles of Pharmacist
- Administration of Drugs

- Drugs from Outside Sources
- Quality Assurance
- Investigational Drugs
- Inspection

Ohio: Institutional Facility

- Definitions
- Responsible Person for an Institutional Pharmacy
- Security and Control of Drugs in an Institutional Facility
- Records
- Controlled Substance Recordkeeping
- Minimum Standards for an Institutional Pharmacy
- Drug Orders for Patients of an Institutional Facility
- Labeling of Prescriptions for Patients of an Institutional Facility
- Labeling of Prescriptions for Outpatients
- D.E.A. Numbers for Hospital Employed Prescribers

Oklahoma: Hospital Pharmacies

- Purpose
- Definitions
- Applicability
- Registration
- Director and Pharmacy Manager
- Staff Pharmacists [Revoked]
- Supportive Personnel
- Pharmacy Technician Qualifications and Training
- Supervision of Pharmacy Technicians
- Pharmacy Technician Tasks
- Prohibited Duties
- Pharmacy Technician Annual Permit Requirement
- Permit Display
- Change of Address and Employment Location Notification
- Multiple Employment Locations
- Work Schedule Display
- Technician Training
- Identification of Pharmacy Technicians
- Absence of Pharmacist
- Hospital Pharmacy Physical Requirements
- Director of Pharmacy Responsibilities
- Labeling
- Physician’s medication orders
- Non-distributive Roles of Pharmacists
- Administration of Drugs to Patients
- Medications from Other Sources
- Performance Improvement
- Investigational Drugs
- Monthly Inspections
- Board of Pharmacy Inspections
- Drug Rooms
- Remote Medication Order Processing (RMOP)

Oregon: Institutional Drug Outlets, Hospitals with Drug Rooms, Hospitals with Pharmacies

- Institutional Drug Outlets
  - Definitions
  - Applicability of Rules
  - Registration
    - 855-041-0115 "All institutional drug outlets shall register annually with the Board of Pharmacy. Institutional drug outlets which also provide outpatient pharmacy services shall also register as retail drug outlets."
- Hospitals with Drug Rooms
  - Supervision of Consulting Pharmacist
  - Drug Distribution and Control from a Drug Room in a Hospital
- Hospitals with Pharmacies
  - Definitions
  - Registration
  - General Pharmacy Requirements

Pennsylvania: Institutions

- Qualified Institutions
- Institutional Regulations
  - 27.42 "Pharmaceutical services in institutions shall always be conducted in accordance with rules and regulations affecting the services which have been or may hereafter be promulgated by the Department of Public Welfare or Department of Health, and the rules and regulations are hereby incorporated automatically. Violation of the rules and regulations constitute a violation of this chapter."

Rhode Island: Board of Health: General Requirements: Institutional Pharmacies

- Physical Requirements
- After-hours Pharmacy Services
- Medication Distribution and Control
- Medication Orders
- Medication Storage and Security
- Labeling
- Records
- Patient's Personal Medication
- Emergency Outpatient Medications
- Monitoring Drug Therapy

South Carolina: Emergency Room Physicians

- 115 "Emergency room physicians or supervisors may not delegate a nurse or other person their personal authority under…to dispense legend drugs to meet the immediate needs of patients."

South Dakota (Statutes):

- Institutional Pharmacy Permits- Scope of services provided – Minimum Standards

South Dakota: Pharmacies in Hospitals, Nursing Facilities, or Related Facilities

- Pharmaceutical Services Supervised by Pharmacist
- Central Area to be Licensed as a Pharmacy
- Dispensing Limited to Pharmacist
- Transferring Drugs from Original Containers Limited to Pharmacists
- Removing a Single Dose from Prescription Container
- Preparing a Solution
- Medication Floor Stocks
- Filling or Refilling of Nursing Station Containers Limited to Pharmacists

- Registration and Renewal
- Schedule of Attendance by Pharmacist
- Supervision of Drugs Located in Areas Other than Pharmacy
- Access to Pharmacy – Records
- Pharmacy Must be in a Separate Room
- Pharmacist Controls Emergency Drugs in Health Care Facilities
- Pharmacist Controls Emergency Kit in Nursing Facility
- Minimum Standards for Pharmacy Service
- Federal and State Statutes Control [Repealed]

Tennessee: Institutional and Alternate or Alternative Infusion Pharmacy Practice Sites

- Applicability
- Personnel
- Physical Requirements
- Prescription Orders
- Distribution and Control of Drugs
- Medication Carts
- Floorstock Drugs
- Controlled Drugs
- Emergency and Home Care Kits
- Unused Drugs, Devices, and Related Materials
- Take-Home and Leave of Absence Drugs, Devices, & Related Materials
- Drugs Brought Into the Facility
- Recalls
- Absence of Pharmacist
- Automated Dispensing Devices in Institutional Practice Sites
- Emergency Rooms
    - 1140-4-.16 "If prescription drugs, devices and related materials in an emergency room are to be dispensed (other than by pharmacy staff) rather than administered, the drugs, devices or related materials must be dispensed by the physician or an emergency room nurse or certified physician assistant at the direction of a physician.
- Investigational Drugs
- Monthly Inspections

Texas: Institutional Pharmacy

- Purpose
- Definitions
- Personnel
- Operational Standards
- Records
- Class C Pharmacies Located in a Freestanding Ambulatory Surgical Center

Vermont: Institutional Pharmacy

- Applicability
- Definitions
- Personnel
- Responsibilities of the Pharmacist-Manager
- Written Policies
- Absence of Pharmacist
- Night Cabinets/Temporary Storage
- Access to Pharmacy During Emergency
- Designated Nurse Access

- Nurse Removal of Drugs
- Doses
- Emergency Kits
- Emergency Kits in Non-Federal Registered Long-term Care Facilities (LTCF)
- Emergency Kit Records
- Authorized Emergency Kit Users
- Physical Requirements
- Hygiene Standards
- Equipment
- Reference Materials
- Storage
- Security
- Labeling
- Dispensed Drugs
- Unit Dose Packaging
- Discontinued Drugs
- Physician's Orders
- Telephone Orders
- Controlled Drug Accountability
- Recall
- Adverse Drug Reactions
- Medications Brought Into the Institution By Patients
- Investigational Drugs
- Records and Reports
- Inspection of Medication Areas

Virginia: Pharmacy Services to Hospitals

- Responsibilities of the Pharmacist-In-Charge
- After-Hours Access to the Pharmacy
- Floor Stock Drugs; Proof of Delivery; Distribution Records
- Emergency Room
- Automated Devices for Dispensing and Administration of Drugs
- Licensed Emergency Medical Services Agencies Program
- Identification for Medical Intern or Resident Prescription Form in Hospitals
- Remote Prescription Order Processing for Hospitals and Long Term Care Facilites

Washington: Hospital Pharmacy Standards

- Definitions
- Applicability
- Licensure
- Personnel
- Absence of a Pharmacist
- Emergency Outpatient Medications
- Physical Requirements
- Drug Procurement, Distribution and Control
- Administration of Drugs
- Investigational Drugs
- Additional Responsibilities of Pharmacy Service

Wyoming: Institutional Pharmacy Practice Regulations

- Authority
- Purpose
- Scope of Chapter

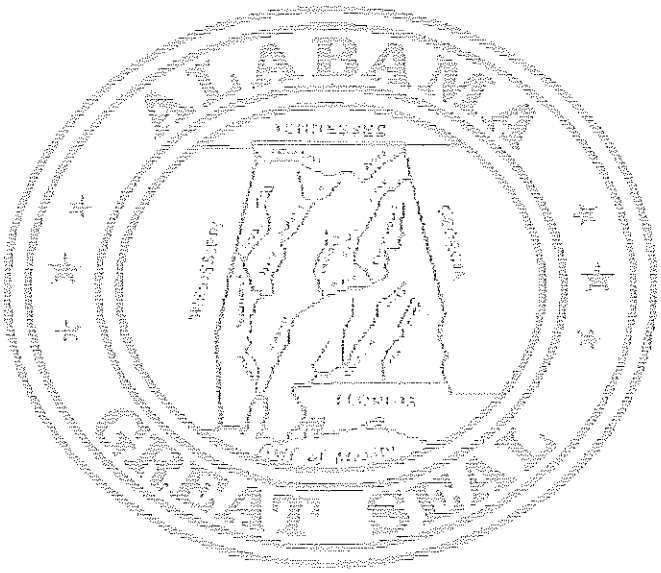
- Definitions
- Licensing
- Change of Ownership
- Personnel
- Environment
- References
- Equipment
- Security
- Absence of Pharmacist
- Emergency Outpatient Medication
- Emergency Drug Carts
- Automated Dispensing Devices
- Parenteral Medications
- Practitioner's Orders
- Dispensing
- Investigational Drugs and Protocols
- Monthly Inspection
- Medications Brought into the Institution by Patients
- Controlled Drugs

States with No Statutes or Rules/Regulations for Hospital/Institutional Pharmacies:

Colorado
Connecticut
District of Columbia
Guam
Hawaii
Massachusetts
Nebraska
New York
Pennsylvania
Puerto Rico
Utah
Virgin Islands
West Virginia
Wisconsin

CODE OF ALABAMA 1975

CUMULATIVE SUPPLEMENT
INCLUDING ACT OF 2009 LEGISLATURE



TITLE 34 CHAPTER 23
PRACTICE OF PHARMACY ACT 205
LEGISLATURE 1966

ALABAMA STATE BOARD OF PHARMACY

January 26, 2012
Includes amendments effective 3-5-2012

34-23-159. Preparation of compounded drug products for over the counter sale.
34-23-160. Preparation of compounded drug products for prescriber's office use; labeling.
34-23-161. Prescriptions for animals.
34-23-162. Rules and regulations.

ARTICLE 1.

GENERAL PROVISIONS.

§ 34-23-1. Definitions.

For the purpose of this chapter, the following words and phrases shall have the following meanings:

(1) **ASSOCIATION.** The Alabama Pharmacy Association.

(2) **BOARD or STATE BOARD**. The Alabama State Board of Pharmacy.

(3) **CHEMICAL.** Any substance of a medicinal nature, whether simple or compound, obtained through the process of the science and art of chemistry, whether of organic or inorganic origin

(4) **DISPENSE.** To sell, distribute, administer, leave with, give away, dispose of, deliver, or supply a drug or medicine to the ultimate user or their agent.

(5) **DRUGS.** All medicinal substances, preparations, and devices recognized by the United States Pharmacopoeia and National Formulary, or any revision thereof, and all substances and preparations intended for external and internal use in the cure, diagnosis, mitigation, treatment, or prevention of disease in man or animal and all substances and preparations other than food intended to affect the structure or any function of the body of man or animal.

(6) **EXTERN**. A candidate for licensure as a pharmacist during the time prior to graduation from an accredited college of pharmacy.

(7) **HOSPITAL**. An institution for the care and treatment of the sick and injured, licensed by the Alabama State Board of Health and authorized to be entrusted with the custody of drugs and medicines, the professional use of drugs and medicines being under the direct supervision of a medical practitioner or pharmacist.

(8) **INTERN**. An individual who is currently licensed by this state to engage in the practice of pharmacy while under the personal supervision of a pharmacist and is satisfactorily progressing toward meeting the requirements for licensure as a pharmacist; or a graduate of an approved college of pharmacy who is currently licensed by the State Board of Pharmacy for the purpose of obtaining practical experience as a requirement for licensure as a pharmacist; or a qualified applicant awaiting examination for licensure.

(9) **LEGEND DRUG**. Any drug, medicine, chemical, or poison bearing on the label the words, "caution, federal law prohibits dispensing without prescription," or similar wording indicating that such drug, medicine, chemical, or poison may be sold or dispensed only upon the prescription of a licensed medical practitioner.

(10) **LICENSE.** The grant of authority by the State Board of Pharmacy to a person authorizing him or her to engage in the practice of pharmacy in this state.

(11) **MANUFACTURER**. A person, except a pharmacy, who prepares, derives, produces, compounds, or packages any drug, medicine, chemical, or poison.

(12) **MEDICAL PRACTITIONER**. Any physician, dentist, or veterinarian, or any other person authorized by law to treat, use, or prescribe medicine and drugs for sick and injured human beings or animals in this state.

(13) **MEDICINE**. Any drug or combination of drugs that has the property of curing, diagnosing, preventing, treating, or mitigating diseases or that which may be used for those purposes.

(14) **PATENT OR PROPRIETARY MEDICINES**. Completely compounded nonprescription packaged drugs, medicines, and nonbulk chemicals which are sold, offered, promoted, or advertised by the manufacturer or primary distributor under a trademark, trade name, or other trade symbol, and the labeling of which conforms to the requirements of the Federal Food, Drug, and Cosmetic Act; provided, that this definition

shall not include:

a. Drugs which are only advertised and promoted professionally to licensed physicians, dentists, or veterinarians by manufacturers or primary distributors.

b. A narcotic or drug containing a narcotic.

c. A drug the label of which bears substantially either the statements "caution-federal law prohibits dispensing without prescription" or "warning-may be habit forming".

d. A drug intended for injection.

(15)**PERMIT.** The grant of authority by the State Board of Pharmacy to any person, firm, or corporation authorizing the operation of a pharmacy, wholesale drug distributor, repackager, bottler, manufacturer, or packer of drugs, medicines, chemicals, or poisons for medicinal purposes. Nonresident wholesale drug distributors registered with the appropriate agency, in the state in which they are domiciled, and operating in compliance with Prescription Drug Marketing Act standards, shall be allowed to do business in this state. No permit shall be required of any physician licensed to practice medicine for any act or conduct related to or connected with his or her professional practice.

(16) **PERSON.** Any individual, partnership, corporation, association, trust, or other entity.

(17) **PHARMACIST**. Any person licensed by the Alabama State Board of Pharmacy to practice the profession of pharmacy in the State of Alabama and whose license is in good standing.

(18) **PHARMACY.** A place licensed by the Alabama State Board of Pharmacy in which prescriptions, drugs, medicines, medical devices, chemicals, and poisons are sold, offered for sale, compounded, or dispensed, and shall include all places whose title may imply the sale, offering for sale, compounding, or dispensing of prescriptions, drugs, medicines, chemicals, or poisons.

(19)**POISON.** Any substance other than agricultural products and pesticides which when applied to, introduced into, or developed within the body in relatively small quantities by its inherent chemical action uniformly produces serious bodily injury, disease, or death.

(20)**PRECEPTOR**. A person who is duly licensed to practice pharmacy in the state and meets the requirements as established by the State Board of Pharmacy.

(21)**PRESCRIPTION**. Any order for drug or medical supplies, written or signed or transmitted by word of mouth, telephone, telegraph, closed circuit television, or other means of communication by a legally competent practitioner, licensed by law to prescribe and administer such drugs and medical supplies intended to be filled, compounded, or dispensed by a pharmacist.

(22)**PROFESSIONAL DEGREE**. A degree in pharmacy requiring a minimum of five academic years.

(23)**REPACKAGER.** A person who purchases or acquires from a manufacturer or distributor, a drug, medicine, chemical, or poison for the purpose of bottling, labeling, or otherwise repackaging for sale or distribution. This definition shall not apply to a physician licensed to practice medicine who as a part of his or her professional practice dispenses, administers, sells or otherwise distributes any drugs to a patient.

(24)**SALE.** Barter, exchange, or gift, or offer of barter, exchange, or gift, and shall include each transaction made by any person, whether a principal, proprietor, agent, servant, or employee.

(25)**WHOLESALE DRUG DISTRIBUTORS**. A person engaged in the business of distributing drugs and medicines for resale to pharmacies, hospitals, practitioners, government agencies, or other lawful outlets permitted to sell drugs or medicines. The sale, purchase, or trade of a drug by a retail pharmacy to another retail pharmacy or practitioner, for relief of temporary shortages, is exempt from this definition. Also exempt from this definition shall be (a) intracompany sales, (b) manufacturer and distributor sales representatives who distribute drug samples, (c) charitable organizations distributing to nonprofit affiliates of that organization, (d) certain purchases by hospitals or other health care entities that are members of a group purchasing organization, and (e) the distributors of blood and blood components. (Acts 1966, Ex. Sess., No. 205, p. 231, § 2; Acts 1991, No. 91-475, pg. 860, § 1; Acts 98-643, p. 1414, §1.)

§ 34-23-2. Objects and purposes of chapter.

The practice of pharmacy and the management and operation of pharmacies are hereby declared to affect the public health, safety and welfare of the people of Alabama, and thereby subject to regulation and control in the public interest. It is further declared to be a matter of public interest and concern that only qualified persons compound or dispense prescription drugs and medicines, and that pharmacies be managed in such a manner as to protect the public, and all provisions of this chapter shall be liberally construed to carry out these objects and purposes. (Acts 1966, Ex. Sess., No. 205, p 231, § 1.)

§ 34-23-3. State drug inspectors.

Each state drug inspector employed by the board following the passage of this chapter must furnish satisfactory proof to the board that he is a person of good moral character and that in the judgment of the members of the board he has sufficient knowledge of the laws pertaining to the practice of pharmacy and law enforcement to enable him to carry out his duties as an inspector consistent with the provisions of this chapter. Each state drug inspector employed by the board shall serve an apprenticeship of a minimum of six months working with and under the supervision of the chief drug inspector or other inspector designated by the board.

Each such inspector, before entering upon his duties, shall post with the state board of pharmacy a bond in the amount of $2,000.00 conditioned upon the faithful performance of his duties. Each state drug inspector shall have the power to inspect the medicines and drugs or drug products or domestic remedies which are manufactured, packaged, packed, made, sold, offered for sale, exposed for sale or kept for sale in this state, and for this purpose shall have the right to enter and inspect during business hours any pharmacy or any other place in this state where medicines or drugs or drug products or proprietary medicines are manufactured, packaged, packed, made, sold, offered for sale or kept for sale, whether or not licensed by the state board of pharmacy.

Each state drug inspector shall be subject to the same restrictions as other officers of the law in regard to search and seizure. They shall report to the board all violations of the laws relating to pharmacy and all rules and regulations of the board. As directed by the board, it shall be the duty of the state drug inspectors to issue citations for violations of such laws, rules or regulations or institute criminal proceedings against persons for such violations. When authorized by the board and where there are specific complaints, the state drug inspector shall have the right to inspect all records, shipping tickets or any other document pertaining to the transfer of drugs or drug preparations, from or to hospitals, pharmacists, wholesale establishments and manufacturers, or any other place or establishment where said preparations of drugs are kept or stored. They shall have the authority to inspect all prescription files, prescription record books, poison registers, exempt narcotic registers and any other records pertaining to the filling and filing of prescriptions. It shall be the duty of the state drug inspector to take possession of all revoked and/or suspended licenses and permits when such licenses and permits are not surrendered voluntarily to the board by the person or pharmacist whose license or permit has been revoked or suspended. Nothing in this chapter shall authorize or require the state drug inspector or state drug inspectors to inspect the offices of doctors of medicine who have duly qualified with the state board of medical examiners. (Acts 1966, Ex. Sess., No. 205, p. 231, § 7.)

§ 34-23-4. Licensure limited to graduates from approved schools and colleges.

The Board of Pharmacy shall consider for licensure graduates from only those schools and colleges of pharmacy which are approved by the board. (Acts 1966, Ex. Sess., No. 205, p. 231, § 8; Act 2006-296; p. 607; §1.)

§ 34-23-5. Pharmacists exempt from jury duty.

Repealed by Acts 1989, No. 89-235, p. 303, §6, effective April 6, 1989.

§ 34-23-13. Penalty for practicing pharmacy without a license; compounding or dispensing prescriptions by unauthorized persons; violations of chapter or rules and regulations of board.

Any person who shall practice pharmacy in this state without having first obtained from the board a license, or who permits prescriptions to be compounded and/or dispensed by unauthorized persons; or who violates any of the provisions of this chapter; or who willfully violates any published rule or regulation of the board; or who does any act described in this chapter as unlawful, the penalty for which is not herein specifically provided, shall be guilty of a misdemeanor and, upon conviction, shall be punished by fine of not more than $1,000.00 for each offense, to be fixed by the court trying said case, and in addition thereto may be, in the discretion of the court trying said case, sentenced to hard labor for the county for a period not to exceed 12 months. (Acts 1966, Ex. Sess., No 205, p. 231, § 10.)

ARTICLE 2.

LICENSES AND PERMITS

Division 1.
General Provisions.

§ 34-23-30. Pharmacy permits generally.

Every pharmacy, hospital pharmacy, drugstore, pharmacy department, prescription department, prescription laboratory, dispensary, apothecary or any other establishment with a title implying the sale, offering for sale, compounding or dispensing of drugs in this state shall register biennially and receive a permit from the Board of Pharmacy. Any person desiring to open, operate, maintain, or establish a pharmacy in this state shall apply to the board for a permit at least 30 days prior to the opening of the business. No pharmacy shall open for the transaction of business until it has been registered, inspected, and a permit issued by the board. The application for a permit shall be made on a form prescribed and furnished by the board which when properly executed shall indicate the ownership desiring such permit and the names and license numbers of all licensed pharmacists employed as well as the location of the pharmacy and other information as the board may require. If more than one pharmacy is operated by the same owner, a separate application for registration shall be made and a separate permit issued for each such establishment. All permits issued under this section shall become due on October 31 and shall become null and void on December 31 of even-numbered years. Every application for a permit for a new pharmacy shall be accompanied by a fee to be determined by the board, but said fee shall not be less than one hundred dollars ($100) nor more than two hundred dollars ($200). Every application for a renewal permit shall be accompanied by a fee to be determined by the board, but the fee shall no be less than fifty dollars ($50) nor more than one hundred fifty dollars ($150). Every application for a permit due to transfer of ownership shall be accompanied by a fee to be determined by the board, but the fee shall not be less than fifty dollars ($50) nor more than one hundred fifty dollars ($150). Each application for the renewal of a permit shall be made on or before October 31 of each even-numbered year, at which time the previous permit shall become null and void on December 31 of even-numbered years. A penalty of twenty-five dollars ($25) for each overdue month shall be assessed in addition to the permit fee for renewal of delinquent permits. The secretary of the board shall issue a permit for each pharmacy whose application is found to be satisfactory by the board. Permits issued under this section shall not be transferable. Any change in the control of ownership or licensed pharmacists shall be reported to the board in writing within 10 days of such occurrence. If the pharmacy is owned by a corporation, the permit shall be issued in the name of the corporation. It shall be the duty of the owners of pharmacies who are not licensed pharmacists to immediately notify the board upon the termination of employment of licensed pharmacists and to cause the surrender of permits as indicated. The further operation of the pharmacy in the absence of licensed pharmacists is forbidden; provided, that the nonregistered owner shall have a period of 30 days within which to comply with this provision. The next of kin of any deceased licensed pharmacist owner shall have a period of 30 days within which to comply with the provisions of this chapter, during which time no prescriptions shall be filled unless a licensed pharmacist is on duty. No mail order pharmacy shall transact

business in this state without a permit from the Board.

Any person who violates this section shall be guilty of a misdemeanor. (Acts 1966, Ex. Sess., No. 205, p. 231 § 14; Acts 1985, No. 85-702, p. 1151, § 1; Acts 2004-450, p. 801, §1.)

§ 34-23-31. Permits for mail-order houses.

Every mail-order house which dispenses drugs or medicines through the United States mail or otherwise from any point in the state of Alabama to any point outside of the state of Alabama, and every such business which dispenses drugs or medicines through the United States mail or otherwise from any point outside the state of Alabama to any point within the state of Alabama shall obtain a permit from the state board of pharmacy as a condition precedent to being qualified and authorized to transact such business in the state of Alabama. (Acts 1966, Ex. Sess., No. 205, p. 231, § 29.)

§ 34-23-32. Manufacturer, bottler, packer, repackager, or wholesale distributor of drugs.

(a) Every manufacturer, bottler, packer, repackager, or wholesale drug distributor, of drugs, medicines, chemicals, or poisons for medicinal purposes shall register biennially with the board by application for a permit on a form furnished by the board and accompanied by a fee to be determined by the board as follows:

(1) The fee shall not be less than five hundred dollars ($500) nor more than two thousand dollars ($2,000) for a new establishment.

(2) The fee shall not be less than two hundred fifty dollars ($250) nor more than one thousand dollars ($1,000) for a renewal permit

(3) The fee shall not be less than two hundred fifty dollars ($250) nor more than one thousand dollars ($1,000) for a permit due to transfer of ownership.

(b) A holder of a permit shall employ a full-time licensed pharmacist whose principal duty shall be confined to on-premise pharmaceutical operations. Wholesale drug distributors, who strictly limit their operation to distribution of drugs, medicines, chemicals, or poisons for medicinal purposes are exempt from the requirement to employ a full-time licensed pharmacist.

(c) The professional practice of any physician licensed to practice medicine is exempt from the requirements of this section.

(d) All permits issued under this section shall become due on October 31 and shall become null and void on December 31 of even-numbered years. Each application for the renewal of the permit shall be made on or before December 31 of even-numbered years. A penalty of twenty-five dollars ($25) for each overdue month shall be assessed in addition to the permit fee for renewal of delinquent permits. For each application for a permit made and found to be satisfactory by the board, the secretary of the board shall issue to the applicant a permit for such manufacturing or wholesale establishment, which permit shall be displayed in a conspicuous place.

(e) All holders of a permit shall, before shipping any drug bearing the legend, "caution, federal law prohibits dispensing without prescription" or similar wording causing these drugs to be known as legend drugs to new customers, assure themselves that the recipient is either a duly licensed doctor of medicine, dentistry, or veterinary medicine or holds a registered pharmacy permit from the board by contacting the office of the board. No holder of a permit shall ship any legend drug to any person or firm after receiving written notice from the board that the person or firm no longer holds a registered pharmacy permit. Any person violating this section shall be guilty of a misdemeanor. (Acts 1966, Ex. Sess., No. 205, p. 231, § 24; Acts 1985, No. 85-702, p. 1151, § 1; Acts 1991, No. 91-475, p. 860, § 1; Acts 2004-450, p. 801, §1.)

($150) to the secretary of the board, the fee being due on October 31and delinquent after December 31 of even-numbered years except, that holders of life certificates to practice pharmacy previously issued shall not be required to pay a renewal fee. The payment of the renewal fee shall entitle the registrants to renewal of their certificates at the discretion of the board. If any pharmacist shall fail to pay a renewal fee on or before the due date, the holder of the certificate may be reinstated as a licensed pharmacist only upon payment of a penalty of ten dollars ($10) for each lapsed month and all lapsed fees, provided the lapsed time of registration shall not exceed five years, in which case reinstatement may be had only upon satisfactory examination by the board.

(b) In addition to any fee requirements, each pharmacist is required to complete 15 hours of continuing education per calendar year, of which three hours shall be live presentation. (Acts 1966, Ex. Sess., No. 205, p. 231, § 13; Acts 1985, No. 85-702, p. 1151, § 1; Acts 2004-450, p. 801, §1.)

§ 34-23-53. Training program for candidates for licensure.

Candidates for licensure as pharmacists shall complete a practical training program as prescribed by the board in keeping with standards established by the national accreditation agencies. The candidate shall apply to the board for proper reporting forms and shall ascertain that the preceptor under whom he or she proposes to take his or her practical training is a qualified preceptor. The candidate shall receive credit for experience gained only in an approved site under the supervision of an approved preceptor. The candidate must keep records as prescribed by the board of all professional experience gained, and upon request, must report to the board and furnish information relative to the practical experience gained. The board may accept internship affidavits from other states, provided the internship requirements are no less than requirements of the National Association of Boards of Pharmacy. (Acts 1966, Ex. Sess., No. 205, p. 231, § 27; Acts 1975, 3rd Ex. Sess., No. 147, p. 393; Act 98-643, p. 1414, §1.)

ARTICLE 3.

PHARMACIES.

§ 34-23-70. Management; display of permit and license; poisons; prescription requirements; violations

(a) Every pharmacy when opened for business shall be under the personal supervision of a duly licensed pharmacist who shall have personal supervision of not more than one pharmacy at the same time. During temporary absences of the licensed pharmacist, not to exceed three hours daily or more than one and one-half hours at any one time, nor more than one week for temporary illness, the prescription department shall be closed, and no prescriptions are to be filled. During the temporary absence of a pharmacist, a sign shall be placed on the prescription counter in a prominent location easily seen by the public stating, "Prescription Department Closed, No Pharmacist on Duty."

(b) The permit issued to each pharmacist by the board and the licensure certificates issued to the licensed pharmacist employed by each pharmacy must be prominently and conspicuously displayed in the pharmacy. The name of the licensed pharmacist on duty must be conspicuously displayed in the prescription department in a place readily observable by the public.

(c) No licensed pharmacist or pharmacy operating within this state shall accept for refund purposes or otherwise any unused portion of any dispensed prescription.

(d)) The sale of poisons is restricted to the immediate supervision of a licensed pharmacist, and such poison shall not be displayed in a pharmacy in such a manner that a customer may obtain possession of such poisons when standing in an area allocated for customer use. No sale of a poison shall be made or delivered to any minor under 12 years of age or to any person known to be of unsound mind or under the influence of alcohol.

(e) No pharmacy shall authorize any person, firm or business establishment to serve as a pick-up station or intermediary for the purpose of having prescriptions filled or delivered, whether for profit or gratuitously. Except with respect to controlled substances, the following federally qualified health care centers are expressly exempt from the provisions of this subsection: Birmingham Health Care, Inc., Central Alabama

Comprehensive Health, Inc., Health Services, Inc., Family Oriented Primary Health Care Clinic/Mobile County Health Department, Franklin Primary Health Center, Quality of Life Health Services, Inc., and Whatley Health Services, Inc. Each named federally qualified health center is authorized to fill certain prescriptions at one location and deliver medications to clinics for patient pick-up subject to the review of the Pharmacy Board.

(f) No prescription blank supplied by a pharmacy or pharmacist to a practitioner shall bear the imprint thereon of the name or address of any pharmacy or bear the name or address of any person registered under this chapter.

(g) No person shall fill or compound a prescription or drug order in an institution unless he is a duly licensed pharmacist or otherwise permitted to do so under the provisions of this chapter. The act of filling or compounding prescriptions or drug orders in an institution shall be as defined in the rules and regulations adopted by the board of pharmacy. However, such rules and regulations shall not apply to the reading, interpreting and writing or verifying the writing of adequate directions as are necessary to assure patient's understanding of the prescriber's intentions by a duly qualified nurse practicing her/his profession in a licensed hospital or similar institution. Nothing in this act shall authorize the Board of Pharmacy to promulgate or to enforce any rule or regulation which governs, regulates, or restricts the professional practice of a physician licensed to practice medicine in this state. No provision of this act, or any rule promulgated under the authority of this act shall be interpreted to amend, alter or modify the provisions of Section 34-23-11 of this Code.

(h) Only a licensed pharmacist or registered intern may accept an oral prescription of any nature. Upon so accepting such oral prescription, it must immediately be reduced to writing, and only a licensed pharmacist or an intern supervised by a licensed pharmacist may prepare a copy of a prescription or read a prescription to any person for purposes of providing reference concerning treatment of the person or animal for whom the prescription was written; and, when said copy is given, a notation shall be made upon the prescription that a copy has been given, the date given and to whom given.

(i) If a prescription is refilled, a record of the date upon which the prescription is refilled must appear on the prescription or in a permanent prescription record book. On prescriptions which may be refilled, written or oral authorization must be received before refilling unless the number of refills is indicated on the original prescription. The prescriptions marked 'refill prn' or equivalent designation shall be refilled only in quantities commensurate with the dosage scheduled.

(j) Each prescription must be written in a manner so that it can be compounded by any registered pharmacist. The coding of any prescription is in violation of this chapter. -No prescription shall be written in any characters, figures or ciphers, other than in the English or Latin language, generally in use among medical and pharmaceutical practitioners.

(k) A prescription file or files shall be kept by every pharmacy for a period of not less than two years in which the original of every prescription compounded or dispensed shall be filed in the order of compounding with number and date of dispensing placed on each prescription. Each pharmacy shall produce any prescription file whenever legally required to do so. Such prescription file shall at all times be open for inspection by the prescriber, the board of pharmacy or its inspectors.

(l) All drugs or drug preparations bearing upon the package the words, 'caution, federal law prohibits dispensing without prescription' or words to the same effect, otherwise known as 'legend drugs', shall be stored within the confines of the prescription department or the prescription department storage room of each pharmacy. Such drugs shall be sold or dispensed only on the prescription of a licensed practitioner authorized to prescribe such drugs and shall not be sold or dispensed as a refilled prescription except upon the express authorization of the prescriber. This shall not be construed to prohibit return to authorized suppliers or sale or transfer to others licensed to possess legend drugs.

(m) Any person who violates any of the provisions of this section shall be guilty of a misdemeanor. (Acts 1966, Ex. Sess., No. 205, p. 231, § 15; Acts 1989, No. 89-747, p. 1513, §1; Act 2009-772, p. 2385, §1.)

§ 34-23-71. Requirements for prescription rooms.

Any new pharmacy or any existing pharmacy which is to be remodeled or which is to be moved to a new location other than a hospital pharmacy must comply with the following requirements for the prescription room area: That portion or part of the entire licensed pharmacy which is to be occupied by the prescription compounding or dispensing department, including that portion or part thereof utilized for the sale of restricted drugs, shall be not less than 240 square feet. The surface of the prescription compounding counter shall be not less than 24 inches in width and not less than 16 square feet of unobstructed working space for one pharmacist and not less than 24 square feet of total working space where two or more pharmacists are to be

on duty at any one time. The aisle space or floor area to be occupied by a dispensing pharmacist shall extend the full length of the prescription compounding counter, and it shall be clear and unobstructed for a minimum distance of 36 inches from the working side of the prescription compounding counter. (Acts 1966, Ex. Sess., No. 205, p. 231, § 16.)

§ 34-23-72. Internship training sites.

Every site approved by the State Board of Pharmacy for intern training shall be managed so that the intern is provided with ample opportunity to meet the training requirements established by the board. The site must have in its employ, or have an arrangement with, a pharmacist who is registered as a preceptor. A site which meets these qualifications may be approved for internship training by the board. (Acts 1966, Ex. Sess., No. 205, p. 231, § 25; Act 98-643, p. 1414, §1.)

§ 34-23-73. Preceptor qualifications.

Every pharmacist serving as a preceptor shall have expressed a willingness to serve as a preceptor. Pharmacist preceptors shall be approved by the board and shall be willing to cooperate with the board in developing the necessary training requirements and shall provide appropriate documentation to the board. Each preceptor shall certify as to the commencement and completion of the training period and may make recommendations to the board concerning the competency of his or her trainee. The preceptor shall report to the board from time to time as requested on the progress of any intern or extern under his or her supervision. It shall be his or her responsibility in a supervisory capacity to see that each intern or extern receives proper training under the objectives of the board for this practical training program. (Acts 1966, Ex. Sess., No. 205, p. 231, § 26; Act 98-643, p. 1414, §1.)

§ 34-23-74. Hospitals and related institutions.

Every pharmacy located in a hospital, skilled nursing home, or other related institution in this state shall be under the supervision of a licensed pharmacist. In general hospitals, skilled nursing homes, and extended care facilities not operating a pharmacy, the drug or medicine room shall be under the direct supervision and direction of a consulting pharmacist or a member of the medical staff who shall be a licensed practitioner of medicine. In nursing homes which are not classified by the State Board of Health as skilled nursing homes, maternity homes, homes for the aged, domiciliary institutions, and all related institutions except those operated by and in conjunction with a licensed hospital, medicines or drugs bearing the wording on the label "caution, federal law prohibits dispensing without prescription" or similar wording that causes the medicines or drugs to be known as prescription legend drugs shall be furnished by a licensed pharmacy on the prescription of a licensed practitioner of medicine for individual patients, and there shall be no prescription legend drugs on the premises of these institutions other than those so prescribed except an emergency kit as authorized by the State Board of Health. In hospitals and skilled nursing homes using vending machines or mechanical devices for the storage and dispensing of drugs, the machines or devices shall be stocked only under the supervision of a licensed pharmacist, and the drugs may be dispensed from the machine or device only by an individual acting in accordance with established institutional hospital pharmacy policy. The State Board of Pharmacy may at any time adopt such additional rules and regulations consistent with this chapter as may be deemed necessary after advising with the Alabama Society of Hospital Pharmacists in regard to the storage and handling of drugs and medicines and the disposition of unused portion of drugs and medicines in hospitals and other related institutions under this section. (Acts 1966, Ex. Sess., No. 205, p. 231, § 28; Acts 1995, No. 95-398, § 1.)

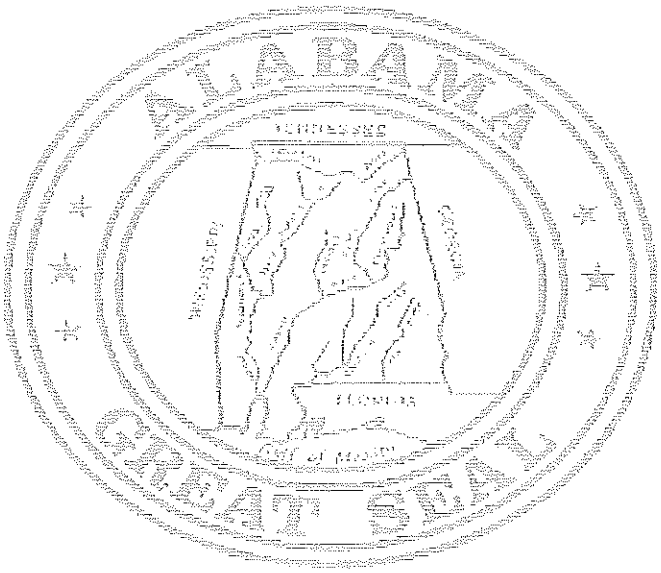
§ 34-23-75. Emergency prescription refill.

In the event a pharmacist receives a request for a prescription refill and the pharmacist is unable to readily obtain refill authorization from the prescriber, the pharmacist may dispense a one-time emergency refill of up to a 72-hour supply of the prescribed medication, providing that:

(1) The prescription is not a medicinal agent listed in Schedule II appearing in Title 20, chapter 2.

CODE OF ALABAMA 1975

CUMULATIVE SUPPLEMENT
INCLUDING ACT OF 2009 LEGISLATURE



TITLE 34 CHAPTER 23
PRACTICE OF PHARMACY ACT 205
LEGISLATURE 1966

ALABAMA STATE BOARD OF PHARMACY

January 26, 2012
Includes amendments effective 3-5-2012

(a) Each Institutional Pharmacy shall be directed by a pharmacist, hereinafter referred to as the Supervising Pharmacist, who is licensed to engage in the practice of pharmacy in this State.

(4) ABSENCE OF PHARMACIST:

(a) During such times as an Institutional Pharmacy may be unattended by a pharmacist, arrangements shall be made in advance by the Supervising Pharmacist for provision of Drugs to the medical staff and other authorized personnel of the Institutional Facility by use of a locked cabinet or other enclosure constructed and located outside of the pharmacy area and, in emergency circumstances, by access to the Pharmacy. A pharmacist shall be available after hours in accordance with established Institutional Policy.

(b) In the absence of a pharmacist, Drugs shall be stored in a cabinet/enclosure constructed and located outside of the Pharmacy area, to which only specifically authorized personnel may obtain access by key or combination, and which is sufficiently secure to deny access to unauthorized persons. The Supervising Pharmacist shall, in conjunction with the appropriate committee of the Institutional Facility, develop inventory listings of those Drugs to be included in such cabinet/enclosure and determine who may have access, and shall ensure that:

1. The Drugs are properly labeled;
2. Only prepackaged Drugs are available, in amounts sufficient for immediate therapeutic requirements;
3. Whenever access to the cabinet/enclosure occurs, written orders of an authorized practitioner and proofs of use are provided;
4. All drugs therein are inventoried regularly based on institutional policy, but no less than every thirty (30) days;
5. A complete audit of all activity concerning such cabinet/enclosure is conducted no less than once per month; and
6. Written policies and procedures are established to implement the requirements of this Section 4.

(c) Whenever any Drug is not available from floor supplies or cabinet/enclosure, and such Drug is required to treat the immediate needs of a patient whose health would otherwise be jeopardized, such Drug may be obtained from the Pharmacy in accordance with the requirements of this Section 4. One supervisory nurse or physician in any given shift is responsible for obtaining Drugs from the pharmacy. The responsible person shall be designated in writing by the appropriate committee of the Institutional Facility. Removal of any Drug from the Pharmacy by an authorized designee must be pursuant to written orders of an authorized practitioner and must be recorded on a suitable form showing patient name, room number, name of Drug, strength, amount, date, and time and signature of designee. The form shall be left with the container from which the drug was removed.

(d) For an Institutional Facility that does not have an Institutional Pharmacy, Drugs may be provided for use by authorized personnel by emergency kits located at such Facility, provided, however, such kits meet the following requirements:

1. The contents of the Emergency kit shall consist of those Drugs needed to effectively manage a critical care incident or need of a patient. A copy of the list of the contents of the emergency kit shall be maintained both at the institution and the pharmacy supplying the drugs.
2. All emergency kit drugs shall be provided and sealed by a pharmacist who is licensed to engage in the practice of pharmacy in this state;
3. The supplying pharmacist and the medical staff of the Institutional Facility shall jointly determine the Drugs, by identity and quantity, to be included in emergency kits;
4. Emergency kits shall be stored in secured areas to prevent unauthorized access, and to ensure a proper environment for preservation of the Drugs within them;
5. The exterior of each emergency kit shall be labeled so as to clearly indicate that it is an emergency drug kit and that it is for use in emergencies only. The label shall contain a listing of the Drugs contained in the kit, including name, strength, quantity, and expiration date of the contents, and the name, address(es), and telephone number(s) of the supplying pharmacist;
6. Drugs shall be removed from emergency kits only pursuant to a valid written order of an authorized practitioner;
7. Whenever an emergency kit is opened, the supplying pharmacist shall be notified and the pharmacist shall stock and reseal the kit within a reasonable time but not more than 72 hours, so as to prevent risk of harm to patients; and
8. The expiration date of an emergency kit shall be the earliest date of expiration of any Drugs

November 1, 2009; Amended January 19, 2012; Effective March 5, 2012.

680-X-2-.19. PARENTERAL THERAPY.

(1) Purpose: Whereas the Alabama State Board of Pharmacy is charged with the duty and responsibility to control the compounding and distribution of prescription drug products in the State of Alabama, and is further charged to protect the citizens from inferior drug products and inappropriate compounding procedures. This rule shall provide guidelines and regulations for the compounding and distributing of parenteral products in Alabama, and to assure the citizens of Alabama of sterile parenteral products that are dispensed or prepared by qualified pharmacists using acceptable pharmaceutical techniques and equipment.

(2) Registration and Certification, Pharmacies: All pharmacies engaged in the compounding of parenterals shall be registered with the Alabama State Board of Pharmacy annually and receive a permit in accordance with Code of Alabama 1975, §34-23-30. Such pharmacies shall be certified, further, by the Alabama State Board of Pharmacy as a parenteral pharmacy.

(3) Registration and Certification, Pharmacists: All pharmacists engaged in compounding and dispensing of Parenteral Solutions including cytoxic agents shall register annually with the Board of Pharmacy in accordance with the Code of Alabama 1975, §§34-23-51, 34-23-52. After January 1, 1994, pharmacists who have not successfully completed a certifying course for parenteral pharmacists which has been approved by the Board, will not be registered as parenteral pharmacists with the Board until they have completed said certifying course. Programs submitted for certification shall be a minimum of five (5) contact hours, including didactic and hands on experience. All programs certified by the Board shall require a written exam as a part of the training.

(a) It shall be the responsibility of the supervising pharmacist to verify the parenteral certification of pharmacists involved in the preparation of parenteral products.

(b) Effective January 1, 1994, the annual one (1) hour of mandatory parenteral continuing education will no longer be required.

(4) Compounding Area for Parenteral Solutions: The parenteral pharmacy shall have a designated area complying with the clean room concept and contain a certified laminar air flow hood with the intact HEPA filters and shall:

(a) Have cleanable surfaces, walls and floors.

(b) Be ventilated with a filtered air source to inhibit the induction of particulate matter from areas outside the clean room.

(c) The laminar air flow hood shall be certified annually, in accordance with Federal Standard 209(b), Clean Room and Work Station Requirements, Controlled Environment, as approved by the Commission, Federal Supply Services, United States General Services Administration, as amended, (available from the U.S. General Services Administration, Specifications Activity, Printed Materials Supply Division, Building 197, Naval Weapons Plant, Washington, D.C. 20407). Certification records must be retained for at least 2 years.

(d) The pharmacy shall be arranged in such a manner that the laminar flow hood is located in an area which is exposed to minimal traffic flow, and is separate from any area used for bulk storage of items not related to the compounding of parenteral solutions. There shall be no obstruction of the intake of the laminar flow hood.

1. There shall be sufficient space, well separated from the laminar flow hood area, for the storage of bulk materials, equipment and waste materials.

(e) A sink with hot and cold running water must be within or adjacent to the parenteral solution compounding area.

(f) There shall be a refrigerator and/or freezer of sufficient capacity to meet the storage requirement for all material requiring refrigeration.

Statutes and Regulations
Pharmacy

December 2011

(Centralized Statutes and Regulations not included)

DEPARTMENT OF COMMERCE, COMMUNITY,
AND ECONOMIC DEVELOPMENT

DIVISION OF CORPORATIONS, BUSINESS AND PROFESSIONAL LICENSING

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Sec. 08.80.145. RECIPROCITY; LICENSE TRANSFER. If another jurisdiction allows licensure in that jurisdiction of a pharmacist licensed in this state under conditions similar to those in this section, the board may license as a pharmacist in this state a person licensed as a pharmacist in the other jurisdiction if the person

(1) submits a written application to the board on a form required by the board;

(2) is at least 18 years of age;

(3) is of good moral character;

(4) possesses at the time of the request for licensure as a pharmacist in this state the qualifications necessary to be eligible for licensure in this state;

(5) has engaged in the practice of pharmacy for at least one year or has met the internship requirements of this state within the one-year period immediately before applying for a license under this section;

(6) presents proof satisfactory to the board that the person is currently licensed as a pharmacist in the other jurisdiction and does not currently have a pharmacist license suspended, revoked, or otherwise restricted except for failure to apply for renewal or failure to obtain the required continuing education credits;

(7) has passed an examination approved by the board that tests the person's knowledge of Alaska laws relating to pharmacies and pharmacists and the regulations adopted under those laws; and

(8) pays all required fees.

Sec. 08.80.147. RENEWAL OF LICENSURE. If a pharmacist fails to apply for renewal of a license within five years from the expiration of the license, the person must pass an examination for license renewal, except that a person who has continually practiced pharmacy in another state under a license issued by the authority of that state may renew an expired license in this state upon fulfillment of the requirements that may be established by the board.

Sec. 08.80.150. TEMPORARY LICENSE. The board shall adopt regulations regarding the issuance of a temporary license to practice pharmacy.

Sec. 08.80.155. EMERGENCY PERMIT. The board shall adopt regulations regarding the issuance of an emergency permit to practice pharmacy.

Sec. 08.80.157. LICENSING OF FACILITIES. (a) A facility engaged in the practice of pharmacy or in the manufacture, production, or wholesale distribution of drugs or devices, and a pharmacy where drugs or devices are dispensed, shall be licensed by the board, and shall renew the license at intervals determined by the board. If operations are conducted at more than one location, each location shall be licensed by the board.

(b) The board may by regulation determine the licensure classifications of facilities and establish minimum standards for the facilities.

(c) The board shall establish by regulation the criteria that a facility must meet to qualify for licensure in each classification. The board may issue licenses with varying restrictions to facilities when the board considers it necessary to protect the public interest.

(d) The board may deny or refuse to renew a license if it determines that the granting or renewing of the license would not be in the public interest.

(e) Licenses issued by the board are not transferable or assignable.

(f) The board shall specify by regulation the minimum standards for responsibility of a facility or pharmacy that has employees or personnel engaged in the practice of pharmacy or engaged in the manufacture, wholesale distribution, production, or use of drugs or devices in the conduct of its business.

(g) A licensed facility shall report to the board

(1) permanent closing;

(2) change of ownership, management, location, or pharmacist-in-charge of a pharmacy;

(3) theft or loss of drugs or devices as defined by regulations of the board;

(4) conviction of an employee of violation of a state or federal drug law;

(5) disasters, accidents, theft, destruction, or loss relating to records required to be maintained by state or federal law;

(6) occurrences of significant adverse drug reactions as defined by regulations of the board;

(7) other matters and occurrences the board may require by regulation.

(h) The board may suspend, revoke, deny, or refuse to renew the license of a facility or pharmacy on the following grounds:

(1) the finding by the board of violations of a federal, state, or local law relating to the practice of pharmacy, drug samples, wholesale or retail drug or device distribution, or distribution of controlled substances;

(2) a felony conviction under federal, state, or local law of an owner of the facility or pharmacy or of an employee of the facility or pharmacy;

(3) the furnishing of false or fraudulent material in an application made in connection with drug or device manufacturing or distribution;

(4) suspension or revocation by federal, state, or local government of a license currently or previously held by the applicant for the manufacture or distribution of drugs or devices, including controlled substances;

(5) obtaining remuneration by fraud, misrepresentation, or deception;

(6) dealing with drugs or devices that are known or should have been known to be stolen drugs or devices;

(7) dispensing or distributing drugs or devices directly to patients by a wholesale drug distributor other than a pharmacy;

(8) violation of this chapter or a regulation adopted under this chapter.

(i) The board's regulations under (b) - (d) and (f) of this section may not establish more stringent licensing requirements for the facilities governed by AS 08.80.390 than are set out in AS 08.80.390.

(j) This section does not apply to the offices of physicians, osteopaths, podiatrists, physician assistants, advanced nurse practitioners, dentists, veterinarians, dispensing opticians, or optometrists.

Sec. 08.80.158. REGISTRATION OF PHARMACIES LOCATED OUTSIDE OF STATE. (a) A pharmacy located outside of the state that regularly ships, mails, or delivers prescription drugs to consumers in the state shall register with the board.

(b) A pharmacy registering with the board under (a) of this section shall furnish to the board annually

(1) the location, names, and titles of all principal corporate officers and of all pharmacists who are dispensing prescription drugs to residents of the state;

(2) a copy of a current valid license, permit, or registration to conduct operations in the jurisdiction in which it is located, and a copy of the most recent report resulting from an inspection of the pharmacy by the regulatory or licensing agency of the jurisdiction in which the pharmacy is located;

(3) a sworn statement indicating that the pharmacy complies with all lawful directions and requests for information from the regulatory or licensing authority of the jurisdiction in which the pharmacy is licensed; and

(4) proof satisfactory to the board that the pharmacy maintains its records of prescription drugs dispensed to persons in the state so that the records are readily retrievable from the records of other prescription drugs dispensed by the pharmacy.

(c) A pharmacy subject to this section shall, during its regular hours of operations, provide a toll-free telephone service to facilitate communication between persons in the state and a pharmacist at the pharmacy who has access to records concerning the dispensing of prescription drugs to persons in the state. The toll-free number and the hours that the service is available shall be disclosed on a label affixed to each container of drugs dispensed to persons in the state. The telephone service shall be available at least 40 hours a week and at least six days a week.

(d) The board may, after a hearing, deny, revoke, or suspend the registration of a pharmacy located outside of the state and subject to this section if the pharmacy fails to comply with the requirements of this section, AS 17.20.080 - AS 17.20.135, or AS 17.30.020 - 17.30.080, or if the license, permit, or registration of the pharmacy is denied, revoked, or suspended by the licensing or regulatory agency of the jurisdiction in which the pharmacy is located.

(e) A pharmacy located outside of the state that is subject to this section but is not registered with the board under this section may not ship, mail, or deliver prescription drugs into the state and may not advertise its services in the state.

(f) A pharmacy subject to this section shall appoint a registered agent in the state who is empowered to accept, on behalf of the pharmacy, process, notice, and demand required or permitted by law to be served upon the pharmacy. If the pharmacy fails to appoint an agent under this subsection, if the registered agent cannot with reasonable diligence be found at the registered office, or if the registration of the pharmacy is suspended or revoked, the commissioner of commerce and economic development is an agent upon whom process, notice, or demand may be served. Service is made upon the commissioner in the same manner as provided for corporations under AS 10.06.175(b), except that for the purposes of AS 10.06.175(b)(2)(A), the address shall be the last registered address of the pharmacy as shown by the records of the board.

(g) The board shall by regulation define "regularly" for this section.

Sec. 08.80.160. FEES. The Department of Commerce, Community, and Economic Development shall set fees under AS 08.01.065 for the following:

(1) examination;
(2) reexamination;
(3) investigation for licensing by license transfer;
(4) pharmacist license;
(5) temporary license;
(6) pharmacy technician license;
(7) pharmacy intern license;
(8) emergency permit;
(9) license amendment or replacement;
(10) registration or licensure of a facility classified under AS 08.80.157(b).

Sec. 08.80.165. CONTINUING EDUCATION REQUIREMENTS. The board shall establish requirements for continuing education in pharmacy that must be satisfied before a license issued under this chapter may be renewed.

Sec. 08.80.261. DISCIPLINARY SANCTIONS. (a) The board may deny a license to an applicant or, after a hearing, impose a disciplinary sanction authorized under AS 08.01.075 on a person licensed under this chapter when the board finds that the applicant or licensee, as applicable,

(1) secured or attempted to secure a license through deceit, fraud, or intentional misrepresentation;

Sec. 08.80.315. CONFIDENTIALITY OF RECORDS. Information maintained by a pharmacist in the patient's records or that is communicated to the patient as part of patient counseling is confidential and may be released only to

(1) the patient or as the patient directs;

(2) a practitioner or pharmacist when, in the pharmacist's professional judgment, release is necessary to protect the patient's health and well-being; and

(3) other persons or governmental agencies authorized by law to receive confidential information.

Sec. 08.80.330. LICENSED PHARMACIST APPOINTED AS "PHARMACIST-IN-CHARGE". (a) Each pharmacy shall have a pharmacist-in-charge. Whenever an applicable law or regulation requires or prohibits action by a pharmacy, responsibility shall be that of the owner and the pharmacist-in-charge, whether the owner is a sole proprietor, partnership, association, corporation, or otherwise. The pharmacist-in-charge shall ensure compliance with all laws and regulations governing the operation of the pharmacy. A licensed pharmacist appointed as pharmacist-in-charge of a pharmacy shall immediately advise the board of that appointment.

(b) A license may not be issued to a pharmacy unless there is a licensed registered pharmacist-in-charge whose name appears on the face of the license.

ARTICLE 4. UNLAWFUL ACTS.

Section

390. Pharmacists required in hospitals and clinics
400. Other licensees not affected
410. Use of term "pharmacist" prohibited
420. Certain advertising prohibited
430. Use of pharmacy symbols prohibited
450. Disciplinary action
460. Penalties

Sec. 08.80.390. PHARMACISTS REQUIRED IN HOSPITALS AND CLINICS. (a) A hospital, clinic, nursing home, infirmary, or related facility that dispenses drugs for outpatient treatment shall have a licensed pharmacist in charge of the dispensary, except that prescriptions may be compounded and dispensed by or under the supervision of the prescribing physician.

(b) The board shall issue a license to a hospital drug room, nursing home drug room, or related facility that dispenses drugs from bulk supply for inpatient treatment, providing the facility employs a licensed pharmacist on a continual or consultant basis.

Sec. 08.80.400. OTHER LICENSEES NOT AFFECTED. This chapter does not affect the practice of medicine by a licensed medical doctor, and does not limit a licensed medical doctor, osteopath, podiatrist, physician assistant, advanced nurse practitioner, dentist, veterinarian, dispensing optician, or optometrist in supplying a patient with any medicinal preparation or article within the scope of the person's license.

Sec. 08.80.410. USE OF TERM "PHARMACIST" PROHIBITED. A person may not assume or use the title "pharmacist," or any variation of the title, or hold out to be a pharmacist, without being licensed.

Sec. 08.80.420. CERTAIN ADVERTISING PROHIBITED. (a) A person may not use or exhibit the title "pharmacist," "assistant pharmacist," or "druggist," or the descriptive term "pharmacy," "drug store," "drug sundries," or other similar title or term containing the word "drug," in any business premises, or in an advertisement through the media of press, or publication, or by radio or television, unless the business has a licensed pharmacist in regular and continuous employment.

(b) *Repealed 1980.*

Sec. 08.80.430. USE OF PHARMACY SYMBOLS PROHIBITED. A person may not display in a place of business the characteristic pharmacy symbol of "Rx" in any form unless the business has a pharmacist licensed under this chapter.

Sec. 08.80.450. DISCIPLINARY ACTION. The board may consider a complaint based upon the alleged violation of any provision of this chapter, and may by a majority vote of a quorum dismiss the complaint, reprimand a licensee, or take other punitive action as the nature of the facts warrant. Orders issued by the board shall be in writing, signed by a majority and filed with the secretary of the board. The accused shall receive an authenticated copy of the order.

Sec. 08.80.460. PENALTIES. (a) A person who violates a provision of this chapter is guilty of a class B misdemeanor.

(b) A person who violates the provisions of AS 08.80.295 is punishable by a civil fine in an amount established

by the board in a schedule or schedules establishing the amount of civil fine for a particular violation. The schedule or schedules shall be adopted by the board by regulation. Any civil fine imposed under this section may be appealed in the manner provided for appeals in the Administrative Procedure Act (AS 44.62).

ARTICLE 5. GENERAL PROVISIONS.

Section

470. Construction
475. Federal facilities not affected
480. Definitions
490. Short title

Sec. 08.80.470. CONSTRUCTION. Nothing in this chapter amends, modifies, repeals or otherwise changes any provision of AS 11.71, AS 17.30, or AS 17.20 (the Alaska Food, Drug and Cosmetic Act).

Sec. 08.80.475. FEDERAL FACILITIES NOT AFFECTED. This chapter does not apply to the safe storage, preservation, dispensing, or control of drugs in a federally operated hospital or institution.

Sec. 08.80.480. DEFINITIONS. In this chapter, unless the context otherwise requires

(1) "administer" means the direct application of a drug to the body of a patient or research subject by injection, inhalation, ingestion, or other means;

(2) "board" means the Board of Pharmacy;

(3) "compounding" means the preparation, mixing, assembling, packaging, or labeling of a drug or device (A) as the result of a practitioner's prescription drug order or initiative based on the relationship of the practitioner, patient, and pharmacist in the course of professional practice or (B) for the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale or dispensing; "compounding" also includes the preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns;

(4) "controlled substance" has the meaning given in AS 11.71.900;

(5) "deliver" or "delivery" means the actual, constructive, or attempted transfer of a drug or device from one person to another, whether or not for consideration;

(6) "device" means an instrument, apparatus, implement, machine, contrivance, implant, or other similar or related article, including a component part or accessory, that is required under federal law to bear the label "Caution: Federal or state law requires dispensing by or on the order of a physician";

(7) "dispense" or "dispensing" means the preparation and delivery of a drug or device to a patient or patient's agent under a lawful order of a practitioner in a suitable container appropriately labeled for subsequent administration to, or use by, a patient;

(8) "distribute" means the delivery of a drug or device other than by administering or dispensing;

(9) "drug" means an article recognized as a drug in an official compendium, or supplement to an official compendium; an article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animal; an article other than food, intended to affect the structure or function of the body of man or animal; and an article intended for use as a component of an article specified in this paragraph but does not include devices or their components, parts, or accessories;

(10) "drug regimen review" includes evaluation of the prescription drug order and patient record for

(A) known allergies;
(B) rational therapy-contraindications;
(C) reasonable dose and route of administration;
(D) reasonable directions for use;
(E) duplication of therapy;
(F) drug-drug, drug-food, and drug-disease interactions;
(G) adverse drug reactions; and
(H) proper utilization, including over- or under-utilization, and optimum therapeutic outcomes;

(11) "equivalent drug product" means a drug product that has the same established name, active ingredients, strength or concentration, dosage form, and route of administration and that is formulated to contain the same amount of active ingredients in the same dosage form and to meet the same compendia or other applicable standards for strength, quality, purity, and identity, but that may differ in characteristics such as shape, scoring configuration, packaging, excipients including colors, flavors, preservatives, and expiration time;

(12) "intern" means an individual who is

(A) currently licensed by this state to engage in the practice of pharmacy while under the personal supervision of a pharmacist and is satisfactorily progressing toward meeting the requirements for licensure as a pharmacist; or

(B) a graduate from a college of pharmacy who is currently licensed by the board for the purpose of obtaining practical experience as a requirement for licensure as a pharmacist;

Statutes and Regulations
Pharmacy

September 2011

(Centralized Statutes and Regulations not included)

DEPARTMENT OF COMMERCE, COMMUNITY,
AND ECONOMIC DEVELOPMENT

DIVISION OF CORPORATIONS, BUSINESS AND PROFESSIONAL LICENSING

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12 AAC 52.670. DRUG RECALLS. A wholesale drug distributor shall prepare and follow a written policy for handling the recall of a drug due to

(1) a voluntary action on the part of the manufacturer;

(2) an order of the Food and Drug Administration, or of any other federal, state, or local government agency; or

(3) the replacement of an existing drug with an improved drug or new package design.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030

12 AAC 52.680. INSPECTIONS. A wholesale drug distributor shall permit an authorized inspector or law enforcement official, who shows proper identification, to enter and inspect that distributor's facilities and delivery vehicles at reasonable times and in a reasonable manner, and to inspect that distributor's records and written operating procedures.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030

12 AAC 52.685. PROHIBITIONS AGAINST DIRECT DISTRIBUTION. A wholesale drug distributor may not distribute a drug or preparation directly to a consumer or patient.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.261
AS 08.80.030

12 AAC 52.690. SALVAGE AND REPROCESSING. A wholesale drug distributor is subject to the provisions of all applicable federal and state statutes and regulations and local ordinances that relate to drug salvaging or reprocessing, including 21 C.F.R. Parts 207, 210, and 211, as amended as of February 6, 1997.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030

12 AAC 52.695. PROVISIONS NOT APPLICATIONS. The following activities do not constitute wholesale distribution of prescription drugs for which a wholesale drug distributor license is required by 12 AAC 52.610 – 12 AAC 52.690:

(1) intracompany sales, defined as any transaction or transfer between any division, subsidiary, parent, and an affiliated or related company under the common ownership and control of a corporate entity;

(2) the purchase or acquisition, by a hospital or other health care entity that is a member of a group purchasing organization, of a drug, for its own use, from the group purchasing organization or from another hospital or health care entity that is a member of the group purchasing organization;

(3) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization described in 26 U.S.C. 501(c)(3) (Internal Revenue Code of 1954), as amended as of February 6, 1997, to a nonprofit affiliate of the organization to the extent otherwise permitted by the law;

(4) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals or other health care entities that are under common control; for purposes of this paragraph, "common control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, by voting rights, by contract, or otherwise;

(5) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons; for purposes of this paragraph, "emergency medical reasons" includes a transfer of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage, if the gross dollar value of the transfer does not exceed five percent of the total prescription drug sales revenue of either the transferor or transferee pharmacy during any 12-consecutive-month period;

(6) the sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug, under a prescription;

(7) the distribution of drug samples by manufacturers' representatives or distributors' representatives; or

(8) the sale, purchase, or trade of blood and blood components intended for transfusion.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.157

ARTICLE 7.
INSTITUTIONAL PHARMACIES.

Section

700. (Repealed)
710. Absence of a pharmacist from an institutional pharmacy

720. **Emergency room outpatient medications**
730. **Drug distribution and control**

12 AAC 52.700. INSTITUTIONAL PHARMACIES. *Repealed 2/26/2000.*

12 AAC 52.710. ABSENCE OF A PHARMACIST FROM AN INSTITUTIONAL PHARMACY. (a) When an institutional pharmacy will be unattended by a pharmacist, the pharmacist-in-charge shall arrange in advance for providing drugs for use within the institutional facility.

(b) When an institutional pharmacy is closed and a drug is required to treat a patient's immediate need and is not available from the drug stock outside of the pharmacy, a person designated by the pharmacist-in-charge and licensed to handle drugs may obtain the drug from the institutional pharmacy. The pharmacist-in-charge is responsible

(1) to record on a suitable form the removal of any drug from the institutional pharmacy by the person designated; the record must show the

(A) patient's name and room number;
(B) name, strength, and amount of the drug;
(C) date and time of removal; and
(D) initials or signature of the person designated who removed the drug from the pharmacy;

(2) when the pharmacy reopens or as soon as is practical to check the stock container or similar unit dose package of the drug removed ; and

(3) to ensure that the quantity of drugs that were removed is only the quantity necessary to sustain the patient until the pharmacy reopens.

(c) If an institutional pharmacy is open and the pharmacist is absent from the pharmacy, but present in the institutional facility, a pharmacy technician may continue to prepare and process drug prescriptions. However, drugs may not be dispensed until the pharmacist has verified the finished prescription product.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.390
AS 08.80.030

12 AAC 52.720. EMERGENCY ROOM OUTPATIENT MEDICATIONS. (a) The pharmacist-in-charge of an institutional pharmacy, in cooperation with the appropriate committee of the institutional facility's medical staff, shall prepare a list of prescription drugs that may be delivered to outpatients receiving emergency treatment and shall determine appropriate quantities for unit-of-use packaging and prepackaging of the prescription drug.

(b) A licensed health care provider on emergency room staff may deliver the medications identified on the list of prescription drugs prepared under (a) of this section to a patient receiving emergency outpatient treatment if

(1) the drug is ordered by an authorized prescribing practitioner either in writing or verbally; a verbal order must be transcribed into writing on the patient's record;

(2) the medication is prepackaged in a child-resistant container under the direct supervision of a pharmacist;

(3) the medication bears a label that contains the

(A) name, address, and telephone number of the institutional facility;
(B) name, strength, and quantity of the drug;
(C) cautionary information required for patient safety and information;
(D) lot number and expiration date if not already contained on the unit-of-use packaging or prepackaging; and
(E) initials of the pharmacist;

(4) no more than one prepackaged container of a drug is delivered to a patient unless more than one package is required to sustain the patient until a retail pharmacist is on duty in the community; however, the amount of the controlled substance delivered may not exceed a 72 hour supply; and

(5) labeling of the container is completed by the licensed health care provider before the container is presented to the patient; the container label must include the

(A) name of the patient;
(B) directions for use by the patient;
(C) date of delivery;
(D) identifying number unique to the patient;
(E) name of the prescribing practitioner; and
(F) initials of the licensed health care provider delivering the prepackaged medication.

(c) Prepackaged medications shall be kept in a secure place within the emergency room.

(d) Following delivery of the prepackaged medication to the patient, the licensed health care provider shall document the quantity issued and initial the patient record containing the prescribing practitioner's order.

(e) This section does not apply to the administration of a single dose to a patient.

(f) In this section, "licensed health care provider" means a physician, physician assistant, or mobile intensive care paramedic licensed under AS 08.64; a dentist licensed under AS 08.36; or a nurse licensed under AS 08.68.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.390
AS 08.80.030

12 AAC 52.730. DRUG DISTRIBUTION AND CONTROL. (a) The pharmacist-in-charge of an institutional pharmacy is responsible for the storage, preparation, distribution, and control of the institutional facility's drug supply and for ensuring that these activities are carried out in conformance with established policies, procedures, and accepted standards.

(b) The pharmacist-in-charge of an institutional pharmacy shall establish written procedures for the distribution and control of drugs and for the provision of pharmacy service. The procedures must be consistent with 12 AAC 52.710 and 12 AAC 52.720. The pharmacist-in-charge shall make an annual updated copy of the policies and procedures available for inspection by the board.

(c) Persons employed at an institutional pharmacy who are licensed under AS 08.80 and this chapter shall provide drug information to the staff and practitioners of the institutional facility.

(d) Persons employed at an institutional pharmacy who are licensed under AS 08.80 and this chapter may assist in the planning of and participate in the institutional facility's education and staff development programs relating to drugs.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.390
AS 08.80.030

ARTICLE 8.
DRUG ROOMS AND FACILITIES WITHOUT A PHARMACY.

Section

800. Drug room license
810. Pharmacist required
820. Responsibilities of the consultant pharmacist
830. Emergency drug kits
840. First dose kits
850. Emergency distribution

12 AAC 52.800. DRUG ROOM LICENSE. (a) An institutional facility that does not maintain a pharmacy but prepares and administers prescription drugs from bulk supplies for patients receiving treatment within the facility must be licensed by the board as a drug room under 12 AAC 52.010 and 12 AAC 52.020.

(b) An institutional facility that does not maintain a pharmacy but stores and administers prescription drugs that are labeled and dispensed for specific patients by a pharmacy does not require a drug room or pharmacy license.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030 AS 08.80.390

12 AAC 52.810. PHARMACIST REQUIRED. An institutional facility described in 12 AAC 52.800(a) must continuously employ a pharmacist or have a written agreement with a pharmacy or pharmacist to provide consultant pharmacist services.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.390
AS 08.80.030

12 AAC 52.820. RESPONSIBILITIES OF THE CONSULTANT PHARMACIST. A pharmacist who, under 12 AAC 52.810, provides consultant pharmacy services shall

(1) provide evaluations and recommendations concerning drug distribution, control, and use;

(2) complete on-site reviews to ensure that drug handling and use procedures conform to AS 08.80, this chapter, and recognized standards of practice;

(3) provide drug information to facility staff and physicians;

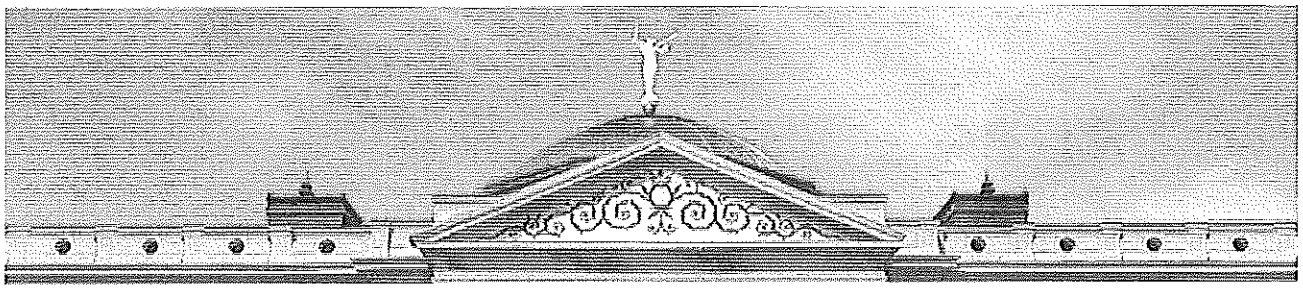
(4) plan and participate in the facility's staff development program relating to drug distribution, control, and use;

(5) assist in establishing policies and procedures to control the distribution and administration of drugs; and

(6) document pharmacy services that are provided and maintain the documentation for a period of at least two years.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030 AS 08.80.390

12 AAC 52.830. EMERGENCY DRUG KITS. (a) An institutional facility described in 12 AAC 52.800(b) may have a limited supply of drugs provided by a pharmacist licensed under this chapter and AS 08.80 in emergency drug kits on-site. An emergency drug kit is for use by personnel authorized to administer the drugs to patients receiving treatment within the institutional facility.



32-1934. Pharmacy operated by hospital

A. A pharmacy operating in connection with a hospital shall comply with all the provisions of this chapter requiring registration and regulation of pharmacies and with board rules.

B. A pharmacy operating in connection with a hospital shall also meet the following requirements:

1. In hospitals with fifty beds or more, the pharmacy shall be under the continuous supervision of a pharmacist during the time it is open for pharmacy services, except that the board by rule may establish requirements to allow a pharmacist who is engaged in hospital business to be in other areas of the hospital that are located outside the pharmacy.

2. In hospitals with less than fifty beds, with the written approval and recommendations of the board, the services of a pharmacist shall be required on a part-time basis according to the needs of the hospital, provided that this approval does not permit the compounding, manufacturing, dispensing, labeling, packaging or processing of drugs by other than a pharmacist.

3. In the pharmacist's absence from the hospital, the supervisory registered nurse may obtain from the pharmacy necessary doses of drugs that are ordered by a medical practitioner and that are needed by a patient in an emergency, according to procedures recommended and approved by the board for each hospital.

4. All drugs and medications furnished from the pharmacy to patients on discharge from the hospital shall be dispensed by a pharmacist and the medication shall be properly labeled.

5. The pharmacist in charge shall initiate procedures to provide for the administrative and technical guidance in all matters pertaining to the acquiring, stocking, record keeping and dispensing of drugs and devices.

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privacy statement

LAWS AND REGULATIONS

August 2011

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(B) The date of dispensing;

(C) The serial number of the prescription;

(D) The name of the patient;

(E) The name of the prescribing practitioner;

(F) The trade name of the medication, if any, or the generic name and identity of the manufacturer of the dispensed medication, if the medication appears generically listed on the drug formulary list as established by this subchapter;

(G) The strength per unit dose of the medication;

(H) The quantity of the medication; and

(I) Directions for use.

(2) If a pharmacist dispenses a generically equivalent product, the person for whom the medication is prescribed shall be informed prior to dispensing or the label should appropriately indicate the substitution.

(3) However, this subsection shall not apply to the dispensing of medication to inpatients in hospitals.

(4) Further, in an appropriate manner, the prescribing practitioner may indicate that the name, manufacturer, and strength of the medication dispensed shall be deleted from the label.

(b) Any authorized person filling a prescription for dispensing to an ultimate patient shall affix to the container a label showing the trade name of the medication or the generic name of the medication unless directed to the contrary by the physician. Failure to comply with this subsection shall be grounds for disciplinary action.

17-92-506. Available drug product lists

A pharmacist may display, within the confines of the pharmacy, lists of available drug products, other than controlled substances, and current charges for the drug products or for the dispensing of the drug products in specified quantities. Upon request, a pharmacy may make such lists available to its customers and other members of the public.

17-92-601. Citation

This subchapter may be cited as the "Hospital Pharmacies Act".

17-92-602. Definitions

As used in this subchapter:

(1) "Board" means the Arkansas State Board of Pharmacy;

(2) "Hospital" means a hospital as defined in § 20-9-201;

(3) "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;

(4) "Hospital pharmacy" means the place or places in which drugs, chemicals, medicines, prescriptions, or poisons are prepared for distribution and administration for the use or benefit of patients in a hospital. The "hospital pharmacy" may also provide pharmacy services to patients in a "swing bed" within the hospital that may periodically swing back and forth from being a short-term acute hospital bed to a longer-term nursing home bed. The "hospital pharmacy" shall also mean the place or places in which drugs, chemicals, medicines, prescriptions, or poisons are compounded for the dispensing to hospital employees, members of the immediate families of hospital employees, patients being discharged, and for other persons in emergency situations;

(5) "Hospital pharmacy technicians" means persons other than licensed pharmacists who perform duties in conjunction with the overall hospital medication distribution system for inpatients; and

(6) "Licensed pharmacist" means any person licensed to practice pharmacy by the board.

17-92-603. Advisory Committee for Hospital Pharmacies

(a) There is created an Advisory Committee for Hospital Pharmacies to assist the Arkansas State Board of Pharmacy in the promulgation of rules, regulations, and standards for hospital pharmacies.

(b) The committee shall consist of five (5) members, each of whom shall be a licensed pharmacist.

(c)

(1) The Arkansas Association of Hospital Pharmacists shall appoint the five (5) members of the committee.

(2) Each member shall serve for a term of three (3) years.

17-92-604. Rules, regulations and standards

(a) The Arkansas State Board of Pharmacy shall adopt, promulgate, and enforce such rules, regulations, and standards as may be necessary to the regulation of the operation of a hospital pharmacy and for the accomplishment of all other purposes of this subchapter.

(b)

(1) The Advisory Committee for Hospital Pharmacies shall advise with the board concerning the rules, regulations, and standards to be promulgated by the board under this subchapter. No rule, regulation, or standard shall be promulgated by the board until it has consulted with the committee.

(2) The rules, regulations, and standards shall include, but shall not be limited to, the following specific matters:

(A) The number of licensed pharmacists and other hospital pharmacy technicians and the scope of duties to be performed by the hospital pharmacy technicians in the inpatient medication distribution system, in keeping with the size and scope of the services of the hospital and its hospital pharmacy and the hospital pharmacy's safe, efficient, and economical operation; and

(B) The equipment and supplies necessary to the hospital pharmacy's safe, efficient, and economical operation.

(c) After consultation with the committee, from time to time, the board may modify, amend, or rescind the rules, regulations, and standards, provided the modification, amendment, or rescission does not in any manner defeat the purposes of this subchapter.

17-92-605. Hospital pharmacy license

(a) All hospital pharmacies shall be licensed by the Arkansas State Board of Pharmacy as provided for by this subchapter. The hospital pharmacy license shall be issued in the name of the hospital.

(b) Any hospital receiving a permit shall advise the board of the name of:

(2) The hospital administrator or other person assuming responsibility for the general administration of the hospital;

(3) The director of the pharmacy, or other person assuming responsibility for the general operation of the hospital pharmacy, who shall be a licensed pharmacist; and

(4) All other licensed pharmacists employed by the hospital in its hospital pharmacy.

(c) The hospital and the director of pharmacy shall be required to report to the board any change in licensed pharmacist personnel.

(d) Upon the receipt of a hospital pharmacy license, a hospital pharmacy may provide the following pharmaceutical services:

(1) Prepare for distribution and administration of drugs, chemicals, medicines, prescriptions, or poisons for the use or benefit of the patients in the hospital as set forth in § 17-92-602(4); and

(2) Compound or dispense drugs, chemicals, medicines, prescriptions, or poisons for the use or benefit of the hospital's employees, members of the immediate families of hospital employees, patients being discharged, and other persons in emergency situations.

17-92-606. Hospital pharmaceutical permit

Any hospital pharmacy holding a hospital pharmaceutical permit issued by the Arkansas State Board of Pharmacy pursuant to § 17-92-403 on March 28, 1975, shall be deemed to be licensed pursuant to this subchapter until the permit shall expire.

17-92-607. Unlawful activity; construction of provision

(a) It shall be unlawful for any nonprofit, tax exempt, or governmentally funded hospital to acquire direct or indirect interest in or otherwise hold directly or indirectly a licensed pharmacy permit pursuant to the provisions of § 17-92-405, for the sale at retail of drugs and medicines.

(b) However, nothing contained in this section shall be construed to prohibit any hospital having a direct or

indirect interest in or otherwise holding either directly or indirectly a permit prior to March 28, 1975, from continuing to have an interest in or holding the permit. Nothing contained in this section shall be construed to prohibit any hospital so holding a permit prior to March 28, 1975, from receiving a renewal of the permit.

17-92-701. Definitions

(a) As used in this subchapter:

(1) "Board" means the Arkansas State Board of Pharmacy;

(2) "Board-approved intervenors" means persons trained in intervention and designated by the board to implement the intervention process when necessary;

(3) "Committee" means a committee appointed by the board to formulate and administer the impaired pharmacists program;

(4) "Impaired pharmacist" means a pharmacist who is unable to practice pharmacy with reasonable skill, competency, or safety to the public because of substance abuse;

(5) "Impaired pharmacist program" means a plan approved by the board for intervention, treatment, and rehabilitation of an impaired pharmacist;

(6) "Intervention" means a process whereby an allegedly impaired pharmacist is confronted by the board or board-approved intervenors who provide documentation that a problem exists and attempt to convince the pharmacist to seek evaluation and treatment;

(7) "Rehabilitation" means the process whereby an impaired pharmacist advances in an impaired pharmacist program to an optimal level of competence to practice pharmacy without endangering the public; and

(8) "Verification" means a process whereby alleged professional impairment is identified or established.

17-92-702. Community organization and administration

(a) The Arkansas State Board of Pharmacy may appoint a committee to organize and administer a program that shall fulfill two (2) functions:

(1) The program shall serve as a diversion program to which the board may refer licensees when appropriate in lieu of or in addition to other disciplinary action; and

(2) The program shall also be a source of treatment or referral for pharmacists who, on a strictly voluntary basis, desire to avail themselves of its services.

(b) The board may appoint a committee of five (5) persons who are recovering pharmacists to serve three-year terms with the initial members appointed to staggered terms.

17-92-703. Duties of committee

(a) The functions of the committee shall include:

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The Pharmacy Law
(Business and Professions Code 4000 et seq.)
Excerpts from the Business and Professions Code
Board of Pharmacy Regulations
(California Code of Regulations, Title 16, Section 1700 et seq.)
Excerpts from the California Uniform Controlled Substances Act
(Health and Safety Code 11000 et seq.)
Excerpts from the Confidentiality of Medical Information Act
(Civil Code 56 et seq.)
Excerpts from the Public Resources Code

care service plan licensed pursuant to Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code.

(c) As used in Section 4052.2, "health care facility" means a facility, other than a facility licensed under Division 2 (commencing with Section 1200) of the Health and Safety Code, that is owned or operated by a health care service plan licensed pursuant to Chapter 2.2 (commencing with Section 1340) of the Health and Safety Code, or by an organization under common ownership or control of the health care service plan; "licensed home health agency" means a private or public organization licensed by the State Department of Public Health pursuant to Chapter 8 (commencing with Section 1725) of Division 2 of the Health and Safety Code, as further defined in Section 1727 of the Health and Safety Code; and "licensed clinic" means a clinic licensed pursuant to Article 1 (commencing with Section 1200) of Chapter 1 of Division 2 of the Health and Safety Code.

(d) "Licensed health care facility" or "facility," as used in Section 4065, means a health facility licensed pursuant to Article 1 (commencing with Section 1250) of Chapter 2 of Division 2 of the Health and Safety Code or a facility that is owned or operated by a health care service plan licensed pursuant to Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code or by an organization under common ownership or control with the health care service plan.

4028. Licensed Hospital

"Licensed hospital" means an institution, place, building, or agency that maintains and operates organized facilities for one or more persons for the diagnosis, care, and treatment of human illnesses to which persons may be admitted for overnight stay, and includes any institution classified under regulations issued by the State Department of Public Health as a general or specialized hospital, as a maternity hospital, or as a tuberculosis hospital, but does not include a sanitarium, rest home, a nursing or convalescent home, a maternity home, or an institution for treating alcoholics.

4029. Hospital Pharmacy

(a) "Hospital pharmacy" means and includes a pharmacy, licensed by the board, located within any licensed hospital, institution, or establishment that maintains and operates organized facilities for the diagnosis, care, and treatment of human illnesses to which persons may be admitted for overnight stay and that meets all of the requirements of this chapter and the rules and regulations of the board.

(b) A hospital pharmacy also includes a pharmacy that may be located outside of the hospital, in another physical plant that is regulated under a hospital's consolidated license issued pursuant to Section 1250.8 of the Health and Safety Code. As a condition of licensure by the board, the pharmacy in another physical plant shall provide pharmaceutical services only to registered hospital patients who are on the premises of the same physical plant in which the pharmacy is located. The pharmacy services provided shall be directly related to the services or treatment plan administered in the physical plant. Nothing in this paragraph shall be construed to restrict or expand the services that a hospital pharmacy may provide.

4030. Intern Pharmacist

"Intern pharmacist" means a person issued a license pursuant to Section 4208.

4031. Laboratory

"Laboratory" means a research, teaching, or testing laboratory not engaged in the dispensing or furnishing of drugs or devices but using dangerous drugs or dangerous devices for scientific or teaching purposes. Every laboratory shall maintain an established place of business and keep purchase records. Every laboratory shall be subject to the jurisdiction of the board.

(b) Notwithstanding any other law, a pharmacist may authorize the initiation of a prescription, pursuant to Section 4052.1, 4052.2, or 4052.3, and otherwise provide clinical advice or information or patient consultation if all of the following conditions are met:

(1) The clinical advice or information or patient consultation is provided to a health care professional or to a patient.

(2) The pharmacist has access to prescription, patient profile, or other relevant medical information for purposes of patient and clinical consultation and advice.

(3) Access to the information described in paragraph (2) is secure from unauthorized access and use.

4052. Furnishing to Prescriber; Permitted Procedures by Pharmacist

(a) Notwithstanding any other provision of law, a pharmacist may:

(1) Furnish a reasonable quantity of compounded drug product to a prescriber for office use by the prescriber.

(2) Transmit a valid prescription to another pharmacist.

(3) Administer, orally or topically, drugs and biologicals pursuant to a prescriber's order.

(4) Perform procedures or functions in a licensed health care facility as authorized by Section 4052.1.

(5) Perform procedures or functions as part of the care provided by a health care facility, a licensed home health agency, a licensed clinic in which there is a physician oversight, a provider who contracts with a licensed health care service plan with regard to the care or services provided to the enrollees of that health care service plan, or a physician, as authorized by Section 4052.2.

(6) Manufacture, measure, fit to the patient, or sell and repair dangerous devices or furnish instructions to the patient or the patient's representative concerning the use of those devices.

(7) Provide consultation to patients and professional information, including clinical or pharmacological information, advice, or consultation to other health care professionals.

(8) Furnish emergency contraception drug therapy as authorized by Section 4052.3.

(9) Administer immunizations pursuant to a protocol with a prescriber.

(b) A pharmacist who is authorized to issue an order to initiate or adjust a controlled substance therapy pursuant to this section shall personally register with the federal Drug Enforcement Administration.

(c) Nothing in this section shall affect the requirements of existing law relating to maintaining the confidentiality of medical records.

(d) Nothing in this section shall affect the requirements of existing law relating to the licensing of a health care facility.

4052.1. Permitted Pharmacist Procedures in Licensed Health Care Facility

(a) Notwithstanding any other provision of law, a pharmacist may perform the following procedures or functions in a licensed health care facility in accordance with policies, procedures, or protocols developed by health professionals, including physicians, pharmacists, and registered nurses, with the concurrence of the facility administrator:

(1) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.

(2) Ordering drug therapy-related laboratory tests.

(3) Administering drugs and biologicals by injection pursuant to a prescriber's order.

(4) Initiating or adjusting the drug regimen of a patient pursuant to an order or authorization made by the patient's prescriber and in accordance with the policies, procedures, or protocols of the licensed health care facility.

(b) Prior to performing any procedure authorized by this section, a pharmacist shall have received appropriate training as prescribed in the policies and procedures of the licensed health care facility.

4052.2. Permitted Pharmacist Procedures in Health Care Facility; Home Health Agency or Clinic with Physician Oversight

(a) Notwithstanding any other provision of law, a pharmacist may perform the following procedures or functions as part of the care provided by a health care facility, a licensed home health agency, a licensed clinic in which there is a physician oversight, a provider who contracts with a licensed health care service plan with regard to the care or services provided to the enrollees of that health care service plan, or a physician, in accordance with the policies, procedures, or protocols of that facility, home health agency, licensed clinic, health care service plan, or physician, and in accordance with subdivision (c):

(1) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.

(2) Ordering drug therapy-related laboratory tests.

(3) Administering drugs and biologicals by injection pursuant to a prescriber's order.

(4) Initiating or adjusting the drug regimen of a patient pursuant to a specific written order or authorization made by the individual patient's treating prescriber, and in accordance with the policies, procedures, or protocols of the health care facility, home health agency, licensed clinic, health care service plan, or physician. Adjusting the drug regimen does not include substituting or selecting a different drug, except as authorized by the protocol. The pharmacist shall provide written notification to the patient's treating prescriber, or enter the appropriate information in an electronic patient record system shared by the prescriber, of any drug regimen initiated pursuant to this paragraph within 24 hours.

(b) A patient's treating prescriber may prohibit, by written instruction, any adjustment or change in the patient's drug regimen by the pharmacist.

(c) The policies, procedures, or protocols referred to in this subdivision shall be developed by health care professionals, including physicians, pharmacists, and registered nurses, and shall, at a minimum, do all of the following:

(1) Require that the pharmacist function as part of a multidisciplinary group that includes physicians and direct care registered nurses. The multidisciplinary group shall determine the appropriate participation of the pharmacist and the direct care registered nurse.

(2) Require that the medical records of the patient be available to both the patient's treating prescriber and the pharmacist.

(3) Require that the procedures to be performed by the pharmacist relate to a condition for which the patient has first been seen by a physician.

(4) Except for procedures or functions provided by a health care facility, a licensed clinic in which there is physician oversight, or a provider who contracts with a licensed health care plan with regard to the care or services provided to the enrollees of that health care service plan, require the procedures to be performed in accordance with a written, patient-specific protocol approved by the treating or supervising physician. Any change, adjustment, or modification of an approved preexisting treatment or drug therapy shall be provided in writing to the treating or supervising physician within 24 hours.

(d) Prior to performing any procedure authorized by this section, a pharmacist shall have done either of the following:

(1) Successfully completed clinical residency training.

(2) Demonstrated clinical experience in direct patient care delivery.

4052.3. Emergency Contraception Drug Therapy; Requirements and Limitations

(a) Notwithstanding any other provision of law, a pharmacist may furnish emergency contraception drug therapy in accordance with either of the following:

(1) Standardized procedures or protocols developed by the pharmacist and an authorized prescriber who is acting within his or her scope of practice.

COLORADO REVISED STATUTES

Title 12
Professions and Occupations

Article 22
Pharmaceuticals and Pharmacists

Effective July 1, 2011

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PART 1
GENERAL PROVISIONS

12-22-101. Public interest.

The practice of pharmacy is declared a professional practice affecting the public health, safety, and welfare and is subject to regulation and control in the public interest. It is a matter of public interest and concern that the practice of pharmacy, as defined in this part 1, merits and receives the confidence of the public and that only qualified persons be permitted to practice pharmacy in this state. This part 1 shall be liberally construed to carry out these objects and purposes. Pursuant to these standards and obligations, the state board of pharmacy may adopt, by rule and regulation, rules of professional conduct.

12-22-102. Definitions.

As used in this part 1, unless the context otherwise requires:

(1) "Administer" means the direct application of a drug to the body of a patient or research subject by injection, inhalation, ingestion, or any other method.

(2) "Advertise" means to publish or display information about prescription prices or drugs in any medium.

(2.5) "Anabolic steroid" has the same meaning as that set forth in section 18-18-102 (3), C.R.S.

(3) Repealed.

(4) "Board" means the state board of pharmacy.

(5) "Casual sale" means a transfer, delivery, or distribution to a corporation, individual, or other entity, other than a consumer, entitled to possess prescription drugs; except that the amount of drugs transferred, delivered, or distributed in such manner by any registered prescription drug outlet or hospital other outlet shall not exceed ten percent of the total number of dosage units of drugs dispensed and distributed on an annual basis by such outlet.

(6) (a) "Compounding" means the preparation, mixing, assembling, packaging, or labeling of a drug or device:

(I) As the result of a practitioner's prescription drug order, chart order, or initiative, based on the relationship between the practitioner, patient, and pharmacist in the course of professional practice; or

(II) For the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale or dispensing.

(b) "Compounding" also includes the preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly-observed prescribing patterns.

prescription.", "Rx only", or "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian."

(30.2) "Prescription drug outlet" means any pharmacy outlet registered pursuant to this article where prescriptions are compounded and dispensed. "Prescription drug outlet" includes, without limitation, a compounding prescription drug outlet registered pursuant to section 12-22-120 (9).

(30.3) "Refill" means the compounding and dispensing of any drug pursuant to a previously executed order.

(31) Repealed.

(32) "Sample" means any prescription drug given free of charge to any practitioner for any reason except for a bona fide research program.

(32.5) "Satellite" means an area outside the prescription drug outlet where pharmaceutical care and services are provided and that is in the same location.

(32.6) "Supervision" means that a licensed pharmacist is on the location and readily available to consult with and assist unlicensed personnel performing tasks described in paragraph (b) of subsection (26) of this section.

(33) "Therapeutically equivalent" or "equivalent" means those compounds containing the identical active chemical ingredients of identical strength, quantity, and dosage form and of the same generic drug type, which, when administered in the same amounts, will provide the same therapeutic effect as evidenced by the control of a symptom or disease.

(33.5) Repealed.

(34) "Wholesaler" means a corporation, individual, or other entity with facilities in this state that buys drugs or devices for resale or distributes drugs or devices to corporations, individuals, or entities entitled to possess such drugs or devices, other than consumers.

12-22-103. State board of pharmacy - creation - subject to termination - repeal of article.

(1) The responsibility for enforcement of the provisions of this part 1 is vested in the state board of pharmacy, which is hereby created. The board shall have all of the duties, powers, and authority specifically granted by and necessary to the enforcement of this part 1, as well as such other duties, powers, and authority as may be granted by statute from time to time. Except as otherwise provided to the contrary, the board shall exercise all its duties, powers, and authority in accordance with the "State Administrative Procedure Act", article 4 of title 24, C.R.S.

(2) The board shall exercise its powers and perform its duties and functions specified by this part 1 under the department of regulatory agencies and the executive director thereof as if the same were transferred to the department by a **type 1** transfer, as such transfer is defined in the "Administrative Organization Act of 1968", article 1 of title 24, C.R.S.

(3) (a) The provisions of section 24-34-104, C.R.S., concerning the termination schedule for regulatory bodies of the state, unless extended as provided in that section, are applicable to the state board of pharmacy created by this section.

(b) An outlet as recognized in section 12-22-120 (1) (e) need not be under the direct charge of a pharmacist, but a licensed pharmacist shall either initially interpret all prescription orders compounded or dispensed from such outlet or provide written protocols for such compounding and dispensing by unlicensed persons. An outlet qualifying for registration under this paragraph (b) may also apply to the board for a waiver of such requirements concerning physical space, equipment, inventory, or business hours as may be necessary and consistent with the outlet's limited public welfare purpose. In determining the grant or denial of such waiver application, the board shall ensure that the public interest criteria set forth in section 12-22-101 are satisfied. All other provisions of this part 1, except as specifically waived by the board, shall apply to such outlet.

(4) The registration of every outlet and the license of every pharmacist and pharmacy intern regularly practicing shall be conspicuously displayed within the premises of the place of practice or outlet.

(5) (a) Repealed.

(b) (I) The pharmacist responsible for the prescription order or chart order may delegate certain specific tasks, as provided in section 12-22-102 (26) (b), to a person who is not a pharmacist or pharmacy intern but who is an unlicensed assistant under such pharmacist's supervision if, in the pharmacist's professional judgment, such delegation is appropriate; except that no such delegation may be made if the delegation jeopardizes the public health, safety, or welfare, is prohibited by rule or regulation of the board, or violates the provisions of section 12-22-126 (1).

(II) This paragraph (b) is effective February 1, 1999.

12-22-120. Registration of facilities.

(1) All outlets with facilities in this state shall register with the board in one of the following classifications:

(a) Prescription drug outlet;

(b) Wholesale drug outlet;

(c) Manufacturing drug outlet;

(d) Repealed.

(e) Any other outlet, as may be authorized by this article or that meets the definition of outlet as set forth in section 12-22-102 (23).

(2) The board shall establish by rule or regulation criteria, consistent with section 12-22-116 and with the public interest as set forth in section 12-22-101, which an outlet that has employees or personnel engaged in the practice of pharmacy must meet to qualify for registration in each classification.

(3) The board shall specify by rule or regulation the registration procedures to be followed, including, but not limited to, the specification of forms for use in applying for registration and the information needed.

(4) Registrations issued by the board pursuant to this section are transferable or assignable only pursuant to this article and rules established by the board.

(5) It shall be lawful for a person to sell and distribute nonprescription drugs. Any person engaged in the sale and distribution of such drugs shall not be deemed to be improperly engaged in the practice of pharmacy, nor shall the board promulgate any rule or regulation pursuant to this part 1 which permits the sale of nonprescription drugs only by a licensed pharmacist or only under the supervision of a licensed pharmacist or which would otherwise apply to or interfere with the sale and distribution of nonprescription drugs.

(6) The board shall accept the licensure or certification of nursing care facilities and intermediate care facilities required by the department of public health and environment as sufficient registration under this section.

(7) A separate registration shall be required under this section for any area outside the outlet that is not a satellite where pharmaceutical care and services are provided and for any such area that is under different ownership from the outlet.

(8) No hospital outlet filling inpatient chart orders shall sell or otherwise transfer any portion of its prescription drug inventory to another registered outlet for sale or dispensing at retail. This subsection (8) shall not be construed to limit any transfer of prescription drugs for the hospital's own use or to limit the ability of a hospital outlet to engage in a casual sale as defined in section 12-22-102 (5).

(9) (a) Subject to paragraph (b) of this subsection (9), a prescription drug outlet may register as a compounding prescription drug outlet.

(b) No facility shall be registered as a compounding prescription drug outlet unless:

(I) The facility has been accredited by a board-approved compounding accreditation entity to be within acceptable parameters to compound more than ten percent of the facility's total sales; and

(II) Ownership of the facility is vested solely in a pharmacist.

(c) To be approved by the board to accredit a compounding prescription drug outlet, a compounding accreditation entity shall be, at a minimum, a scientific organization with expertise in compounding medications.

12-22-121. Compounding - dispensing - sale of drugs and devices - rules.

(1) Except as otherwise provided in this section and part 3 of this article, no drug, controlled substance, as defined in section 12-22-303 (7), or device shall be sold, compounded, dispensed, given, received, or held in possession unless it is sold, compounded, dispensed, given, or received in accordance with this section.

(2) Except as provided in subsection (7) of this section, a manufacturer of drugs may sell or give any drug to:

(a) Any wholesaler of drugs;

Sec. 20-576. (Formerly Sec. 20-164). Regulations. (a) The commissioner may, with the advice and assistance of the commission, adopt regulations, in accordance with chapter 54, to govern the performance of the commission's duties, the practice of pharmacy and the business of retailing drugs and devices. Such regulations may include, but are not limited to, provisions (1) concerning the licensing of any pharmacist or pharmacy, disciplinary action that may be taken against a licensee, the conduct of a pharmacist and the operation of a pharmacy, (2) specifying various classes of pharmacy licenses issued under section 20-594, including, but not limited to, licenses for infusion therapy pharmacies and nuclear pharmacies and specifying requirements for operation of pharmacies under the classes of pharmacy licenses permitted under the regulations, (3) concerning creation and maintenance of prescription records, and (4) concerning registration and activities of pharmacy interns, registered pharmacy technicians and certified pharmacy technicians.

(b) The commissioner shall, with the advice and assistance of the commission, adopt regulations, in accordance with chapter 54, governing (1) the storage and retrieval of prescription information for noncontrolled substances, including refills, by pharmacists through the use of electronic data processing systems or other systems for the efficient storage and retrieval of information, (2) the operation of institutional pharmacies pursuant to chapters 368a and 418, and sections 17a-210 to 17a-273, inclusive, 19a-490 to 19a-520, inclusive, and 20-570 to 20-630, inclusive, and (3) the activities of pharmacy technicians in pharmacies and institutional pharmacies, including ratios of registered pharmacy technicians and certified pharmacy technicians to pharmacists in pharmacies and institutional pharmacies.

(1949 Rev., S. 4464; 1955, S. 2236d; September, 1957, P.A. 11, S. 13; P.A. 75-254, S. 1, 2; P.A. 77-614, S. 197, 610; P.A. 95-264, S. 7; P.A. 98-31, S. 3; P.A. 99-175, S. 11; P.A. 04-208, S. 1.)

History: P.A. 75-254 deleted authority for commission to publish and distribute regulations and to employ attorney to conduct prosecutions for violations of chapter, allowed commission to compel production of documents by subpoena, required annual report to commissioner of consumer protection rather than to governor and required certification of records "by executive secretary to the commission", replacing less specific requirement for certification "by its secretary"; P.A. 77-614 transferred power to adopt regulations from commission to commissioner of consumer protection, retaining commission in advisory role and deleted provision re election of chairman, effective January 1, 1979; P.A. 95-264 added Subsec. (a)(1) to (4), inclusive, and Subsec. (b) re matters subject to regulation; Sec. 20-164 transferred to Sec. 20-576 in 1997; P.A. 98-31 amended Subsec. (a)(4) by adding reference to pharmacy technicians; P.A. 99-175 made technical changes and amended Subsec. (b) to require regulations to be adopted in accordance with chapter 54 and to replace reference to Sec. 20-625 with reference to Sec. 20-630; P.A. 04-208 added references to registered pharmacy technicians and certified pharmacy technicians, effective June 3, 2004.

Sec. 20-610. (Formerly Sec. 20-166). Dispensing or retail sale of legend drugs, legend devices and certain other drugs by other than pharmacies and hospitals, prohibited. (a) No legend drug, legend device or drugs listed in subsection (b) of this section may be dispensed or

sold at retail except (1) in a pharmacy, (2) by a hospital licensed under sections 19a-490 to 19a-503, inclusive, to an employee of the hospital when prescribed by a prescribing practitioner for the employee or the employee's spouse or dependent children, or (3) by such hospital to a retiree of such hospital or the retiree's spouse in accordance with the retiree's retirement or pension plan.

(b) The following drugs may not be sold at retail except as permitted in subsection (a) of this section: (1) Injectable or ingestible antibiotics; (2) injectable biologicals; (3) sulfonamides and their compounds which are designed to be taken into the stomach for systemic action; (4) injectable or ingestible corticosteroids; or (5) camphorated tincture of opium.

(c) Any person who violates any provision of this section shall be fined not less than one hundred dollars nor more than five hundred dollars.

(1949 Rev., S. 4465; 1951, 1955, S. 2237d; 1959, P.A. 616, S. 53; 1963, P.A. 367; February, 1965, P.A. 319; 1967, P.A. 109, S. 3; 555, S. 77; 1971, P.A. 134; June, 1971, P.A. 8, S. 60; 1972, P.A. 223, S. 7; P.A. 73-670, S. 1, 2; P.A. 74-100, S. 1, 2; P.A. 76-286; P.A. 77-614, S. 199, 610; P.A. 79-16; P.A. 81-107; P.A. 85-241, S. 2; P.A. 86-403, S. 41, 132; P.A. 89-251, S. 95, 203; P.A. 94-36, S. 33, 42; P.A. 95-264, S. 32; P.A. 01-65, S. 1, 2.)

History: 1959 act increased permit fee for towns with population of less than 5,000 from $3 and doubled fee for towns with population of more than 5,000; 1963 act added corticosteroids and mild silver protein to, and deleted argyrol from, provision listing items prohibited from sale; 1965 act added penalty proviso for failure to renew in timely fashion and prohibited issuance of renewal permit until fee and penalty paid; 1967 acts added references to dentist's prescriptions and deleted descriptive references to opium, morphine and codeine content of preparations and compounds and substituted "any controlled drug as defined in section 19-443, except as permitted in sections 20-180 and part II of chapter 359" and added similar reference to "controlled drug" in list of items prohibited for sale by stores or shops not licensed as pharmacies; 1971 acts required permittee for sale of drugs, etc. to be at least 21, allowed imposition of penalty for failure to record change in permittee with commission of pharmacy and doubled permit fees; 1972 act established separate renewal fee of $10; P.A. 73-670 added exception to prohibition of retail sales except by pharmacist for methadone sold by hospitals; P.A. 74-100 expanded exception to include sales by hospitals to employees for themselves or their dependents; P.A. 76-286 deleted age, citizenship and moral character requirements for permit holders, deleted provision re sales by store not licensed as a pharmacy under special permit, replaced differential fees based on population with single fee of $35, raised renewal fee from ten to $25, made penalties $10 rather than 50% of permit fee, deleted provision allowing appeal by person who has been refused a permit and prohibited sales of "legend drugs" as defined in Sec. 20-184a; P.A. 77-614 replaced commission's regulations with regulations "established under this chapter", effective January 1, 1979; P.A. 79-16 deleted exception re sales of methadone by hospitals; P.A. 81-107 qualified as "injectable" or "ingestible" the antibiotics and corticosteroids which may not be stored, kept, sold or offered for sale by stores or shops other than licensed pharmacies; P.A. 85-241 clarified that the sale of veterinary medicines, poisons or chemicals by permittees is not prohibited and substituted references to licensed practitioners for references to physicians and dentists; P.A. 86-403 made technical change; P.A. 89-251 increased the original fee from $35 to $70 and increased the renewal fee from $25 to $50;

P.A. 94-36 deleted the provision allowing the collection of late license renewal fees, effective January 1, 1995; P.A. 95-264 divided sections into Subsecs., substituted reference to legend drugs for reference to substances used to compound medicine, deleted provisions re sale of patent medicines and specified certain types of drugs to be sold only as permitted in Subsec. (a) in new provision designated as Subsec. (b); Sec. 20-166 transferred to Sec. 20-610 in 1997; P.A. 01-65 amended Subsec. (a) by designating existing exceptions as Subdivs. (1) and (2) and adding new Subdiv. (3) re retirees of hospital, effective June 6, 2001.

See Sec. 21a-4(c) re fines for late license renewals.

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TITLE 24

Professions and Occupations

CHAPTER 25. PHARMACY

Subchapter IV. Pharmacies

§ 2526. Permit required for each pharmacy.

(a) A person may not operate a pharmacy within the State without first having obtained a permit to operate a pharmacy from the Board. A person who desires to operate more than 1 pharmacy must make a separate permit application for each pharmacy. However, separate permits are not required for sites designated as pharmacies within the same institution at 1 general location, provided that each site is approved by the Board.

(b) The Board shall issue a separate permit for each qualifying pharmacy. A permit to operate a pharmacy granted by the Board may not be assigned or otherwise transferred to another person except upon such conditions as the Board specifically designates, and then only pursuant to the written consent of the Board or its designee. A permit must be available on site for inspection by authorized persons.

Code 1935, § 956A; 41 Del. Laws, c. 87, § 2; 24 Del. C. 1953, § 2551; 62 Del. Laws, c. 251, § 13; 68 Del. Laws, c. 206, § 1; 76 Del. Laws, c. 167, § 1.;

§ 2527. Application fees for permits.

The application for a permit to operate a pharmacy must be made on a form furnished by the Board and must be accompanied by the application fee and/or permit fee established pursuant to § 2511 of this title.

Code 1935, § 956A; 41 Del. Laws, c. 87, § 2; 24 Del. C. 1953, § 2552; 53 Del. Laws, c. 90, § 18; 62 Del. Laws, c. 251, § 14; 68 Del. Laws, c. 206, § 1; 76 Del. Laws, c. 167, § 1.;

§ 2528. Requirements for and issuance of permit.

(a) In determining if a permit to operate a pharmacy should be issued, the Board shall consider, but is not limited to considering, the probability that:

(1) The pharmacy will be operated in full compliance with the law and with the rules and regulations of the Board;

(2) The pharmacy will be managed by a pharmacist-in-charge who is licensed to practice pharmacy in the State and who will serve as a pharmacist-in-charge in only that pharmacy;

DEPARTMENT OF STATE
DIVISION OF PROFESSIONAL REGULATION

2500 Board of Pharmacy

1.0 Pharmacist Licensure Requirements

1.1 Definitions

Words and terms defined in **Delaware Code** Title 1, Section 302 and Title 24, Section 2502 of the **Delaware Code** are applicable to these regulations. The following additional words and terms, when used within these regulations, shall have the following meaning unless the context clearly indicates otherwise or an alternate definition has been given:

"**Automated Data Processing System (ADPS)**" means a system utilizing computer software and hardware for the purposes of recordkeeping.

"**Cell**" means any container that holds the medication for automatic dispensing.

"**Central Prescription Processing**" means the processing by a pharmacy of a request from another pharmacy to fill or refill a prescription drug order or to perform processing functions such as dispensing, DUR, claims adjudication, refill authorizations, and therapeutic interventions.

"**Common Database**" means a file or database created by an ADPS that enables authorized users to have common access to this file regardless of physical location.

"**Compounding**" means the art of the extemporaneous preparation and manipulation of drugs as a result of a practitioner's prescription order or initiative based on the practitioner-patient-pharmacist relationship in the course of professional practice, including the preparation of drugs in anticipation of drug orders based on routine, regularly observed prescribing patterns. Reconstitution of oral solutions is not considered compounding.

"**Computer**" means a programmable electronic device, capable of multifunctions including but not limited to storage, retrieval and processing of information.

"**Controlled Substance**" means those drug items regulated by Federal (CSA of 1970) and/or State Controlled (dangerous) Substances Act.

"**CRT**" means a Cathode Ray Tube used to impose visual information on a screen.

"**Delivery**" means the transfer of a dispensed prescription to the ultimate user (patient) or his/her agent.

"**Dispensing**" means to furnish or deliver a drug to an ultimate user by or pursuant to the lawful order of a practitioner; including the preparation, packaging, labeling or compounding necessary to prepare the drug for that delivery.

"**Downtime**" means that period of time when a computer is not operable.

"**Facsimile (FAX) Prescription**" means a facsimile prescription is an order which is transmitted by an electronic device over telephone lines which sends an exact copy image to the receiver (pharmacy).

"**New Medication**" means a medication not previously dispensed by the pharmacy for the ultimate user.

"**Patient Counseling**" means the offer to discuss the patient's prescription made by the pharmacist or the pharmacist's designee in a face-to-face communication with the patient or his agent, unless in the professional judgment of the pharmacist it is deemed impracticable and in such instances, it would be permissible for the offer to counsel to be made through alternative means.

"**Pertinent Patient Medication Information**" means information which increases the patient's ability to minimize the risks and enhance the benefits of drug use. The type of information the pharmacist should consider is contained in the latest edition of USP DI "Advice for the Patient."

"**Prescriber**" means a practitioner authorized to prescribe and acting within the scope of this authorization.

"**Prescription**" or "**Prescription drug order**" means the lawful written or verbal order of a practitioner for a drug, but does not include an order for medication which is dispensed for immediate administration to the ultimate user, (e.g., an order to dispense a drug to a bed patient for immediate administration in a hospital is not a prescription.)

"**Printout**" means a hard copy produced by computer that is readable without the aid of any special device.

"**Reduced to Writing**" means the preparation of a paper document containing all the information required for a written prescription including the State requirement for drug product selection;

the disposition of outdated drugs. This documentation shall be maintained for three (3) years after disposition of the outdated drugs.

8.6.4 A procedure for reporting criminal or suspected criminal activities involving the inventory of a drug or drugs to the Board, FDA, and, if applicable, DEA and the Office of Narcotics and Dangerous Drugs (ONDD) within three (3) business days.

8.7 Salvaging and Reprocessing. Wholesale distributors shall be subject to the provisions of any applicable Federal, State, or local laws or rules that relate to drug product salvaging or reprocessing.

8.8 Security and Anti-Counterfeiting. All facilities.

8.8.1 Shall be secure from unauthorized entry:

8.8.1.1 Access from outside the premises shall be kept to a minimum and be well-controlled,

8.8.1.2 The outside perimeter of the premises shall be well-lighted, and

8.8.1.3 Entry into areas where drugs are held shall be limited to authorized personnel.

8.8.2 Shall be equipped with a security system that will provide suitable protection against theft and diversion. Appropriateness of security systems is subject to approval by the Board or its authorized agent. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

8.8.3 Shall be equipped with inventory management and control systems that protect against, detect, and document any instances of theft, diversion, or counterfeiting;

8.8.4 Shall be equipped with security systems to protect the integrity and confidentiality of data and documents and make such data and documents readily available to the Board and other federal, state, or local law enforcement officials; and

8.8.5 May possess and maintain, in good working order, technology and equipment that allows the wholesale distributor to authenticate, track, and trace drugs. The technology and equipment shall satisfy standards set by the Board and shall only be used to conduct tracking, tracing, and authentication of drugs. Wholesale distributors shall employ, train, and document the training of personnel in the proper use of such technology and equipment.

10 DE Reg. 1628 (4/1/07)

9.0 Hospital Pharmacy

9.1 Definition:

A hospital pharmacy is defined as a pharmacy registered with the Board located in a hospital facility. "Hospital pharmacy" shall not include a pharmacy operated by a hospital facility at a location other than the site of a permanent facility at which in-patient care and medical services are rendered.

9.2 Personnel

9.2.1 Director of Pharmacy. The storage, compounding, repackaging, dispensing and distribution of drugs by a hospital pharmacy shall be under the direction, supervision and responsibility of the pharmacist-in-charge, hereinafter referred to as the Director of Pharmacy, who shall be responsible for operating the pharmacy in compliance with appropriate State and Federal Statutes and Regulations. Written policies and procedures will be established defining the operation and scope of services provided by the hospital pharmacy. The Manual shall include policy and procedures concerning:

9.2.1.1 Preparation and sterilization of parenteral medications if done within the hospital pharmacy.

9.2.1.2 Establishment of specifications for procurement of drugs, chemicals and biologicals. The procedures are subject to the approval of the appropriate committee of the hospital.

9.2.1.3 Maintaining readily available inventory of emergency drugs both in the pharmacy and patient care areas. Current antidote information and telephone numbers of regional poison control centers must also be available.

9.2.1.4 Participation in the development of a Formulary or drug list for the hospital.

9.2.1.5 The filling and labeling of all containers from which drugs are to be administered in compliance with applicable Statutes and Regulations.

9.2.1.6 The records of the transactions of the pharmacy that are required by applicable law and that are necessary for accurate control and accountability. This should include procedures for wastage of controlled substances in all areas of the hospital.

9.2.1.7 Polices and procedures shall specify the duties to be performed by pharmacy personnel.

9.2.1.8 Discontinued drug procedures to insure that discontinued drugs and containers with worn, illegible or missing labels are returned to the pharmacy for proper disposition or disposal. All outdated products should be removed from all areas and stored in a separate section in the pharmacy for proper disposition or disposal.

9.2.1.9 A recall procedure that can be implemented to insure proper disposition of the recalled materials.

9.2.1.10 A policy for drugs brought in by patients.

9.2.1.11 A policy for the proper handling of investigational drugs must be in compliance with FDA and State requirements.

9.2.1.12 A policy and procedure outlining therapeutic drug selection.

9.2.1.13 The pharmacist shall be involved with the utilization review process as it pertains to drug therapy.

9.2.2 Registered Pharmacists. The Director of Pharmacy may be assisted by additional registered pharmacists who are also responsible for compliance with the applicable laws.

9.2.3 Pharmacy Technicians. Pharmacy technicians may be utilized in assisting the pharmacist. Pharmacy technicians must be supervised by a registered pharmacist who is present within the hospital and is responsible for the activities of the pharmacy technicians.

9.2.4 Pharmacy technicians must meet the requirements of Regulation 19.

9.3 Absence of Pharmacist. When a pharmacist is not on duty, drugs may be provided for use by physicians and other authorized staff via night cabinets or other areas designated by the hospital, and in emergency circumstances by access to the pharmacy. A pharmacist shall be available to provide professional services.

9.4 Night Cabinets or Other Designated Areas

9.4.1 These drug storage areas must be securely locked and substantially constructed in a manner which prevents easy entry.

9.4.2 Access must be limited to authorized personnel.

9.4.3 Contents and use procedures should be determined by the pharmacy and those departments with access to the night cabinet or other designated areas in accordance with the hospital's policies and procedures.

9.4.4 Drugs must be properly labeled and prepackaged in sufficient quantities as defined by the hospital.

9.4.5 Accountability records documenting withdrawal and replacement of drugs must be readily available.

9.4.6 The transaction shall be reviewed by the pharmacy when it reopens and incorporated into the hospital pharmacy's medication recordkeeping system.

9.5 Access to Pharmacy. When a pharmacist is not available and medications cannot be obtained immediately from any other source, authorized persons may enter the pharmacy and obtain drugs per procedures established by the hospital. The procedures must include the following stipulations:

9.5.1 Entry shall be by two persons; registered nurse or physician with another nurse, physician, or security person present approved by the hospital.

9.5.2 Persons authorized to enter the pharmacy shall indicate the name and strength and amount of drug removed, the date, time and their signature, and the name and location of the patient. The transaction shall be reviewed by the pharmacy when it reopens and incorporated into the hospital pharmacy's medication recordkeeping system.

9.6 Emergency Drugs. Emergency drugs must be available for use by authorized personnel at strategic locations throughout the hospital. The drugs must be available to authorized personnel and must be stored in a manner to preserve the integrity of the contents.

9.6.1 Emergency Drugs Defined - Emergency drugs are those drugs which may be required to meet the immediate therapeutic needs of patients and which are not available from any other authorized source in sufficient time to prevent risk or harm to patients.

9.6.2 Emergency drug supplies shall be clearly identified for emergencies. A list showing the contents and the strength and quantity of each item shall be attached to the exterior.

9.6.3 Removal of Drugs - Drugs shall be removed from an emergency drug supply only pursuant to a valid physician's order or by authorized personnel.

9.6.4 Notification - Whenever an emergency drug supply is accessed, the pharmacist or pharmacist's designee shall be notified within 24 hours, and the pharmacist or pharmacist's designee shall restock and reseal or replace the kit or cart within forty-eight hours.

9.7 Equipment and Texts. Each hospital pharmacy shall have the equipment and texts required by Board Regulation 3.0 and Regulation 10.0.

9.8 Drug Storage. Drugs must be stored in compliance with State and Federal Statutes and Regulations and according to USP/NF requirements.

9.9 Labeling

9.9.1 The drug dispensed for inpatient use shall contain a label with the name and the strength of the medication. If the medication is prepacked, it must also show the source, lot number and expiration date, in compliance with the Board's prepacking regulation.

9.9.2 All drugs dispensed for outpatients must be labeled in compliance with the Pharmacy Statutes.

9.9.3 Admixtures in parenteral bags and bottles shall be labeled in accordance with Regulation 10.0.

9.10 Abbreviations. The hospital should establish a standard list of abbreviations to be used whenever medications are prescribed.

9.11 Outpatient Orders. Medication dispensed for outpatients via prescriptions are governed by applicable State and Federal Statutes Regulations. A patient profile must be maintained and counseling must be provided for each person according to Regulation 5.0.

9.12 Suspected Adverse Drug Reaction. When an adverse reaction is documented, the pharmacy department shall receive a copy.

9.13 Maintenance of Medication Orders. Patient Profile - A patient medication profile must be maintained for each inpatient whose medication is directly dispensed from the pharmacy. It must show the patient's name, location, age, allergies and diagnosis(es) as available. The profile must show the name, strength and quantity of the drug dispensed and appropriate directions and the initials of the dispenser. Prior to administration of the first dose, the pharmacist must examine the profile to determine the possibility of a harmful drug interaction or reaction. Upon recognizing a significant potential for harm, the pharmacist should notify the prescriber and other appropriate persons. The profile must be retained and readily retrievable for 30 days after discharge.

9.14 Medication Error. Medication error as defined by the hospital shall be documented and reported immediately to the pharmacy. It should also be reported to the attending physician.

9.15 Monthly Inspections. A member of the pharmacy staff shall conduct monthly inspections of each nursing station and patient care areas where medications are dispensed, administered or stored. Such documented inspections shall verify that:

9.15.1 Disinfectants and drugs for external use are stored separately.

9.15.2 Drugs are stored under proper conditions.

9.15.3 No outdated drugs are present.

9.15.4 Distribution, administration, and disposition of controlled substances audits indicates proper recordkeeping and administration.

9.15.5 Emergency drug supplies and floor stock drug levels are properly maintained.

9.15.6 Drugs are properly secured.

9 DE Reg. 85(7/1/05)

10 DE Reg. 1629 (4/1/07)

13 DE Reg. 1581 (06/01/10)

10.0 Sterile Pharmaceuticals and Antineoplastic Agents

This regulation contains minimum pharmacy practices for the preparation, compounding and dispensing of sterile preparations and antineoplastic agents by licensed pharmacies.

10.1 Definitions. As used in this part, the following terms shall have the meanings specified:

"Admixture" A solution for parenteral administration to which one or more additional drugs have been added.

"Antineoplastic Agent" A drug used to treat various forms of cancer.

"Aseptic Technique" A procedure for compounding sterile preparations designed to minimize/prevent contamination during the compounding procedure.

"Class 100" A classification of an airflow unit capable of producing an environment containing no more than 100 airborne particles of a size 0.5 micron and larger per cubic foot (3.5 particles/liter) of air.

"Enteral Nutrition" The administration into the gastro-intestinal tract of calories, nitrogen, and/or other nutrients to achieve tissue synthesis and anabolism for patients requiring medically prescribed, defined formula, liquid diets.

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465.003Definitions.—As used in this chapter, the term:

(1)"Administration" means the obtaining and giving of a single dose of medicinal drugs by a legally authorized person to a patient for her or his consumption.

(2)"Board" means the Board of Pharmacy.

(3)"Consultant pharmacist" means a pharmacist licensed by the department and certified as a consultant pharmacist pursuant to s. 465.0125.

(4)"Data communication device" means an electronic device that receives electronic information from one source and transmits or routes it to another, including, but not limited to, any such bridge, router, switch, or gateway.

(5)"Department" means the Department of Health.

(6)"Dispense" means the transfer of possession of one or more doses of a medicinal drug by a pharmacist to the ultimate consumer or her or his agent. As an element of dispensing, the pharmacist shall, prior to the actual physical transfer, interpret and assess the prescription order for potential adverse reactions, interactions, and dosage regimen she or he deems appropriate in the exercise of her or his professional judgment, and the pharmacist shall certify that the medicinal drug called for by the prescription is ready for transfer. The pharmacist shall also provide counseling on proper drug usage, either orally or in writing, if in the exercise of her or his professional judgment counseling is necessary. The actual sales transaction and delivery of such drug shall not be considered dispensing. The administration shall not be considered dispensing.

(7)"Institutional formulary system" means a method whereby the medical staff evaluates, appraises, and selects those medicinal drugs or proprietary preparations which in the medical staff's clinical judgment are most useful in patient care, and which are available for dispensing by a practicing pharmacist in a Class II institutional pharmacy.

(8)"Medicinal drugs" or "drugs" means those substances or preparations commonly known as "prescription" or "legend" drugs which are required by federal or state law to be dispensed only on a prescription, but shall not include patents or proprietary preparations as hereafter defined.

(9)"Patent or proprietary preparation" means a medicine in its unbroken, original package which is sold to the public by, or under the authority of, the manufacturer or primary distributor thereof and which is not misbranded under the provisions of the Florida Drug and Cosmetic Act.

(10)"Pharmacist" means any person licensed pursuant to this chapter to practice the profession of pharmacy.

(11)(a)“Pharmacy” includes a community pharmacy, an institutional pharmacy, a nuclear pharmacy, a special pharmacy, and an Internet pharmacy.

1.The term “community pharmacy” includes every location where medicinal drugs are compounded, dispensed, stored, or sold or where prescriptions are filled or dispensed on an outpatient basis.

2.The term “institutional pharmacy” includes every location in a hospital, clinic, nursing home, dispensary, sanitarium, extended care facility, or other facility, hereinafter referred to as “health care institutions,” where medicinal drugs are compounded, dispensed, stored, or sold.

3.The term “nuclear pharmacy” includes every location where radioactive drugs and chemicals within the classification of medicinal drugs are compounded, dispensed, stored, or sold. The term “nuclear pharmacy” does not include hospitals licensed under chapter 395 or the nuclear medicine facilities of such hospitals.

4.The term “special pharmacy” includes every location where medicinal drugs are compounded, dispensed, stored, or sold if such locations are not otherwise defined in this subsection.

5.The term “Internet pharmacy” includes locations not otherwise licensed or issued a permit under this chapter, within or outside this state, which use the Internet to communicate with or obtain information from consumers in this state and use such communication or information to fill or refill prescriptions or to dispense, distribute, or otherwise engage in the practice of pharmacy in this state. Any act described in this definition constitutes the practice of pharmacy as defined in subsection (13).

(b)The pharmacy department of any permittee shall be considered closed whenever a Florida licensed pharmacist is not present and on duty. The term “not present and on duty” shall not be construed to prevent a pharmacist from exiting the prescription department for the purposes of consulting or responding to inquiries or providing assistance to patients or customers, attending to personal hygiene needs, or performing any other function for which the pharmacist is responsible, provided that such activities are conducted in a manner consistent with the pharmacist’s responsibility to provide pharmacy services.

(12)“Pharmacy intern” means a person who is currently registered in, and attending, a duly accredited college or school of pharmacy, or who is a graduate of such a school or college of pharmacy, and who is duly and properly registered with the department as provided for under its rules.

(13)“Practice of the profession of pharmacy” includes compounding, dispensing, and consulting concerning contents, therapeutic values, and uses of any medicinal drug; consulting concerning therapeutic values and interactions of patent or proprietary preparations, whether pursuant to prescriptions or in the absence and entirely independent of such prescriptions or

orders; and other pharmaceutical services. For purposes of this subsection, “other pharmaceutical services” means the monitoring of the patient’s drug therapy and assisting the patient in the management of his or her drug therapy, and includes review of the patient’s drug therapy and communication with the patient’s prescribing health care provider as licensed under chapter 458, chapter 459, chapter 461, or chapter 466, or similar statutory provision in another jurisdiction, or such provider’s agent or such other persons as specifically authorized by the patient, regarding the drug therapy. However, nothing in this subsection may be interpreted to permit an alteration of a prescriber’s directions, the diagnosis or treatment of any disease, the initiation of any drug therapy, the practice of medicine, or the practice of osteopathic medicine, unless otherwise permitted by law. “Practice of the profession of pharmacy” also includes any other act, service, operation, research, or transaction incidental to, or forming a part of, any of the foregoing acts, requiring, involving, or employing the science or art of any branch of the pharmaceutical profession, study, or training, and shall expressly permit a pharmacist to transmit information from persons authorized to prescribe medicinal drugs to their patients. The practice of the profession of pharmacy also includes the administration of influenza virus immunizations to adults pursuant to s. 465.189.

(14)“Prescription” includes any order for drugs or medicinal supplies written or transmitted by any means of communication by a duly licensed practitioner authorized by the laws of the state to prescribe such drugs or medicinal supplies and intended to be dispensed by a pharmacist. The term also includes an orally transmitted order by the lawfully designated agent of such practitioner. The term also includes an order written or transmitted by a practitioner licensed to practice in a jurisdiction other than this state, but only if the pharmacist called upon to dispense such order determines, in the exercise of her or his professional judgment, that the order is valid and necessary for the treatment of a chronic or recurrent illness. The term “prescription” also includes a pharmacist’s order for a product selected from the formulary created pursuant to s. 465.186. Prescriptions may be retained in written form or the pharmacist may cause them to be recorded in a data processing system, provided that such order can be produced in printed form upon lawful request.

(15)“Nuclear pharmacist” means a pharmacist licensed by the department and certified as a nuclear pharmacist pursuant to s. 465.0126.

(16)“Centralized prescription filling” means the filling of a prescription by one pharmacy upon request by another pharmacy to fill or refill the prescription. The term includes the performance by one pharmacy for another pharmacy of other pharmacy duties such as drug utilization review, therapeutic drug utilization review, claims adjudication, and the obtaining of refill authorizations.

(17)“Automated pharmacy system” means a mechanical system that delivers prescription drugs received from a Florida licensed pharmacy and maintains related transaction information.

History.—ss. 1, 7, ch. 79-226; s. 322, ch. 81-259; ss. 14, 15, ch. 81-302; ss. 2, 3, ch. 81-318; ss. 1, 2, ch. 82-179; s. 1, ch. 83-101; s. 36, ch. 83-216; s. 3, ch. 83-265; s. 29, ch. 83-329; s. 1, ch. 85-35; ss. 2, 26, 27, ch. 86-256; s. 1, ch. 88-172; s. 1, ch. 89-77; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429; s. 123, ch. 94-218; s. 239, ch. 97-103; s. 87, ch. 97-264; s. 118, ch. 99-397; s. 1, ch. 2002-182; s. 1, ch. 2004-25; s. 1, ch. 2004-387; s. 2, ch. 2007-152.

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Title XXXII
REGULATION OF PROFESSIONS AND OCCUPATIONS

Chapter 465 View Entire Chapter
PHARMACY

465.019 Institutional pharmacies; permits.—

(1) Any institution desiring to operate an institutional pharmacy shall apply to the department. If the board certifies that the application complies with the laws of the state and the rules of the board governing pharmacies, the department shall issue the permit.

(2) The following classes of institutional pharmacies are established:

(a) "Class I institutional pharmacies" are those institutional pharmacies in which all medicinal drugs are administered from individual prescription containers to the individual patient and in which medicinal drugs are not dispensed on the premises, except that nursing homes licensed under part II of chapter 400 may purchase medical oxygen for administration to residents. No medicinal drugs may be dispensed in a Class I institutional pharmacy.

(b) "Class II institutional pharmacies" are those institutional pharmacies which employ the services of a registered pharmacist or pharmacists who, in practicing institutional pharmacy, shall provide dispensing and consulting services on the premises to patients of that institution, for use on the premises of that institution. However, an institutional pharmacy located in an area or county included in an emergency order or proclamation of a state of emergency declared by the Governor may provide dispensing and consulting services to individuals who are not patients of the institution. However, a single dose of a medicinal drug may be obtained and administered to a patient on a valid physician's drug order under the supervision of a physician or charge nurse, consistent with good institutional practice procedures. The obtaining and administering of such single dose of a medicinal drug shall be pursuant to drug-handling procedures established by a consultant pharmacist. Medicinal drugs may be dispensed in a Class II institutional pharmacy, but only in accordance with the provisions of this section.

(c) "Modified Class II institutional pharmacies" are those institutional pharmacies in short-term, primary care treatment centers that meet all the requirements for a Class II permit, except space and equipment requirements.

(3) Medicinal drugs shall be stocked, stored, compounded, dispensed, or administered in any health care institution only when that institution has secured an institutional pharmacy permit from the department.

(4) Medicinal drugs shall be dispensed in an institutional pharmacy to outpatients only when that institution has secured a community pharmacy permit from the department. However, an individual licensed to prescribe medicinal drugs in this state may dispense up to a 24-hour supply of a medicinal drug to any patient of an emergency department of a hospital that operates a Class II institutional pharmacy, provided that the physician treating the patient in such hospital's emergency department determines that the medicinal drug is warranted and that community pharmacy services are not readily accessible, geographically or otherwise, to the patient. Such dispensing from the emergency department

must be in accordance with the procedures of the hospital. For any such patient for whom a medicinal drug is warranted for a period to exceed 24 hours, an individual licensed to prescribe such drug must dispense a 24-hour supply of such drug to the patient and must provide the patient with a prescription for such drug for use after the initial 24-hour period. The board may adopt rules necessary to carry out the provisions of this subsection.

(5) All institutional pharmacies shall be under the professional supervision of a consultant pharmacist, and the compounding and dispensing of medicinal drugs shall be done only by a licensed pharmacist. Every institutional pharmacy that employs or otherwise uses registered pharmacy technicians shall have a written policy and procedures manual specifying those duties, tasks, and functions that a registered pharmacy technician is allowed to perform.

(6) In a Class II institutional pharmacy, an institutional formulary system may be adopted with approval of the medical staff for the purpose of identifying those medicinal drugs and proprietary preparations that may be dispensed by the pharmacists employed in such institution. A facility with a Class II institutional permit which is operating under the formulary system shall establish policies and procedures for the development of the system in accordance with the joint standards of the American Hospital Association and American Society of Hospital Pharmacists for the utilization of a hospital formulary system, which formulary shall be approved by the medical staff.

History.—ss. 1, 7, ch. 79-226; ss. 2, 3, ch. 81-318; s. 2, ch. 83-101; ss. 26, 27, ch. 86-256; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429; s. 29, ch. 93-211; s. 244, ch. 98-166; s. 36, ch. 99-397; s. 79, ch. 2001-277; s. 6, ch. 2008-216.

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TITLE 26. FOOD, DRUGS, AND COSMETICS
CHAPTER 4. PHARMACISTS AND PHARMACIES
ARTICLE 1. GENERAL PROVISIONS

§ 26-4-5. Definitions As used in this chapter, the term:
(1) "Administer" or "administration" means the provision of a unit dose of medication to an individual patient as a result of the order of an authorized practitioner of the healing arts.

(2) "Board of pharmacy" or "board" means the Georgia State Board of Pharmacy.

(3) "Brand name drug" means the proprietary, specialty, or trade name used by a drug manufacturer for a generic drug and placed upon the drug, its container, label, or wrapping at the time of packaging.

(4) "Compounding" means the preparation, mixing, assembling, packaging, or labeling of a drug or device as the result of a practitioner's prescription drug order or initiative based on the relationship between the practitioner, patient, and pharmacist in the course of professional practice or for the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale or dispensing. Compounding also includes the preparation of drugs or devices in anticipation of prescription drug orders based on routine and regularly observed prescribing patterns.

(5) "Confidential information" means information maintained by the pharmacist in the patient's records or which is communicated to the patient as part of patient counseling which is privileged and may be released only to the patient or, as the patient directs, to those practitioners and other pharmacists where, in the pharmacist's professional judgment, such release is necessary to protect the patient's health and well-being; and to such other persons or governmental agencies authorized by law to receive such confidential information.

(6) "Controlled substance" means a drug, substance, or immediate precursor in Schedules I through V of Code Sections 16-13-25 through 16-13-29, Schedules I through V of 21 C.F.R. Part 1308, or both.

(7) "Dangerous drug" means any drug, substance, medicine, or medication as defined in Code Section 16-13-71.

(8) "Deliver" or "delivery" means the actual, constructive, or attempted transfer of a drug or device from one person to another, whether or not for a consideration.

(9) "Device" means an instrument, apparatus, contrivance, or other similar or related article, including any component part or accessory, which is required under federal law to bear the label, "Caution: federal or state law requires dispensing by or on the order of a physician."

(10) "Dispense" or "dispensing" means the preparation and delivery of a drug or device to a patient, patient's caregiver, or patient's agent pursuant to a lawful order of a practitioner in a suitable container appropriately labeled for subsequent administration to, or use by, a patient.

(11) "Distribute" means the delivery of a drug or device other than by administering or dispensing.
(11.1) "Division director" means the division director of the professional licensing boards division, as provided in Chapter 1 of Title 43.

(12) "Drug" means:
(A) Articles recognized as drugs in any official compendium, or supplement thereto, designated from time to time by the board for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals;
(B) Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals;
(C) Articles, other than food, intended to affect the structure or any function of the body of humans or animals; and
(D) Articles intended for use as a component of any articles specified in subparagraph (A), (B), or (C) of this paragraph but does not include devices.

(13) "Drug regimen review" includes but is not limited to the following activities:
(A) Evaluation of any prescription drug order and patient record for: (i) Known allergies; (ii) Rational therapy-contraindications; (iii) Reasonable dose and route of administration; and (iv) Reasonable directions for use;
(B) Evaluation of any prescription drug order and patient record for duplication of therapy;
(C) Evaluation of any prescription drug order and patient record for the following interactions: (i) Drug-drug; (ii) Drug-food; (iii) Drug-disease; and (iv) Adverse drug reactions; and
(D) Evaluation of any prescription drug order and patient record for proper utilization, including overutilization or underutilization, and optimum therapeutic outcomes.

(14) "Drug researcher" means a person, firm, corporation, agency, department, or other entity which handles, possesses, or utilizes controlled substances or dangerous drugs, as defined in Chapter 13 of Title 16, for purposes of conducting research, drug analysis, animal training, or drug education, as such purposes may be further defined by the board, and is not otherwise registered as a pharmacist, pharmacy, drug wholesaler, distributor, supplier, or medical practitioner.
(14.1) "Electronic data prescription drug order" means any digitalized prescription drug order transmitted to a pharmacy, by a means other than by facsimile, which contains the secure, personalized digital key, code, number, or other identifier used to identify and authenticate the prescribing practitioner in a manner required by state laws and board regulations and includes all other information required by state laws and board regulations. "Electronic data prescription drug order" also includes any digitalized prescription drug order transmitted to a pharmacy that is converted into a visual image of a prescription order during the transmission process, is received by the pharmacy through a facsimile, and includes the practitioner's electronic signature.
(14.2) "Electronic data signature" means:
(A) A secure, personalized digital key, code, number, or other identifier used for secure electronic data transmissions which identifies and authenticates the prescribing practitioner as a part of an electronic data prescription drug order transmitted to a pharmacy; or
(B) An electronic symbol or process attached to or logically associated with a record and executed or adopted by a prescribing practitioner with the intent to sign an electronic data prescription drug order, which identifies the prescribing practitioner, as a part of an electronic data prescription drug order transmitted to a pharmacy.
(14.3) "Electronic signature" means an electronic visual image signature or an electronic data signature of a practitioner which appears on an electronic prescription drug order.

(14.4) "Electronic visual image prescription drug order" means any exact visual image of a prescription drug order issued by a practitioner electronically and which bears an electronic reproduction of the visual image of the practitioner's signature, is either printed on security paper and presented as a hard copy to the patient or transmitted by the practitioner via facsimile machine or equipment to a pharmacy, and contains all information required by state law and regulations of the board.
(14.5) "Electronic visual image signature" means any exact visual image of a practitioner's signature reproduced electronically on a hard copy prescription drug order presented to the patient by the practitioner or is a prescription drug order transmitted to a pharmacy by a practitioner via facsimile machine or equipment.

(15) "Emergency service provider" means licensed ambulance services, first responder services or neonatal services, or any combination thereof.

(16) "Extern" or "pharmacy extern" means an individual who is a student currently enrolled in an approved school or college of pharmacy and who has been assigned by the school or college of pharmacy to a licensed pharmacy for the purposes of obtaining practical experience and completing a degree in pharmacy. For the purposes of this chapter, a pharmacy extern may engage in any activity or perform any function which a pharmacy intern may perform under the direct supervision of a licensed pharmacist.

(17) "Federal act" or "Federal Food, Drug, and Cosmetic Act" means the Federal Food, Drug, and Cosmetic Act of the United States of America, approved June 25, 1938, officially cited as Public Document 717, 75th Congress (Chapter 675-3rd Sess.) and all amendments thereto, and all regulations promulgated thereunder by the commissioner of the Federal Food and Drug Administration.

(18) "Generic name" means a chemical name, a common or public name, or an official name used in an official compendium recognized by the Federal Food, Drug, and Cosmetic Act, as amended.
(18.05) "Hard copy prescription drug order" means a written, typed, reproduced, or printed prescription drug order prepared on a piece of paper.
(18.1) "Institution" means any licensed hospital, nursing home, assisted living community, personal care home, hospice, health clinic, or prison clinic.

(19) "Intern" or "pharmacy intern" means an individual who is:
(A) A student who is currently enrolled in an approved school or college of pharmacy, has registered with the board, and has been licensed as a pharmacy intern;
(B) A graduate of an approved school or college of pharmacy who is currently licensed by the board for the purpose of obtaining practical experience as a requirement for licensure as a pharmacist; or
(C) An individual who does not otherwise meet the requirements of subparagraph (A) or (B) of this paragraph and who has established educational equivalency by obtaining a Foreign Pharmacy Graduate Examination Committee (FPGEC) certificate and is currently licensed by the board for the purpose of obtaining practical experience as a requirement for licensure as a pharmacist.

(20) Reserved.

(21) "Labeling" means the process of preparing and affixing a label to any drug container exclusive, however, of the labeling by a manufacturer, packer, or distributor of a nonprescription drug or

commercially packaged legend drug or device. Any such label shall include all information required by federal, state, or federal and state law or rule.

(22) "Manufacturer" means a person engaged in the manufacturing of drugs or devices.

(23) "Manufacturing" means the production, preparation, propagation, conversion, or processing of a drug or device, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical or biological synthesis and includes any packaging or repackaging of any substance or labeling or relabeling of its container and the promotion and marketing of such drugs or devices. Manufacturing also includes the preparation and promotion of commercially available products from bulk compounds for resale by pharmacies, practitioners, or other persons. (23.5) "Narcotic treatment program clinic pharmacy" means a pharmacy which is attached to, located in, or otherwise a part of and operated by a narcotic treatment program which provides an opiate replacement treatment program, as designated or defined by the Department of Behavioral Health and Developmental Disabilities or such other state agency as may be designated as the state authority for the purposes of implementing the narcotic treatment program authorized by federal and state laws and regulations.

(24) "Nonprescription drug" means a drug which may be sold without a prescription and which is labeled for use by the consumer in accordance with the requirements of the laws and rules of this state and the federal government.

(25) "Patient counseling" means the oral communication by the pharmacist of information, as defined in the rules of the board, to the patient, patient's caregiver, or patient's agent, in order to improve therapy by ensuring proper use of drugs and devices.

(26) "Person" means an individual, corporation, partnership, or association.

(27) "Pharmaceutically equivalent" means drug products that contain identical amounts of the identical active ingredient, in identical dosage forms, but not necessarily containing the same inactive ingredients.

(28) "Pharmacist" means an individual currently licensed by this state to engage in the practice of pharmacy. This recognizes a pharmacist as a learned professional who is authorized to provide patient services and pharmacy care.

(29) "Pharmacist in charge" means a pharmacist currently licensed in this state who accepts responsibility for the operation of a pharmacy in conformance with all laws and rules pertinent to the practice of pharmacy and the distribution of drugs and who is personally in full and actual charge of such pharmacy and personnel.

(30) "Pharmacy" means:
(A) The profession, art, and science that deals with pharmacy care, drugs, or both, medicines, and medications, their nature, preparation, administration, dispensing, or effect; or
(B) Any place licensed in accordance with this chapter wherein the possessing, displaying, compounding, dispensing, or selling of drugs may be conducted, including any and all portions of the building or structure leased, used, or controlled by the licensee in the conduct of the business or profession licensed by the board at the address for which the license was issued.

(31) "Pharmacy care" means those services related to the interpretation, evaluation, or dispensing of prescription drug orders, the participation in drug and device selection, drug administration, and drug regimen reviews, and the provision of patient counseling related thereto.

(32) "Pharmacy technician" means those support persons utilized in pharmacies whose responsibilities are to provide nonjudgmental technical services concerned with the preparation for dispensing of drugs under the direct supervision and responsibility of a pharmacist.

(33) "Practitioner" or "practitioner of the healing arts" means a physician, dentist, podiatrist, or veterinarian and shall include any other person licensed under the laws of this state to use, mix, prepare, dispense, prescribe, and administer drugs in connection with medical treatment to the extent provided by the laws of this state.

(34) "Preceptor" means an individual who is currently licensed as a pharmacist by the board, meets the qualifications as a preceptor under the rules of the board, and participates in the instructional training of pharmacy interns.

(35) "Prescription drug" or "legend drug" means a drug which, under federal law, is required, prior to being dispensed or delivered, to be labeled with either of the following statements: "Caution: federal law prohibits dispensing without prescription" or "Caution: federal law restricts this drug to use by, or on the order of, a licensed veterinarian"; or a drug which is required by any applicable federal or state law or rule to be dispensed pursuant only to a prescription drug order or is restricted to use by practitioners only; or a controlled substance, as defined in paragraph (6) of this Code section or a dangerous drug as defined in paragraph (7) of this Code section.

(36) "Prescription drug order" means a lawful order of a practitioner for a drug or device for a specific patient; such order includes an electronic visual image prescription drug order and an electronic data prescription drug order.

(37) "Prospective drug use review" means a review of the patient's drug therapy and prescription drug order, as defined in the rules of the board, prior to dispensing the drug as part of a drug regimen review. (37.1) "Remote automated medication system" means an automated mechanical system that is located in a skilled nursing facility or hospice licensed as such pursuant to Chapter 7 of Title 31 that does not have an on-site pharmacy and in which medication may be dispensed in a manner that may be specific to a patient.

(38) "Reverse drug distributor" means a person, firm, or corporation which receives and handles drugs from within this state which are expired, discontinued, adulterated, or misbranded, under the provisions of Chapter 3 of this title, the "Georgia Drug and Cosmetic Act," from a pharmacy, drug distributor, or manufacturer for the purposes of destruction or other final disposition or for return to the original manufacturer of a drug.
(38.5) "Security paper" means a prescription pad or paper that has been approved by the board for use and contains the following characteristics:
(A) One or more industry recognized features designed to prevent unauthorized copying of a completed or blank prescription form;
(B) One or more industry recognized features designed to prevent the erasure or modification of information written on the prescription form by the practitioner; and
(C) One or more industry recognized features designed to prevent the use of counterfeit prescription forms. Where security paper is in the form of a prescription pad, each pad shall bear an identifying

lot number, and each piece of paper in the pad shall be numbered sequentially beginning with the number one.

(39) "Significant adverse drug reaction" means a drug related incident that may result in serious harm, injury, or death to the patient.

(40) "Substitution" means to dispense pharmaceutically equivalent and therapeutically equivalent drug products as regulated by the board in place of the drug prescribed.

(41) "Wholesale distributor" means any person engaged in wholesale distribution of drugs, including but not limited to manufacturers; repackagers; own label distributors; private label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; and retail and hospital pharmacies that conduct wholesale distributions.

HISTORY: Code 1981, § 26-4-5, enacted by Ga. L. 1998, p. 686, § 1; Ga. L. 1999, p. 81, § 26; Ga. L. 1999, p. 277, § 1.1; Ga. L. 2000, p. 1706, § 22; Ga. L. 2004, p. 738, §§ 2, 3; Ga. L. 2007, p. 47, § 26/SB 103; Ga. L. 2009, p. 453, § 3-2/HB 228; Ga. L. 2010, p. 266, § 1/SB 195; Ga. L. 2011, p. 227, § 7/SB 178; Ga. L. 2011, p. 308, § 5/HB 457; Ga. L. 2011, p. 659, § 3/SB 36.

Georgia Secretary of State
Brian P. Kemp

LINKS:

- **Definitions. Amended**
  480-13-.01
- **Licensure and Registration. Amended** pdf
  480-13-.02
- **Personnel. Amended**
  480-13-.03
- **Absence of Pharmacist. Amended**
  480-13-.04
- **Physical Requirements. Amended**
  480-13-.05
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480-13-.01 Definitions.

For purposes of these Rules and Regulations, the following definitions apply:
(a) Hospital. As defined by the Department of Human Resources;
(b) Hospital pharmacy. Hospital pharmacy is defined as that portion of a hospital facility which is engaged in the manufacture, production, sale and distribution of drugs, medications, devices, and other materials used in the prevention, diagnosis and treatment of injury, illness and disease (hereinafter referred to as "drugs"); and which is registered with the State Board of Pharmacy pursuant to O.C.G.A. § 26-4-110;
(c) Hospital pharmacy license. Hospital pharmacy license shall mean a pharmacy license issued by the Georgia State Board of Pharmacy to said hospital pharmacies, pursuant to the provisions of O.C.G.A. Sections 26-4-27, 26-4-28 and 26-4-110 whereas the licensee shall be subject to special hospital pharmacy regulations as set forth herein, but exempt from other certain regulations and requirements. To obtain the hospital pharmacy license, there must be employed a Director of Pharmacy.
1. The Board authorizes the holder of a hospital pharmacy license to service patients of Nursing Homes, Long Term Care Facilities or Hospices as long as these entities are under the same ownership as the hospital pharmacy; however, such entities can only be serviced by the hospital pharmacy subject to the requirements as set forth by Georgia State Board of Pharmacy Rules 480-24, the rule for providing services to nursing homes, long term care facilities, and hospices. The hospital pharmacy is prohibited from maintaining standard ward (Floor Stock) inventories in such entities, but, it would allow the hospital pharmacy to supply emergency kits.
(d) In-patient. In-patient shall mean a patient who is confined to the hospital;
(e) Out-patient. Out-patient shall mean a patient who is not an in-patient, including patients on leave of absence;
(f) Remote Location. Remote location shall mean a location away from the hospital or hospital pharmacy where a pharmacist reviews and enters patient specific prescription drug orders for a hospital's patients.
(g) Remote Order Entry. Remote order entry shall mean the entry a pharmacist makes from a remote location indicating that the pharmacist has reviewed the patient specific drug order for a hospital patient, has approved or disapproved the administration of the drug for said patient, and has entered the information on the hospital's patient record system.
(h) Remote Order Entry Pharmacist. A remote order entry pharmacist shall mean a pharmacist who is licensed to practice pharmacy in the State of Georgia, who is at a remote location, and who is under contract with or employed by the hospital to review and enter patient specific prescription drug orders for hospital patients when the hospital pharmacy is closed.
(i) Standard ward inventory. The Director of Pharmacy or his/her pharmacist designee may, in the best interest of the patients served, establish one or more lists of the kind and quantity of legend drugs to be kept at one or more locations at all times within said hospital and such stocks of legend drugs shall be known as standard ward inventory. The use of standard ward inventory shall be minimized. A copy of the list of items on standard ward inventory must be kept by the Director of Pharmacy or his/her pharmacist designee. A standard ward inventory may be placed on an emergency vehicle licensed

with the State Department of Human Resources. A contract or agreement must be signed between the hospital and the ambulance service and filed with the Department of Human Resources Licensure Division and the Georgia Drugs and Narcotics Agency (GDNA) before any legend drugs may be placed on said licensed vehicle. An agreement can be made with only one hospital.

Authority O.C.G.A. Secs. 26-4-27 to 26-4-29, 26-4-83, 26-4-84, 26-4-110. **History.** Original Rule entitled "Hospitals, Nursing Homes, Extended Care Facilities, Pharmaceutical Services" adopted. F. Oct. 6, 1970; eff. Oct. 26, 1970. **Repealed:** New Rule entitled "Definitions" adopted. F. Jan. 24, 1977; eff. Feb. 13, 1977. **Repealed:** New Rule of same title adopted. F. May 5, 1980; eff. May 25, 1980. **Repealed:** New Rule of same title adopted. F. July 24, 2002; eff. Aug. 13, 2002. **Repealed:** New Rule of same title adopted. F. Mar. 13, 2008; eff. Apr. 2, 2008.

480-13-.02 Licensure and Registration. Amended.

All hospital pharmacies shall renew biennially by June 30th of each odd-numbered year with the Georgia State Board of Pharmacy; certificates of registration shall be issued only to those hospital pharmacies which comply with the provisions of O.C.G.A. § 26-4-110, and with these Rules and Regulations.
(a) Minimum Required Information for Licensure. The Board requires the following information from each hospital pharmacy as part of the initial licensing procedure and as part of any renewal of such license:
(b) The name, complete street address for the business, and telephone number of the applicant/licensee;
(c) All trade or business names used by the applicant/licensee;
(d) Address, telephone numbers, and the name(s) of the Hospital Administrator;
(e) The type of ownership or operation (i.e., partnership, corporation, or sole proprietorship); and
(f) The name(s) of the owner and/or operator of the applicant/licensee, including:
1. If a partnership, the name of each partner, and the name of the partnership;
2. If a sole proprietorship, the complete name of the proprietor;
3. If a corporation, the name and title of each corporate officer and director, the corporate name and the state of incorporation; and the name of the parent company, if any.
(g) Where operations are conducted at more than one location by a single hospital pharmacy, each such location shall be licensed by the Board.
1. Applications for Licensure.
(i) Registration of a hospital pharmacy shall be considered filed with the Board when an application is received by the Board, and the fee is paid, and a report from the Director of the Georgia Drugs and Narcotics Agency (GDNA) certifying the applicant possesses the necessary qualifications for a license is received by the Board.
(h) Application fees shall not be refundable.
(i) A license shall be null and void upon the sale, transfer or change of mode of operation or location of the business.
(j) Licenses may be renewed for two year periods and shall expire on June 30th of each odd numbered year and may be renewed upon the payment of the required fee for each place of business and the filing of an application for renewal for each place of business. If the application for renewal is not filed with the Board, and the fee paid before September 1st of each odd numbered year, the license shall lapse and may not be renewed except by application for a new license.
(k) A licensee must submit any change of name, mode of operation or address to the Board prior to such change.
1. Minimum Qualifications.
(i) The Board shall consider the following factors when determining eligibility for licensure for each person in charge of the facility and when considering an application for a hospital pharmacy license:
(I) Any convictions of the applicant under any Federal, State, or local laws relating to drugs, wholesale or retail drug distribution, or distribution of controlled substances;
(II) Any felony convictions of the applicant under any Federal, State, or local laws;

(III) The furnishing by the applicant of false or fraudulent material or information in any application;
(IV) Suspension or revocation by any Federal, State, or local government of any pharmacist, pharmacy or other health care license currently or previously held by the applicant;
2. Failure to comply with any licensing requirements under a previously held license, if any;
3. Failure to comply with any requirements to maintain records and/or make available, said records to any State Licensing Authority or to any Federal, State, or local law enforcement officials;
4. Other factors or qualifications the Board considers relevant to and consistent with the public's health and safety;
5. The Board reserves the right to deny a license to an applicant if it determines that the granting of such a license would not be in the best interest of the public.

Authority O.C.G.A. Secs. 26-4-27, 26-4-28, 26-4-110. **History.** Original Rule entitled "Hospital Pharmacy License" adopted. F. Feb. 4, 1972; eff. Feb. 24, 1972. **Repealed:** New Rule entitled "Registration" adopted. F. Jan. 24, 1977; eff. Feb. 13, 1977. **Repealed:** New Rule of same title adopted. F. May 5, 1980; eff. May 25, 1980. **Repealed:** New Rule entitled " Licensure and Registration" adopted. F. July 24, 2002; eff. Aug. 13, 2002.

480-13-.03 Personnel.

(1) Director of Pharmacy. Each hospital pharmacy shall be directed by a pharmacist, hereinafter referred to as the Director of Pharmacy, who is licensed to engage in the practice of pharmacy in this State, and who is knowledgeable in and thoroughly familiar with the specialized functions of hospital pharmacies. The Director of Pharmacy shall be responsible for all activities of the hospital pharmacy, and for meeting the requirements of the Georgia Pharmacy Laws and Rules and Regulations of the Board of Pharmacy. The Director of Pharmacy or his/her pharmacist designee should be employed on a fulltime basis consistent with need.

(2) Supportive personnel. The Director of Pharmacy shall be assisted by a sufficient number of additional pharmacists, and ancillary personnel as may be required to operate such pharmacy competently, safely, and to meet the needs of the patients of the hospital facility.

(a) The Director of Pharmacy shall insure that trained personnel shall be employed in the pharmacy. The Director of Pharmacy shall develop and implement written policies and procedures to specify the duties to be performed by such personnel. These policies and procedures shall, at a minimum, specify that such personnel are personally and directly supervised by a licensed pharmacist and that such personnel are not assigned duties which may be performed only by licensed pharmacists. The Director of Pharmacy shall be responsible for the implementation of the written policies and responsible to the Georgia State Board of Pharmacy for the activities of the pharmacy.

(b) Secretarial and clerical assistance and support shall be provided as required to assist with record keeping, report submission, and other administrative duties, provided such personnel do not perform any dispensing duties.

(3) Supervision. All of the activities and operations of each hospital pharmacy shall be personally and directly supervised by its Director of Pharmacy. All functions and activities of non-licensed pharmacy personnel shall be personally and directly supervised by an adequate number of licensed pharmacists to insure that all such functions and activities are performed competently, safely, and without risk of harm to patients. Personal supervision can only be accomplished by the physical presence of a licensed pharmacist in the hospital.

Authority O.C.G.A. Secs. 26-4-27 to 26-4-29, 26-4-83, 26-4-84, 26-4-110. **History.** Original Rule entitled "Personnel" adopted. F. Jan. 24, 1977; eff. Feb. 13, 1977. **Repealed:** New Rule of same title adopted. F. May 5, 1980; eff. May 25, 1980. **Repealed:** New Rule of same title adopted. F. July 24, 2002; eff. Aug. 13, 2002. **Repealed:** New Rule of same title adopted. F. Mar. 13, 2008; eff. Apr. 2, 2008.

480-13-.04 Absence of Pharmacist.

(1) General. When a licensed pharmacist is not physically present in the hospital and the pharmacy is closed, written policies and procedures shall be prepared in advance by the Director of Pharmacy for the provision of drugs to the medical staff and other authorized personnel of the hospital by use of night cabinets and/or by access to the pharmacy. The policies and procedures may include the use of remote order entry pharmacist to ensure that in-patient needs are met at the hospital when a licensed pharmacist is not physically present. All policies and procedures providing for the use of night cabinets and/or access to the pharmacy when a licensed pharmacist is not physically present shall be made available to the Georgia State Board of Pharmacy, its designee, or a representative of the Georgia Drugs and Narcotics Agency (GDNA), upon request.

(2) A hospital utilizing a remote order entry pharmacist shall maintain a record of the name and address of such pharmacist, evidence of current licensure in the State of Georgia, and the address of each location where the pharmacist will maintain records of remote order entries.

(3) The Director of Pharmacy shall insure that any remote order entry pharmacist shall have secure electronic access to the hospital pharmacy's patient information system and to other electronic systems that the on-site pharmacist has access to when the pharmacy is open. The remote order entry pharmacist must be able to contact the prescribing practitioner to discuss any concerns identified during the pharmacist's review of the patient information. Each remote entry record must comply with all recordkeeping requirements and shall identify, by name or other unique identifier, the pharmacist involved in the preview and verification of the order. The remote entry pharmacist shall maintain records of any and all records entered for the hospital for a minimum of two (2) years, and such records shall be readily available for inspection, copying by, or production of upon request by the Board, its designee, or a representative for the Georgia Drugs and Narcotics Agency (GDNA), upon request.

(4) Night cabinets. Access to drugs, in the absence of a licensed pharmacist, shall be by locked cabinet(s) or other enclosure(s) constructed and located outside of the pharmacy area to which only specifically authorized personnel as indicated by written policies and procedures may obtain access by key or combination, and which is sufficiently secure to deny access to unauthorized persons. The Director of Pharmacy shall, in conjunction with the appropriate committee of the hospital, develop inventory listings of those drugs to be included in such cabinet(s) and shall insure that:

(a) Such drugs are available therein, properly labeled, with drug name, strength, lot number and expiration date;

(b) Only pre-packaged drugs are available therein, in amounts sufficient for immediate therapeutic requirements;

(c) Whenever access to such cabinet(s) has been gained, written practitioner's orders and proofs of use for controlled substances must be provided;

(d) All drugs therein are inventoried no less than once per week. A system of accountability must exist for all drugs contained therein; and

(e) Written policies and procedures are established to implement the requirements of this subsection.

(5) Access to pharmacy. Whenever a drug is not available from floor supplies or night cabinets, and such drug is required to treat the immediate needs of a patient whose health would otherwise be jeopardized, such drug may be obtained from the pharmacy pursuant to the practitioner's order and the requirements of this subsection. One nursing supervisor (registered professional nurse or licensed practical nurse) in any given shift may have access to the pharmacy and may remove drugs there from. Such licensed nurse shall be designated in writing by the Director of Pharmacy of the hospital and shall, prior to being permitted to obtain access to the pharmacy, receive thorough education and training approved by the Director of Pharmacy, in the proper methods of access, removal of drugs, and records and procedures required. The Director of Pharmacy, or designee, shall document the nurse's competence following the education and training. In addition, such licensed nurse accessing a closed pharmacy must receive specific step-by-step instructions in a policy manual, approved by the Director of Pharmacy, before accessing the pharmacy. At any time that a nurse is accessing a closed pharmacy, the Director of Pharmacy must designate a licensed pharmacist, not a remote order entry pharmacist, who is available to the nurse by telephone, and who, in the event of an emergency, is available to come to the hospital. When a nurse accesses drugs directly from the closed pharmacy, the nurse must:

(a) provide a copy of the order,

(b) document on a suitable form the name of the drug, the strength and amount of the drug removed, the date and time it was removed, and sign the form.

(c) The container from which the drug is removed shall then be placed conspicuously to be promptly reviewed and inspected by the next pharmacist coming on duty. The Director of Pharmacy's policies and procedures must provide that the next pharmacist physically coming into the pharmacy must document that they have reviewed the drugs removed and the orders filled.

(6) Emergency kits/crash carts. Drugs may also be provided for use by authorized personnel by emergency kits/crash carts, provided such kits/carts meet the following requirements:

(a) Emergency kit/crash cart drugs defined. Emergency kit/crash cart drugs are those drugs which may be required to meet the immediate therapeutic needs of patients and

which are not available from any other authorized source in sufficient time to prevent risk of harm to patients;

(b) Drugs included. The Director of Pharmacy and the medical staff of the hospital shall jointly determine the drugs, by identity and quantity, to be included in the emergency kits/crash carts;

(c) Storage. Emergency kits/crash carts shall be sealed and stored in limited access areas to prevent unauthorized access, and to insure a proper environment for preservation of the drugs within them;

(d) Labeling — exterior. The exterior of emergency kits/crash carts shall be labeled so as to clearly and unmistakably indicate that it is an emergency drug kit/crash cart and is for use in emergencies only. In addition, a listing of the drugs contained therein, including name, strength, quantity, and expiration date of the contents shall be attached. Nothing in this section shall prohibit another method of accomplishing the intent of this section, provided such method is approved by an agent of the Board;

(e) Labeling — interior. All drugs contained in emergency kits/ crash carts shall be labeled in accordance with such State and Federal Laws and Regulations which pertain thereto; and shall also be labeled with such other and further information as may be required by the medical staff of the hospital to prevent misunderstanding or risk of harm to the patients;

(f) Removal of drugs. Drugs shall be removed from emergency kits/crash carts only pursuant to a valid practitioner's order, by authorized personnel, or by a pharmacist of the institutional facility;

(g) Notification. Whenever an emergency kit/crash cart is opened, the pharmacy shall be notified; and pharmacy personnel shall restock and re-seal the kit/cart within a reasonable time so as to prevent risk of harm to patients. In the event the kit/cart is opened in an unauthorized manner, the pharmacy and other appropriate personnel of the facility shall be notified;

(h) Inspections. Each emergency kit/crash cart shall be opened and its contents inspected by a pharmacist at least once every ninety (90) days. Upon completion of inspection, the emergency kit/crash cart shall be re-sealed;

(i) Procedures. The Director of Pharmacy shall, in conjunction with the medical staff of the hospital, develop and implement written policies and procedures to insure compliance with the provisions of this subsection.

(7) Authoritative, current antidote information as well as the telephone number of the regional poison control information center shall be readily available in areas outside the pharmacy where these drugs are stored.

(8) Nothing in this rule shall be construed to relieve the hospital pharmacy of the requirement of having an on-site pharmacist to provide routine pharmacy services within the hospital in order to qualify as a licensed pharmacy.

Authority O.C.G.A. Secs. 26-4-27 to 26-4-29, 26-4-83, 26-4-84, 26-4-110. **History.** Original Rule entitled "Absence of Pharmacist" adopted. F. Jan. 24, 1977; eff. Feb. 13, 1977. **Repealed:** New Rule of same title adopted. F. May 5, 1980; eff. May 25, 1980. **Repealed:** New Rule of same title adopted. F. July 24, 2002; eff. Aug. 13, 2002. **Repealed:** New Rule of same title adopted. F. Mar. 13, 2008; eff. Apr. 2, 2008. **Amended:** F. July 26, 2010; eff. Aug. 15, 2010.

480-13-.05 Physical Requirements. Amended.

(1) Area. A hospital pharmacy shall have within the hospital which it serves, sufficient floor space allocated to it to insure that drugs are prepared in sanitary, well-lighted and enclosed places, and which meet the other requirements of this section and the Georgia Pharmacy Laws. The hospital pharmacy space requirements should be a minimum of 10 square feet per hospital bed, which includes all areas assigned and under the direct control of the Director of Pharmacy.
(2) Equipment and supplies. Each hospital pharmacy shall have sufficient equipment and physical facilities for proper compounding, dispensing, and storage of drugs, including parenteral preparations. The equipment and physical facilities shall include the following:
(a) Compounding and dispensing area:
1. A refrigerator in operating condition with a thermometer, preferably a biological refrigerator;
2. A sink in operating condition with hot and cold running water;
3. A Class A Balance and an assortment of metric weights if utilizing a Class A Balance or a Class I or II Electronic Balance as approved in writing by the Board;
4. Graduates of assorted sizes;
5. Mortar and pestle;
6. Two (2) spatulas and a counting tray;
7. Typewriter, word processor, or computer with a label printer;
8. Pill tile; and
9. Other equipment as deemed necessary by the Director of Pharmacy.
(b) Parenteral solution additives area as required in 480-13- .06(2)(a); 1. Laminar flow hood; and
2. Facility for light-dark field examination.
(c) Storage and receiving area;
(d) Manufacturing and packaging area; and
(e) Office space area.
(3) Each hospital pharmacy shall maintain a reference library which includes, at a minimum, the following:
(a) Copy of and/or electronic or computer access to the latest edition of the Georgia Pharmacy Practice Act, the Georgia Controlled Substances Act and the Rules and Regulations of the Georgia State Board of Pharmacy;
(b) Copies of and/or electronic or computer access to current reference materials appropriate to the practice of the hospital pharmacy;
(c) Copy of and/or electronic or computer access to the latest edition of the American Society of Health-system Pharmacists Formulary Service;
(d) Compatibility charts;
(e) Current drug interaction references;
(f) Current antidote information;
(g) Copy of and/or electronic access or computer access to the latest edition of text and reference works covering theoretical and practical pharmacy, reference materials on general, organic, pharmaceutical and biological chemistry, toxicology, pharmacology, sterilization and disinfection.

(4) Storage. All drugs shall be stored in the hospital pharmacy within designated areas which are sufficient to insure proper sanitation, temperature, light, ventilation, moisture control, segregation, and security. Drug storage cabinets and unit dose carts at the nursing station shall be locked when the station is not in attendance by nursing personnel.
(5) Controlled drug storage for Schedule II drugs. An enclosed controlled room with limited access capable of showing forced entry is preferable. However, a safe or metal cabinet adequately locked that is permanently affixed to the structure is acceptable.
(6) Unattended areas. Whenever any area of a hospital pharmacy is not under the personal and direct supervision of authorized personnel, such areas shall be locked.
(7) Security. All areas occupied by a hospital pharmacy shall be capable of being locked by key or combination, so as to prevent access by unauthorized personnel by force. The Director of Pharmacy shall designate in writing, by name and specific area, those persons who shall have access to particular areas within the pharmacy. These areas shall meet the security requirements of Federal and State Laws and Regulations. Only those persons so authorized shall be permitted to enter these areas.
(8) Variances.
(a) The Director of Pharmacy may submit to the Board a typed request for a variance to the provisions relating to minimum equipment requirements. The reasons for the request for a variance must be included. A variance may be granted by the Board only when, in the judgment of the Board, there are sound reasons for granting the variance which relate to the necessary or efficient delivery of health care. After consideration by the Board, the Director of Pharmacy will be notified of the Board's decision in writing.
(b) If approved, said letter(s) will serve as proof of the Board's approval for each variance(s) indicated in the letter, and shall be posted next to the Georgia Drugs and Narcotics Agency inspection report.

Authority O.C.G.A. Secs. 26-4-27, 26-4-28, 26-4-110. **History.** Original Rule entitled "Physical Requirements" adopted. F. Jan. 24, 1977; eff. Feb. 13, 1977. **Repealed:** New Rule of same title adopted. F. May 5, 1980; eff. May 25, 1980. **Repealed:** New Rule of same title adopted. F. July 24, 2002; eff. Aug. 13, 2002.

480-13-.06 Drug Distribution and Control. Amended.

(1) General. A drug distribution system is the entirety of that mechanism by which a prescription drug order is executed, from the time the practitioner transmits the order either orally or in writing to an authorized health professional to the time the ordered drug is administered to the patient or delivered to the patient for self-administration.
(2) Responsibility. The Director of Pharmacy shall be responsible for the safe and efficient distribution, control, and accountability for drugs, including IV solutions and irrigation solutions. The other professional staff of the hospital shall cooperate with the Director of Pharmacy in meeting this responsibility and in ordering, administering, and accounting for the pharmaceutical materials to achieve this purpose. The Director of Pharmacy shall establish written procedures for the distribution of parenteral medications to achieve this goal. Accordingly, the Director of Pharmacy shall be responsible for, at a minimum, the following:
(a) The compounding, admixture, and quality control of large volume parenterals is the responsibility of a pharmacist and shall be prepared under a Laminar Flow Hood or utilizing such other equipment to protect the integrity of the product, within the pharmacy department. Individuals who prepare or administer large volume parenterals must have special training to do so. These functions of IV admixture compounding shall be done primarily by the pharmacy department with exceptions allowed for specialty-care areas such as Intensive Care Units, Cardiac Catheterization Laboratories Intensive Care Units, etc., during emergency situations, or during unattended hours of the pharmacy department. When any part of the above functions (preparing, sterilizing, and labeling parenteral medications and solutions) is performed within the hospital but not under direct pharmacist supervision, the Director of Pharmacy shall be responsible for providing written guidelines and for approving the procedures to assure that all pharmaceutical requirements are met;
(b) All drugs must be identified up to the point of administration;
(c) The pharmacy must receive a direct copy or mechanical copy of a practitioner's order before the first dose of medication is dispensed except as defined by hospital stat order policy;
(d) Utilization of a pharmacy-generated patient profile. The patient profile shall be the official record of medications dispensed to the patient. The patient profile or the ability to generate such profile electronically shall be under the control of the Director of Pharmacy for a period of two (2) years. The patient profile shall contain at a minimum:
1. Given and last name of the patient;
2. Age;
3. Sex;
4. Provisional diagnosis;
5. Room number;
6. Drug product dispensed, date dispensed, strength, dosage form, quantity and directions, and identification of dispensing pharmacist;
7. Identification or differentiation of controlled substances;
8. Intravenous therapy;
9. Selected medical data;
10. Drug history interview (when possible); and

11. Sensitivities and allergies to drugs and foods;
(e) No more than a 72-hour supply of a patient's medication shall be available at the patient-care area at any time except for those drugs in bulk packages which cannot be repackaged in unit-dose containers;
(f) Manufacture of drugs, if applicable;
(g) Establishment of specifications or use of compendia specifications for procurement of drugs, chemicals, devices and biologicals, subject to approval of the appropriate committee of the hospital;
(h) Participation in the development of a drug formulary for the hospital;
(i) filling and labeling all containers from which drugs are to be administered, after visual screening to determine that same are neither adulterated nor misbranded;
(j) Maintaining and making available a sufficient inventory of antidotes and other emergency drugs. Current antidote information, telephone numbers of regional poison control center(s) and other emergency assistance organizations, and other material and information as may be deemed necessary shall be maintained;
(k) Records of all transactions of the hospital pharmacy as may be required by law, and as may be necessary to maintain accurate control over the accountability for all pharmaceutical drugs, devices and materials. Nothing in this section shall prohibit the use of computer hard copy, where such copy meets all other requirements of the law;
(l) Participation in those aspects of the hospital patient care evaluation program which relate to pharmaceutical drug, device and material utilization and effectiveness; and
(m) Efficient messenger and delivery service to connect the pharmacy with appropriate parts of the facility throughout the normal workday.
(3) Labeling.
(a) For use inside the hospital, all drugs dispensed by a hospital pharmacy, including those for standard ward inventory, shall be dispensed in appropriate containers and adequately labeled so as to identify at a minimum, brand name or generic name, strength, lot number, and expiration date.
(b) For use outside the hospital, all drugs dispensed by a hospital pharmacy to patients about to be discharged or on leave of absence shall be labeled with the following information:
1. Name, address, and telephone number of the hospital pharmacy;
2. Date and identifying serial number;
3. Patient's given and last name;
4. Name of drug, (brand or generic) and strength;
5. Directions for use by patient;
6. Name of prescribing practitioner;
7. Required precautionary information regarding controlled substances; and
8. Such other and further accessory cautionary information as may be required or desirable for proper use by and safety of the patient.
(c) Drugs added to parenteral solutions. Wherever any drugs are added to parenteral solutions, whether within or outside the direct and personal supervision of a licensed pharmacist, such admixture shall be labeled with a distinctive supplementary label indicating the name and amount of the drug added, date and time of addition, expiration date and time if applicable, and the identity of the person so adding.

(4) Discontinued drugs. The Director of Pharmacy shall develop and implement policies and procedures to insure that outdated drugs and containers with worn, illegible, or missing labels are returned to the pharmacy for proper disposition.
(a) Full doses of controlled substances prepared for administration and not given must be destroyed by a licensed pharmacist or a licensed nurse and one witness. Any portions of controlled substances discontinued and taken from a medication delivery device shall be destroyed by a licensed pharmacist or a licensed nurse and one witness. The two persons witnessing the destruction must sign the destruction record at the time of destruction. The destruction record shall be returned to the pharmacy and must be signed by the pharmacist who is ultimately responsible for the accuracy of the information contained therein.
(b) In accordance with the policies and procedures developed by the Director of Pharmacy, discontinued non-controlled substances dispensed to hospital patients shall be returned to the pharmacy and evaluated by the licensed pharmacist to assure the integrity of the medication. If the integrity can be assured, the medication may be returned to the hospital's drug distribution system for re-issue. When the integrity cannot be assured, the medication must be separated immediately from the regular drug inventory and destroyed or transferred to a reverse distributor with a current license issued by the Board. The following method of destruction of non-controlled substances is approved by the Board for medications dispensed to hospital patients or patients residing in nursing homes or long term care units which are part of a hospital facility;
1. Placed in a secure storage area at the facility separated from other medications. The drugs may be destroyed at the facility by the pharmacist and another licensed healthcare practitioner designated by the facility. However, before the destruction can take place, it must be verified that an inventory has been taken and recorded. The facility must maintain a written record of the destruction and the inventory for a two year period. This record shall include at a minimum the date, time, and personnel involved with the destruction and the method of destruction; or
2. If the drugs are to be transferred to a reverse distributor with a current license issued by the Board, a record of the following must be maintained by the hospital pharmacy for a minimum of two years:
(i) An inventory of the drugs to be transferred including the names of the drugs; the dosage form(s) of the drugs and the quantity of the drugs; the inventory shall be verified by a pharmacy representative and a representative of the reverse distributor;
(ii) The date and time the drugs were taken from the pharmacy;
(iii) The name, Board permit number, address and telephone number of the destruction firm removing the drugs;
(iv) The name and signature of the responsible person representing the reverse distributor who is physically removing the drug(s);
(v) The name and signature of the pharmacist representing the pharmacy transferring the drug(s) to the reverse distributor.
(c) The following methods of destruction of controlled substances are approved by the Board of Pharmacy:
1. A securely attached wooden or metal cabinet within a locked limited-access area shall be used to store the drugs until the drugs are destroyed. When controlled drugs are discontinued or the patient expires, the medication shall be pulled from the active stock

immediately and inventoried and verified by a pharmacist along with another licensed healthcare professional. The inventory must be recorded into a permanent record and the drugs shall then be placed in the aforementioned cabinet. This medication shall remain within the locked cabinet until such time as it is removed for destruction.
2. The pharmacist shall establish a form, which shall include the following data:
(i) Date of discontinuance or inventory date;
(ii) Name of patient;
(iii) Name of pharmacy;
(iv) Identifying serial numbers;
(v) Name and strength of the drug; and
(vi) Quantity of the drugs in container(s) at the time of inventory.
3. A licensed pharmacist or licensed nurse and one witness must destroy the drugs.
4. Inventory of the drugs included in the final destruction must be taken with one copy retained by the facility. The inventory shall be certified by the two witnesses present at the destruction in the following format:
"We, whose signatures appear below, certify that these controlled substances have been reconciled, accounted for, and destroyed at _____ (location) on _____(date) at _____o'clock."
Name of drug
Strength of drug
Dosage form
Quantity of drug

_____
(Signature and Title)

_____
(Signature and Title)

_____
(Signature and Title)

5. The Board and/or the GDNA may prohibit any pharmacist or hospital pharmacy from utilizing this method.
(d) A method of off-site destruction allowable by the Board is as follows:
1. The drugs to be destroyed shall be immediately removed from the active stock and stored in a separate and secure location in the pharmacy until the drugs are transferred. When the drugs are transferred to a reverse distributor licensed by the Board, an inventory must be recorded and include the following information: the names of the drugs, the dosage forms of the drugs and the quantities of the drugs taken and witnessed by an authorized representative of the hospital pharmacy and the responsible person representing the reverse distributor.
2. A receipt including the date and time the drugs were taken from the pharmacy; the name, Board permit number, address and telephone number of the reverse distributor removing the drugs; the inventory of the drugs; the name, signature and title of the responsible person representing the reverse distributor; and the name, signature and title of the pharmacy representative transferring the drugs. This receipt/record must be maintained by the hospital pharmacy for a minimum of two years.

(5) Prescription drug orders. Drugs may be dispensed from the hospital pharmacy only upon written orders, direct or mechanical copies thereof, of authorized practitioners.
(a) Authorization. The appropriate committee of the hospital shall, from time to time as appropriate, designate those practitioners who are authorized to issue prescription drug orders to the pharmacy.
(b) Abbreviations. Orders employing abbreviations and chemical symbols shall be utilized and filled only if such abbreviations and symbols appear on a published list of accepted abbreviations developed by the appropriate committee of the hospital.
(c) Requirements — Prescription drug orders for drugs, devices or materials for use by in-patients. Prescription drugs orders for use by in-patients shall, at a minimum, contain:
1. Patient name and room number;
2. Drug name, strength, directions for use; and
3. Date and practitioner's signature.
(d) Requirements — Prescription drug orders for drugs, devices or materials for use by out-patients. Prescription drug orders for drugs, devices or materials for use by out-patients shall, at a minimum, contain all of the information required by Rule 480-13-.06(5)(c), and in addition include:
1. Quantity to be dispensed;
2. Practitioner's address and Drug Enforcement Administration identification code, if applicable, and
3. Patient's address, if applicable.
(6) Accountability of controlled drugs.
(a) Proof of use of controlled drugs on standard ward inventory. Proof of use of controlled substances and such other drugs as may be specified by the appropriate committee of the hospital, shall be submitted to the pharmacy, on forms provided by the pharmacy. Proof of use forms shall specify at a minimum:
1. Name of drug, strength, and dosage form;
2. Dose administered;
3. Name of authorized practitioner. This shall include, at a minimum, the initial and last name;
4. Given and last name of the patient;
5. Date and time of administration to the patient;
6. Signature of the individual administering, which shall include at a minimum, the initial, last name, and title;
7. Documentation of the destruction of any and all unused portions by two signature verifications;
8. Proof of receipt of the medications that bears identifying serial numbers; and
9. Date the medication was issued and the date that the proof of use form was returned to the pharmacy.
(b) Anesthesia departments that obtain controlled drugs from the hospital pharmacy must show accountability of the controlled drugs by proof of use as defined above.
(c) Use of computer generated hard copy is permitted where such copy meets all other requirements of the law.
(d) Any hospital pharmacy licensed by the Georgia State Board of Pharmacy and in which controlled substances are administered to patients, may make on-premises

destruction of small quantities of controlled substances prepared for parenteral and oral administration provided:
1. The controlled substance is either a whole dose or a partial dose of a single-dosage unit; and
2. The single-dosage unit from which the ordered dose was prepared is the nearest possible size to the dose ordered.
(e) Perpetual inventory of Schedule II substances shall be required and accountability of said drugs shall be by a proof of use form.
(7) Recall. The Director of Pharmacy shall develop and implement a policy and procedure to assure that all drugs within the hospital included on a recall are returned to the pharmacy for proper disposition.
(8) Suspected adverse drug reactions. All suspected adverse drug reactions shall be reported immediately to the ordering authorized practitioner, the pharmacy, and to the appropriate committee of the hospital. An appropriate entry on the patient's medical record shall also be made.
(9) Records and reports. The Director of Pharmacy shall maintain access to and submit, as appropriate, such records and reports as are required to insure the patient's health, safety and welfare. Such records shall be readily available and subject to inspections by the Board of Pharmacy, the GDNA or its employees. These shall include, at a minimum, the following:
(a) Patient profile;
(b) Proof of use;
(c) Reports of suspected adverse drug reactions;
(d) Inventories of night cabinets and emergency kits/crash carts;
(e) Inventories of the pharmacy;
(f) Biennial controlled substances inventories;
(g) Alcohol and flammables reports; and
(h) Such other records and reports as may be required by state Law and the Rules and Regulations of the Board of Pharmacy.
(10) Standard ward inventory (floor stock). The pharmacy department may distribute drugs within a hospital for the purpose of establishing and/or maintaining a standard ward inventory. Such drugs may be distributed only upon a signed requisition from a nurse or other authorized representative of said hospital or by an inventory replacement system. These drugs may be administered only pursuant to a practitioner's order. This practitioner's order will be forwarded to the pharmacy and these medications will be recorded on the pharmacy patient profile. A record of administration of drugs administered to patients in ancillary areas such as but not limited to the operating room, emergency room, anesthesiology, and x-ray shall be forwarded to the pharmacy and these medications shall be recorded on the patient profile. A survey of usage trends of each standard ward inventory shall be prepared monthly. Such records shall be retained for a period of two years.
(11) Emergency room dispensing. An authorized practitioner may, when drugs or controlled substances are not otherwise available from a licensed pharmacy, dispense an emergency amount of medication, but only sufficient quantities until such time as medication can be obtained from a pharmacy licensed as a retail pharmacy. Nurses or other unauthorized personnel may not dispense medication from the emergency room.

The total act of dispensing shall be performed by an authorized practitioner in accordance with Pharmacy Laws, Rules and Regulations. Such medications shall be labeled as required in Section 480-13-.06(3)(b).

Authority O.C.G.A. Secs. 26-4-27, 26-4-28, 26-4-37, 26-4-110. **History.** Original Rule entitled "Drug Distribution and Control" adopted. F. Jan. 24, 1977; eff. Feb. 13, 1977. **Repealed:** New Rule of same title adopted. F. May 5, 1980; eff. May 25, 1980. **Amended:** F. Feb. 4, 1987; eff. Feb. 24, 1987. **Amended:** F. Nov. 7, 1994; eff. Nov. 27, 1994. **Repealed:** New Rule of same title adopted. F. July 24, 2002; eff. Aug. 13, 2002.

480-13-.07 Administration of Drugs. Amended.

(1) General. Drugs shall be administered only upon the orders of those members of the medical staff who have been granted staff privileges. Drugs shall be administered by authorized licensed personnel in accordance with policies and procedures specified by the appropriate committee of the facility, under applicable Law and Rules and Regulations, and by usual and customary standards of good medical practice. The Director of Pharmacy shall develop and implement policies and procedures concerning self-administration of medication.
(2) Self-administration. Self-administration of drugs by patients shall be permitted only when specifically authorized by the patient's authorized practitioner, provided, however, the patient has been educated and trained in the proper manner of self-administration and there is no risk of harm to the patient. The Director of Pharmacy shall develop policies and procedures relating to the self-administration of drugs.

Authority O.C.G.A. Secs. 26-4-27, 26-4-28, 26-4-110. **History.** Original Rule entitled "Administration of Drugs" adopted. F. Jan. 24, 1977; eff. Feb. 13, 1977. **Repealed:** New Rule of same title adopted. F. May 5, 1980; eff. May 25, 1980. **Repealed:** New Rule of same title adopted. F. July 24, 2002; eff. Aug. 13, 2002.

480-13-.08 Drugs from Outside Sources. Amended.

The Director of Pharmacy shall establish policies and procedures relating to drugs brought into the hospital by patients or patients' family members. Such drugs shall not be administered unless they can be precisely identified. Administration shall be pursuant only to an authorized practitioner's prescription drug order. If such drugs are not to be administered, the medication shall be returned to an adult member of the patient's family or stored by the pharmacy and re- turned to the patient upon discharge. Medications received from an outside source, but not to be administered, may not be stored on the patient care unit. Nothing in this section shall prohibit another method of accomplishing the intent of this section provided such method is approved by an agent of the Board of Pharmacy.

Authority O.C.G.A. Secs. 26-4-27 to 26-4-29, 26-4-110, 26-4-115. **History.** Original Rule entitled "Drugs from Outside Sources" adopted. F. Jan. 24, 1977; eff. Feb. 13, 1977. **Repealed:** New Rule of same title adopted. F. May 5, 1980; eff. May 25, 1980. **Repealed:** New Rule of same title adopted. F. July 24, 2002; eff. Aug. 13, 2002.

480-13-.09 Investigational Drugs. Amended.

Investigational drugs shall be properly labeled and shall be administered only under the personal and direct supervision of the principal practitioner- investigator or his/her authorized clinician(s) with prior approval of the appropriate committee(s) of the hospital. Investigational drugs shall be administered in accordance with an approved protocol that includes any requirements for a patient's appropriate informed consent. Nurses may administer such drugs only after they have been educated regarding such drugs by the clinician or the pharmacist. A central unit shall be maintained wherein essential information regarding such drugs may be obtained. Investigational drugs in use shall be properly stored, distributed, and controlled maintaining the confidentiality of patient-medical staff information. The Director of Pharmacy shall be responsible for policies and procedures concerning use of investigational drugs.

Authority O.C.G.A. Secs. 26-4-27, 26-4-28, 26-4-110. **History.** Original Rule entitled "Investigational Drugs" adopted. F. Jan. 24, 1977; eff. Feb. 13, 1977. **Repealed:** New Rule of same title adopted. F. May 5, 1980; eff. May 25, 1980. **Repealed:** New Rule of same title adopted. F. July 24, 2002; eff. Aug. 13, 2002.

480-13-.10 Inspections. Amended.

(1) Monthly. The Director of Pharmacy shall no less than once per month, personally or by qualified designee, inspect all matters within his/her jurisdiction and responsibility and make appropriate written records of such inspections. Such inspections shall, at a minimum, verify that:
(a) Drugs are dispensed only by licensed pharmacists or licensed pharmacy interns acting under the direct supervision of a licensed pharmacist;
(b) Non-licensed pharmacy personnel are properly directed and supervised;
(c) Drugs for external use are stored separately, and apart from drugs for internal use or injection;
(d) Drugs requiring special storage conditions to insure their stability are properly stored;
(e) No outdated drugs are stocked in the hospital pharmacy or the facility it serves;
(f) Distribution and administration of controlled substances are properly and adequately documented and reported by both pharmacy and other licensed medical personnel;
(g) Standard ward inventory (floor stock). Verification of standard ward inventory lists and accountability, including such updating, if applicable, are maintained;
(h) All necessary and required security and storage standards are met;
(i) Metric-apothecaries' weight and measure conversion tables and charts are available;
(j) All policies and procedures of the Director of Pharmacy and of appropriate committees of the hospital relevant to the pharmacy are followed;
(k) All discounted and out-dated medications are returned to the pharmacy for proper disposition; and
(l) Disinfectants and other similar supplies intended for external use are stored separately and apart from drugs intended for internal (oral) or parenteral use.
(2) Board Inspection. The Board of Pharmacy inspections shall be conducted by representatives of the Georgia Drugs and Narcotics Agency (GDNA) no less than once every two (2) years. Such inspections shall include all aspects of the management and operation of all hospital pharmacies in this State to verify compliance with the Pharmacy Laws, the Rules and Regulations of the Board of Pharmacy, and such other standards as may be appropriate to insure that the health, safety and welfare of patients of the hospital serviced by the pharmacy are protected. A written report shall be filed with the GDNA, the Director of Pharmacy, and the hospital administrator. Any discrepancies or deficiencies noted shall be corrected within a reasonable time. Written notice of such corrections shall be filed with the GDNA within thirty (30) days after receipt of the inspection notice.
(a) The Director of Pharmacy of each hospital pharmacy shall obtain a copy of the current Board permit of every drug wholesaler and/or reverse distributor from which controlled substances and/or dangerous drugs are purchased and/or returned. Such copies shall be made available during the GDNA's inspection.

Authority O.C.G.A. Secs. 26-4-27, 26-4-28, 26-4-110. **History.** Original Rule entitled "Inspection" adopted. F. Jan. 24, 1977; eff. Feb. 13, 1977. **Repealed:** New Rule of same title adopted. F. May 5, 1980; eff. May 25, 1980. **Repealed:** New Rule entitled "Inspections" adopted. F. July 24, 2002; eff. Aug. 13, 2002.

CHAPTER 461 PHARMACISTS AND PHARMACY

SECTION

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§461-1 Definitions. For the purposes of this chapter:

"Institutional facility" *[Definition kept per Act 51, SLH 2010, §3.]* means an organization or facility whose primary purpose is to provide a physical environment for patients to obtain health care services or at-home care services, and that uses the services of an on-site pharmacy, an off-site pharmacy, or a pharmacist contractor at which medication storage is managed by personnel of the facility. "Institutional facility" includes but is not limited to a:

(1) Hospital;
(2) Convalescent home;
(3) Skilled nursing facility;
(4) Intermediate care facility;
(5) Extended care facility;
(6) Rehabilitation center;
(7) Health maintenance organization clinic;
(8) Psychiatric center;
(9) Mental retardation center;

(10) Penal institution;
(11) Hospice facility;
(12) Supervised living group; or
(13) Prescribed practitioner's office.

Amended 0910

§461-14 Permits for operation of pharmacy; notification of remote dispensing pharmacy. *[To be repealed on January 1, 2013, per Act 212, SLH 2008, §7. Repeal date amended to January 2, 2014, per Act 96, SLH 2009, §7.]* (a) It shall be unlawful for any person to operate, maintain, open, change location, or establish any pharmacy or remote dispensing pharmacy within the State without having first obtained a permit or prior notification from the board.
(b) Application for permits and notifications shall be made on a form to be prescribed by the board. Separate applications shall be made and separate permits and notifications issued for each separate place at which is carried on any of the operations for which a permit or notification is required.
(c) On evidence satisfactory to the board, a permit or notification shall be issued; provided that:
(1) The pharmacy for which the permit or notification is sought is or will be in full compliance with this chapter and rules of the board;
(2) The location and appointments of the pharmacy are such that it can be operated and maintained without endangering the public health or safety; and
(3) The pharmacy will be under the personal and immediate supervision of a registered pharmacist.
(d) An application for a permit shall be refused for noncompliance with this section but only after notice to the applicant and a full and fair hearing.
(e) To operate a remote dispensing pharmacy, a responsible pharmacy shall submit to the board the following information:
(1) A completed form prescribed by the board;
(2) The name, address, and permit number of the responsible pharmacy;
(3) The name and license number of the pharmacist in charge of the responsible pharmacy;
(4) The name of the institutional health care facility and the address of the remote dispensing pharmacy;
(5) A floor plan of the remote dispensing pharmacy, which shall indicate the space or location of the remote dispensing machine;
(6) The date the remote dispensing pharmacy will be ready for operations;
(7) A description of the security system;
(8) A description of the computer link, video link, and audio link; and

(9) Photographs of the remote dispensing pharmacy area, including but not limited to the remote dispensing machine, the security system, computer link, video link, audio link, confidential-communications area, and locked cabinet.

A remote dispensing pharmacy's failure to notify the board in writing within thirty days of any changes to the information described in paragraphs (1) to (9) or failure to comply with this chapter shall be considered a violation of this chapter and shall result in disciplinary action against the pharmacist in charge and the responsible pharmacy.

(f) Permits and licenses issued under this section and section 461-15 may be closed upon written request from the holder of the permit or license. The board shall approve all requests by the holder for closure of a permit or license. Once the closure is approved, the holder of the closed permit or license shall be required to reapply as a new applicant to conduct business where a permit or license is required.

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TITLE 54
PROFESSIONS, VOCATIONS, AND BUSINESSES

CHAPTER 17
PHARMACISTS

54-1705. DEFINITIONS. In this chapter:

(1) "Board of pharmacy" or "board" means the Idaho state board of pharmacy.

(2) "Counseling" or "counsel" means the effective communication by the pharmacist of information as set out in this chapter, to the patient or caregiver, in order to improve therapeutic outcomes by maximizing proper use of prescription medications and devices. Specific areas of counseling shall include, but are not limited to:

(a) Name and strength and description of the medication;

(b) Route of administration, dosage, dosage form, continuity of therapy and refill information;

(c) Special directions and precautions for preparation, administration, storage and use by the patient as deemed necessary by the pharmacist;

(d) Side effects or adverse effects and interactions and therapeutic contraindications that may be encountered, including their avoidance, which may interfere with the proper use of the medication or device as was intended by the prescriber, and the action required if they occur;

(e) Techniques for self-monitoring drug therapy; and

(f) Action to be taken in the event of a missed dose.

(3) "Deliver" or "delivery" means the actual, constructive or attempted transfer of a drug or device from one (1) person to another, whether or not for a consideration.

(4) "Device" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar related article including any component part or accessory which is:

(a) Recognized in the official United States Pharmacopoeia or official National Formulary, other drug compendia or any supplement to them;

(b) Intended for use in the diagnosis of disease or other conditions, or the cure, mitigation, treatment or prevention of disease in man or other animal;

(c) Intended to affect the structure or any function of the body of man or other animal, and which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animal, and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

(5) "Dispense" or "dispensing" means the preparation and delivery of a prescription drug pursuant to a lawful order of a practitioner in a suitable container appropriately labeled for subsequent administration to or use by a patient or other individual entitled to receive the prescription drug.

(6) "Distribute" means the delivery of a drug other than by administering or dispensing.

(7) "Drug" means:

(a) Articles recognized as drugs in the official United States Pharmacopoeia, official National Formulary, official Homeopathic Pharmacopoeia, other drug compendia or any supplement to any of them;

(b) Articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animal;

(c) Articles, other than food, intended to affect the structure or any function of the body of man or other animals; and

(d) Articles intended for use as a component of any articles

(23) "Pharmacist" means an individual licensed by this state to engage in the practice of pharmacy or a pharmacist licensed in another state who is registered by the board of pharmacy to engage in the practice of telepharmacy across state lines.

(24) "Pharmacy" means any facility, department or other place where prescriptions are filled or compounded and are sold, dispensed, offered or displayed for sale, which has, as its principal purpose, the dispensing of drug and health supplies intended for the general health, welfare and safety of the public.

(25) "Practice of telepharmacy" means the provision of pharmaceutical care by registered or licensed pharmacies and pharmacists located within United States jurisdictions through the use of telecommunications or other technologies to patients at distances that are located within United States jurisdictions, as defined in the rules of the board.

(26) "Practice of telepharmacy across state lines" means the practice of telepharmacy when the patient is located within the state of Idaho and the pharmacist is located in a United States jurisdiction outside the state of Idaho, as defined in the rules of the board.

(27) "Practitioner" means a person licensed in this state and permitted by such license to dispense, conduct research with respect to or administer drugs in the course of professional practice or research in this state.

(28) "Precursor" means a substance, other than a legend drug which is an immediate chemical intermediate that can be processed or synthesized into a legend drug, and is used or produced primarily for use in the manufacture of a legend drug by persons other than persons licensed to manufacture such legend drugs by the Idaho board of pharmacy, registered by the state board of health and welfare, or licensed to practice pharmacy by the Idaho board of pharmacy.

(29) "Preceptor" means a pharmacist licensed in the state and in good standing, who supervises the internship training of a registered intern. The preceptor shall be actively engaged in the practice of pharmacy on a full-time employment basis at a registered preceptor site.

(30) "Preceptor site" means any training site for pharmacy interns and externs registered with the board pursuant to board rule.

(31) "Prescription drug or legend drug" means a drug which, under federal law is required, prior to being dispensed or delivered, to be labeled with one (1) of the following statements:

(a) "Caution: Federal law prohibits dispensing without a prescription"; or

(b) "Rx Only"; or

(c) "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian";

or a drug which is required by any applicable federal or state law or regulation to be dispensed on prescription only or is restricted to use by practitioners only.

(32) "Prescription drug order" means a lawful written or verbal order of a practitioner for a drug or device for an ultimate user of the drug or device, issued and signed by a practitioner, or an order transmitted verbally from a practitioner or the practitioner's agent to a pharmacist in a pharmacy, or transmitted verbally from a practitioner and immediately reduced to writing by a licensed practical nurse or licensed professional nurse in an institutional facility for a patient or resident of such facility.

(33) "Prospective drug review" includes, but is not limited to, the following activities:

(a) Evaluation of the prescription or medication order for:

(i) Known allergies;

(ii) Rational therapy contraindications;

(iii) Reasonable dose and route of administration; and

(iv) Reasonable directions for use.

(b) Evaluation of the prescription or medication order for duplication of therapy.

(c) Evaluation of the prescription or medication order for interactions:

(i) Drug-drug;

(ii) Drug-food; and

(iii) Drug-disease.

(d) Evaluation of the prescription or medication order for proper utilization:

(i) Over or under utilization; and

(ii) Abuse/misuse.

(34) "Record" means all papers, letters, memoranda, notes, prescriptions, drug orders, invoices, statements, patient medication

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TITLE 54
PROFESSIONS, VOCATIONS, AND BUSINESSES

CHAPTER 17
PHARMACISTS

54-1729. REGISTRATION AND LICENSURE OF FACILITIES. (1) All drug or device outlets doing business in or into Idaho shall annually register with or be licensed by, as applicable, the board of pharmacy.

(2) Each drug or device outlet shall apply for a certificate of registration or a license in one (1) of the following classifications:

(a) Retail pharmacy;
(b) Institutional facility;
(c) Manufacturer;
(d) Wholesaler;
(e) Veterinary drug outlet;
(f) Telepharmacy across state lines;
(g) Mail service pharmacy;
(h) Limited service outlet.

(3) The board shall establish by rule under the powers granted to it under sections 54-1718 and 54-1719, Idaho Code, the criteria which each drug outlet, that has employees or personnel engaged in the practice of pharmacy, must meet to qualify for registration or licensure in each classification designated in subsection (2) of this section. The board may issue various types of certificates with varying restrictions to such limited service outlets in subsection (2) where the board deems it necessary by reason of the type of drug outlet requesting a certificate.

(4) It shall be lawful for a drug outlet registered or licensed under this section to sell and distribute nonprescription drugs. Drug outlets engaging in the sale and distribution of such items shall not be deemed to be improperly engaged in the practice of pharmacy. No rule will be adopted by the board under this chapter which shall require the sale of nonprescription drugs by a licensed pharmacist or under the supervision of a licensed pharmacist or otherwise apply to or interfere with the sale and distribution of such medicines.

(5) Drug outlets registered under subsection (2)(f) of this section shall pay the same registration fee as those registering under subsection (2)(b) of this section, but shall also pay the actual costs of the out-of-state inspection of the drug outlet as may be required by the board, including the transportation, lodging and related expenses of the board's inspector. Nothing in this section shall preclude the board, in lieu of an inspection by the board, from relying on an inspection of the drug outlet conducted by the regulatory authority of the state within which the drug outlet is located.

History:

[54-1729, added 1979, ch. 131, sec. 3, p. 420; am. 1985, ch. 21, sec. 1, p. 33.; am. 2009, ch. 244, sec. 5, p. 753; am. 2011, ch. 135, sec. 3, p. 379.]

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Prior to the commencement of structural remodeling that impacts the periphery or security of an existing pharmacy, a floor plan must be submitted to, and approved by, the Board. The prescription preparation area (including the patient consultation, merchandising, and waiting areas, if applicable), storeroom, restroom, partitions (including, but not limited to, walls, doors, and windows), trade fixtures, and appropriate elevations must be indicated on the submitted floor plan. (3-21-12)

609. PHARMACY CHANGE OF OWNERSHIP OR PERMANENT CLOSING.

01. Board Notification. The registrant must notify the Board of a pharmacy's change of ownership or permanent closure at least ten (10) days prior to the event. The notice must include: (3-21-12)

a. The name and address of the pharmacy to be sold or closed; (3-21-12)

b. The date of sale or closure; (3-21-12)

c. The name and address of the business acquiring the prescription inventory; and (3-21-12)

d. The name and address of the pharmacy acquiring the prescription files and patient profiles in compliance with the records retention requirement. (3-21-12)

02. Public Notice. A registrant must notify the general public of the pharmacy's permanent closing at least ten (10) days prior to closing. The notice must include the date of closure and the new location of the prescription files. Notice must be provided by prominent posting in a public area of the pharmacy. (3-21-12)

03. Pharmacy Signs. Unless sold and transferred to another pharmacy operator, a registrant must remove or completely cover each sign and other exterior indication that the premises was a pharmacy within thirty (30) days after the date a pharmacy permanently ceases operations. (3-21-12)

04. Transfer or Other Disposition of Drugs and Prescription Files. The PIC of a pharmacy that ceases operation must adequately secure and protect the drug product inventory from diversion, deterioration, or other damage until lawful transfer or disposition and must retain a closing inventory of controlled substances. (3-21-12)

05. Pharmacy Change of Ownership. A change of ownership of a currently registered pharmacy will require the submission and approval of a new pharmacy registration application but will not require an onsite inspection prior to issuance of a pharmacy registration unless structural remodeling occurs. (3-21-12)

610. -- 619. (RESERVED)

620. INSTITUTIONAL FACILITY -- PRACTICE OF PHARMACY AND ADMINISTRATION AND CONTROL OF DRUGS AND DEVICES.

These institutional facility rules are applicable to the practice of pharmacy and the administration and control of drugs and devices within institutional facilities or by persons employed by them. (3-21-12)

621. INSTITUTIONAL FACILITY WITH ONSITE PHARMACY -- MINIMUM RESPONSIBILITIES.

01. Institutional Pharmacy Staffing. The director must be assisted by a sufficient number of additional pharmacists, student pharmacists, and technicians as may be required to operate the pharmacy competently, safely, and adequately to meet the needs of the patients of the facility. (3-21-12)

02. Inventory Management. The professional staff of the institutional facility must cooperate with the director to manage the responsibilities of ordering, administering, and accounting for drugs, devices, and other pharmaceutical materials. (3-21-12)

03. Prescribers Authorized by Institutional Facility. The institutional facility must designate and notify the pharmacy of the prescribers authorized to issue drug orders for facility patients. (3-21-12)

04. Approved Use of Abbreviations and Chemical Symbols. A listing of acceptable, or alternatively unacceptable, abbreviations and chemical symbols used by prescribers on drug orders must be developed and distributed by the appropriate committee of the institutional facility. (3-21-12)

05. Director Participation in Patient Care Evaluation Program. The director must participate in the aspects of the institutional facility's patient care evaluation program that relate to pharmaceutical utilization and effectiveness. (3-21-12)

622. INSTITUTIONAL PHARMACY DIRECTOR -- MINIMUM RESPONSIBILITIES.
Each institutional pharmacy must be supervised and directed by an Idaho-licensed pharmacist (referred to herein as "the director") who is knowledgeable in, and thoroughly familiar with, the specialized functions of institutional pharmacies. The director is responsible for ensuring compliance with applicable law and for each activity of the institutional pharmacy, including at least the following: (3-21-12)

01. Policies and Procedures. In coordination with the appropriate institutional facility personnel, the adoption of policies and procedures with sufficient specificity regarding the handling, storage, and dispensing of drugs within the institution to protect public health and safety and ensure compliance with these rules and other applicable law. (3-21-12)

02. Formulary or Drug List Development. The participation in any development of a formulary or drug list for the facility. (3-21-12)

03. Product Procurement. The procurement of drugs, chemicals, biologicals, devices, or other products used by the institutional facility for patient pharmaceutical care services or for which a drug order is required. (3-21-12)

04. Drug Use, Storage, and Accountability. The safe and efficient dispensing, distribution, control, and secured storage of, and accountability for, drugs within the facility, including at least the following: (3-21-12)

a. Ensuring that drugs stored within the institutional pharmacy or in alternative secured storage areas have proper sanitation, temperature, light, ventilation, moisture control, segregation and security; (3-21-12)

b. Ensuring that outdated or other unusable drugs are identified and stored in a manner that prevents their distribution or administration prior to disposition; (3-21-12)

c. Ensuring that emergency drugs are in adequate and proper supply at designated locations; (3-21-12)

d. Ensuring that requirements applicable to the purchasing, storing, distribution, dispensing, recordkeeping, and disposal of controlled substances are met throughout the institution, including but not limited to, ensuring that controlled substances stored in surgery or emergency departments, nursing stations, ambulatory clinics, diagnostic laboratories or other locations outside of the pharmacy are inaccessible to unauthorized personnel; (3-21-12)

e. Ensuring accurate filling and labeling of containers from which drugs are to be administered or dispensed; (3-21-12)

f. Ensuring appropriate admixture of parenteral products, including serving in an advisory capacity for nursing personnel concerning incompatibility and the provision of proper incompatibility information; and (3-21-12)

g. Ensuring appropriate provision and maintenance, in both the pharmacy and patient care areas, of a sufficient inventory of antidotes and other emergency drugs, current antidote information, telephone numbers of regional poison control centers and other emergency assistance organizations, and other materials and information determined necessary by the appropriate institutional facility personnel. (3-21-12)

05. Emergency Drug Access Protocol. In coordination with the appropriate institutional facility

personnel, the development of an emergency drug access protocol and related training of R.N.s to ensure appropriate knowledge of the proper methods of access, removal of drugs, documentation, and other required procedures prior to the R.N.'s designation for access to emergency drug supplies. (3-21-12)

06. Suspected Adverse Drug Reaction Reporting. The reporting in a timely manner of a suspected adverse drug reaction to the ordering physician and to the appropriate institutional facility personnel. The director may use discretion and, if deemed necessary or advisable for public health or safety, report a suspected reaction to others such as MedWatch, the manufacturer, and the USP. (3-21-12)

07. Records Maintenance. The maintenance of records of institutional pharmacy transactions required by law. (3-21-12)

08. Teaching, Research, and Patient Care Evaluation Programs. The cooperation with any teaching and research programs and the participation in any patient care evaluation programs relating to pharmaceutical utilization and effectiveness within the institutional facility. (3-21-12)

09. Continuous Quality Improvement Program. The development and implementation of a continuous quality improvement program to review and evaluate pharmaceutical services and recommend improvements. (3-21-12)

623. -- 629. (RESERVED).

630. INSTITUTIONAL FACILITY -- GENERAL STANDARDS FOR ADMINISTRATION AND CONTROL OF DRUGS AND DEVICES.

01. Drugs and Devices Dispensed for Administration or Use Within an Institutional Facility. Within an institutional facility, drugs and devices may be dispensed for administration to, or for self-administration or use by, a patient while in the institutional facility only as permitted by applicable law and these rules consistent with usual and customary standards of good medical practice, as follows: (3-21-12)

a. Upon the drug orders of licensed facility prescribers; (3-21-12)

b. Pursuant to an emergency protocol for the administration of drugs without an order in life or death situations; and (3-21-12)

c. By self-administration or use if specifically authorized by the treating or ordering prescriber, the patient has been appropriately educated and trained to perform self-administration, and there is no risk of harm. (3-21-12)

02. Drugs and Devices Dispensed for Administration or Use Outside an Institutional Facility. A drug or device prepared for self-administration or use by a patient while outside the confines of the institutional facility must comply with the standard prescription drug labeling requirements. (3-21-12)

03. Controlled Substances Reporting and Documentation. Distribution, dispensing, delivery, or administration of controlled substances within an institutional facility or by facility personnel must be properly and adequately documented and reported in the time and manner required by the appropriate committee of the institutional facility and the director. (3-21-12)

04. Patient's Personal Drug Supplies. If an admitted patient brings a drug into the institutional facility, the drug must not be administered or used except pursuant to a drug order and only if it can be precisely identified and the quantity and quality of the drug visually evaluated by a pharmacist. (3-21-12)

a. If a patient's drug will not be administered or used, the pharmacy must package, seal, and return the drug to an adult member of the patient's immediate family or store and return it to the patient upon discharge. (3-21-12)

b. Drugs not returned to the patient or the patient's family may be disposed of after a reasonable

number of days following discharge or death. (3-21-12)

05. Suspected Adverse Drug Reaction Reporting. Suspected adverse drug reactions must be communicated in a timely manner to the pharmacy. (3-21-12)

06. Required Pharmacy Returns. Discontinued, expired, and damaged drugs and containers with worn, illegible, or missing labels must be returned to the pharmacy for proper handling. (3-21-12)

631. INSTITUTIONAL FACILITY -- EMERGENCY DRUG ACCESS AND PHARMACIST ABSENCE. The director must make advance arrangements necessary to facilitate continuity of patient care and for the provision of drugs to the medical staff and other authorized personnel of the institutional facility in emergencies and during the absences of a pharmacist in compliance with this rule. (3-21-12)

01. Emergency Pharmacy Access. If a drug is unavailable from any other authorized emergency source in sufficient time to prevent risk of harm to a patient that would result from a delay in obtaining the drug and in the absence of a pharmacist from the premises of the institutional facility, it may be retrieved from an institutional pharmacy by an R.N. as follows: (3-21-12)

a. One (1) R.N. may be designated per shift for emergency access to the pharmacy; (3-21-12)

b. Access may only occur if controlled substances are secured in a locked cabinet or other appropriate means to prevent unauthorized access; and (3-21-12)

c. Only a non-controlled substance may be removed and only in an amount necessary to treat a patient's immediate need until the pharmacy is again attended by a pharmacist. (3-21-12)

02. Emergency Cabinets. A cabinet or similar enclosure located outside an institutional pharmacy may be used for emergency access of drugs by an R.N. as follows: (3-21-12)

a. The emergency cabinet must be accessible only by key, combination, or otherwise sufficiently secured to deny access to unauthorized persons; and (3-21-12)

b. Drugs stocked in the emergency cabinet must be approved, prepared, stored, and handled as specified by these rules for emergency drug supplies. (3-21-12)

03. Emergency Drug Access Conditions and Documentation. Emergency access by an R.N. to an institutional pharmacy or an emergency cabinet or similar enclosure must be documented as follows: (3-21-12)

a. Removal of a drug must be pursuant to a valid drug order; (3-21-12)

b. Removal of a drug must be documented in a record that includes at least: (3-21-12)

i. The patient's name and location; (3-21-12)

ii. The name and strength of the drug; (3-21-12)

iii. The amount; (3-21-12)

iv. The date and time; and (3-21-12)

v. The signature of the designated nurse. (3-21-12)

c. The removal record and a copy of the drug order must be left conspicuously in the pharmacy, emergency cabinet, or alternative location to facilitate prompt accuracy verification and initialing by a pharmacist. (3-21-12)

04. Temporary Pharmacist Absence. To accommodate periods of temporary absence of a pharmacist

from the institutional pharmacy, pharmacy students and technicians may remain within the pharmacy under the following conditions: (3-21-12)

a. No other person may be allowed access or entrance to the pharmacy; (3-21-12)

b. Drugs or devices may not leave the pharmacy except if requested by, and immediately delivered to, the pharmacist; and (3-21-12)

c. Neither student pharmacists nor technicians may remain in the pharmacy during periods of pharmacist absence from the institutional facility. (3-21-12)

632. INSTITUTIONAL FACILITY -- EMERGENCY DRUG SUPPLY PREPARATION AND MONITORING.
The director or PIC and the appropriate institutional facility personnel must jointly approve and develop a listing of drugs, by identity and quantity, for inclusion in an emergency cabinet, emergency kit, crash cart, or other similar resource that is specifically approved for use by that type of institutional facility and for delivery to patients receiving emergency treatment. In addition to other applicable provisions of these rules, approved drugs are subject to the following limitations, restrictions, and requirements: (3-21-12)

01. **Prepackaged Amounts.** The drugs must be prepackaged in amounts sufficient to satisfy immediate therapeutic requirements only; (3-21-12)

02. **Content Labeling.** The drugs must be labeled as required by these rules for prepackaged products and with any additional information as may be required to prevent misunderstanding or risk of harm to patients; (3-21-12)

03. **Access Documentation.** Access to the emergency drugs must be documented by drug orders and, if applicable, proofs of use; (3-21-12)

04. **Drug Expiration Monitoring.** Drug expiration dates must be monitored and the drugs replaced as needed to ensure the emergency drug supply contains no outdated products; and (3-21-12)

05. **Regular Inventory and Inspection.** Emergency drug supplies must be regularly inventoried and inspected to ensure that they are properly stored and secured against pilferage or tampering. (3-21-12)

633. INSTITUTIONAL FACILITY -- EMERGENCY KITS AND CRASH CARTS -- GENERAL RULES.
Emergency drugs prepared and packaged as required by these rules may be approved for inclusion in emergency kits or crash carts for use by personnel with authority granted by state or federal law to administer prescription drugs. (3-21-12)

01. **Storage and Security.** Emergency kits or crash carts must be sealed in a tamper-evident manner and stored in limited access areas to prevent unauthorized access and to ensure a proper environment for preservation of the drugs within them. (3-21-12)

02. **Exterior Kit Labeling.** The exterior of emergency kits must be clearly labeled as an emergency drug kit to be used only in emergencies. Additionally, an immediately retrievable list of the drugs contained therein must include: (3-21-12)

a. The name, strength, and quantity of each drug; (3-21-12)

b. The expiration date of the first expiring drug; and (3-21-12)

c. The name, address, and telephone number of the supplying pharmacist, if applicable. (3-21-12)

03. **Drug Removal.** Drugs must only be removed from emergency kits or crash carts by persons with authority granted by state or federal law to administer prescription drugs, pursuant to a valid drug order, or by a pharmacist. (3-21-12)

04. Notification of Authorized Use. Whenever an emergency kit or crash cart is opened, the pharmacy must be notified and the kit or cart must restocked and resealed within a reasonable time. (3-21-12)

05. Notification of Unauthorized Use. If an emergency kit or crash cart is opened in an unauthorized manner, the pharmacy and other appropriate personnel of the institutional facility must be promptly notified. (3-21-12)

634. INSTITUTIONAL FACILITY -- NURSING HOME EMERGENCY KITS.
In nursing homes without an institutional pharmacy, drugs may be provided by a licensed pharmacy, retained by the facility, in emergency kits located at the facility. (3-21-12)

01. Provider Pharmacy Documentation. The nursing home must document the pharmacy retained in writing. (3-21-12)

02. Provider Pharmacy Ownership of Prescription Drug. Prescription drugs included in a nursing home emergency kit must remain the property of, and under the responsibility of, the supplying pharmacy. (3-21-12)

635. HOME HEALTH OR HOSPICE EMERGENCY KITS.
A pharmacy may supply emergency kits for state licensed or Medicare certified home health or hospice agencies, or both, as follows: (3-21-12)

01. Storage and Security. Emergency kits used by home health or hospice agencies must be stored in locked areas suitable for preventing unauthorized access and for ensuring a proper environment for the preservation of the drugs, except that nurses licensed by the Idaho Board of Nursing and employed by state-licensed or Medicare-certified home health or hospice agencies may carry emergency kits on their person while on duty and in the course and scope of their employment for the agency. While not on duty or working within the course and scope of their employment, the nurses must return the emergency kits to a locked storage area. (3-21-12)

02. Prescription Drugs. Prescription drugs included in a home health or hospice agency emergency kit must remain the property of, and under the responsibility of, the Idaho-registered supplying pharmacy. (3-21-12)

03. Controlled Substances. Emergency kits supplied to home health or hospice agencies must not include controlled substances. (3-21-12)

636. INSTITUTIONAL FACILITY -- HOSPITAL FLOOR STOCK.
Hospitals may use floor stock drugs if limited to a formulary of drugs and routinely used items developed and approved by the director in coordination with the appropriate institutional facility personnel. (3-21-12)

01. Pharmacist Routine Monitoring. Floor stock drugs must be routinely monitored by a pharmacist to ensure appropriate use and storage. (3-21-12)

02. Prescription Drugs. Prescription drugs included in floor stock must be in unit dose or unit-of-use packaging. (3-21-12)

03. Controlled Substances. For controlled substances included in the floor stock formulary, the director must ensure that: (3-21-12)

a. The floor stock contains appropriate controlled substances that are prepackaged in amounts sufficient for only immediate therapeutic requirements; (3-21-12)

b. Controlled substances maintained as floor stock are accessible only by key, combination, or otherwise sufficiently secured to deny access to unauthorized persons; (3-21-12)

c. Controlled substances removed from floor stock are documented by appropriate written drug orders and proofs of use, if applicable, and in a record that includes at least: (3-21-12)

i. The patient's name and location; (3-21-12)

ii. The name and strength of the drug; (3-21-12)

iii. The amount; (3-21-12)

iv. The date and time; and (3-21-12)

v. The signature or electronic personal verification of the person delivering the drug; and (3-21-12)

d. Controlled substances are inventoried at least weekly. (3-21-12)

637. INSTITUTIONAL FACILITY -- EMERGENCY OUTPATIENT DRUG DELIVERY BY HOSPITAL EMERGENCY ROOMS.
A limited supply of drugs, not including Schedule II controlled substances, may be approved for delivery to outpatients receiving hospital emergency room treatment if stored in the emergency room pursuant to applicable law and these rules pertaining to emergency drug product storage and if accessed and delivered as permitted or restricted by this rule. (3-21-12)

01. Limitations. No more than one (1) prepackaged container of the same drug may be delivered unless more than one (1) package is required to sustain the patient until the first available pharmacist is on duty in the community except that the full course of therapy for anti-infective medications may be provided. (3-21-12)

02. Documentation. Delivery must occur only pursuant to a valid drug order and must be documented as required by these rules for institutional facility emergency drug access. (3-21-12)

03. Labeling. A label must be affixed to the container with the information required by these rules for outpatient dispensing. (3-21-12)

04. R.N. Staff Personnel Only. This rule does not authorize any person other than an R.N. on a hospital's emergency room staff to prepare or deliver prescription drugs to outpatients receiving emergency treatment. (3-21-12)

638. -- 639. (RESERVED)

640. INSTITUTIONAL FACILITY -- OFFSITE PHARMACY PRACTICE STANDARDS.

01. Offsite Pharmacy Services. If an institutional facility without an institutional pharmacy obtains drugs, devices, or other pharmacy services from outside the institutional facility, arrangements must be made to ensure that the offsite pharmacy provides services with sufficient professionalism, quality, and availability to adequately protect the safety of the patients and properly serve the needs of the facility. (3-21-12)

02. Written Agreement. The arrangements must be made in writing and must, at a minimum, specify that: (3-21-12)

a. An offsite pharmacist will act in the capacity of a part-time director; (3-21-12)

b. For nursing homes, on-call services by a pharmacist will be available at all times; (3-21-12)

c. The pharmacy will provide adequate storage facilities for drugs; and (3-21-12)

d. Drugs housed in an LTCF must be labeled as required by the general provisions of these rules and, unless maintained in an electronic record, must include a lot number for administration of recalls. (3-21-12)

641. INSTITUTIONAL FACILITY -- OFFSITE SERVICES -- FIRST DOSE PHARMACY.
A contracted offsite pharmacy that provides prescription processing or filling services for an institutional facility without an institutional pharmacy or for patients of a home health or hospice agency may centralize these services to

another pharmacy if in compliance with these rules. (3-21-12)

642. -- 649. (RESERVED)

650. INSTITUTIONAL FACILITY -- CENTRALIZED PHARMACY SERVICES.
An institutional pharmacy may centralize prescription drug order processing or filling services if: (3-21-12)

01. Limited Purpose. The centralizing of prescription drug order processing or filling services is for the limited purpose of ensuring that drugs or devices are attainable to meet the immediate needs of patients and residents of the institutional facility or if the originating pharmacy cannot provide services for the institutional facility on an ongoing basis; (3-21-12)

02. Institutional Facility Approval. The originating pharmacy obtains approval from the institutional facility to centralize prescription drug order processing or filling services for its patients and residents; (3-21-12)

03. Written Contract. The originating pharmacy has a written contract with the central pharmacy outlining the services to be provided and the responsibilities and accountabilities of each party in fulfilling the terms of the contract; and (3-21-12)

04. Drug or Chart Orders. The originating pharmacy provides a valid verbal, electronic, or paper drug order to the contracted central pharmacy. A single drug order may be shared by an originating pharmacy and a central pharmacy with no transfer required. (3-21-12)

651. INSTITUTIONAL FACILITY -- PRACTICE OF TELEPHARMACY.

01. Contracted Telepharmacy Services. An institutional pharmacy may centralize pharmacy services through the practice of telepharmacy if: (3-21-12)

a. The central pharmacy provides a training and orientation program that ensures that pharmacists who are providing telepharmacy services are competent to review and approve drug orders; (3-21-12)

b. Appropriate video, telecommunications, or other systems allow the pharmacist within the central pharmacy to readily communicate with the prescribers within the institutional facility; (3-21-12)

c. The parties share a common electronic file or utilize other technology that allows access by the central pharmacy to information required to fill or refill a prescription drug order; and (3-21-12)

d. The parties implement and maintain a continuous quality improvement program for telepharmacy 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. (3-21-12)

02. Policies and Procedures. An institutional pharmacy and its contracted central pharmacy that provides telepharmacy services must adopt policies and procedures and retain documentation that evidences at least the following: (3-21-12)

a. A copy of the approval required by these rules; (3-21-12)

b. A copy of the contract required by these rules; (3-21-12)

c. Identification of the director of the central pharmacy and of the institutional pharmacy; (3-21-12)

d. The maintenance of appropriate records to identify the pharmacists providing centralized prescription drug order processing or filling services; (3-21-12)

e. The protocol for ensuring that the central pharmacy maintains sufficient Board licensed or registered pharmacists to meet the centralized pharmacy services needs of the institutional facility; (3-21-12)

f. The maintenance of a mechanism for tracking the prescription drug order during each step in the dispensing process; (3-21-12)

g. The documentation and protocols demonstrating adequate security to protect the privacy of PHI; (3-21-12)

h. The protocol for accessing prescription drugs in the institutional pharmacy contracting with the central pharmacy and for maintaining the security of the drugs; (3-21-12)

i. Essential information utilized by the institutional facility, such as its therapeutic interchange list, formulary, standard drip concentrations, standard medication administration times, standardized or protocol orders, pharmacokinetic dosing policies, and renal dosing policies, as well as protocols for ensuring timely and complete communication of changes to the information; and (3-21-12)

j. The protocol for the central pharmacy to perform a review of the patient's profile, including but not limited to performing a prospective drug review. (3-21-12)

652. -- 669. (RESERVED)

670. VDO -- OWNER AND MANAGER RESPONSIBILITIES.
Owners and managers of VDOs each have corresponding and individual responsibility for unauthorized drug distribution from, or other unlawful conduct in, the registered outlet and must have sufficient understanding of the regulated activities to detect improper conduct. (3-21-12)

671. VDO -- POLICIES AND PROCEDURES.
Owners or managers must adopt policies and procedures for the handling of veterinary drug orders, managing product inventory, and other topics as needed to ensure compliance with applicable law and Board rules. (3-21-12)

672. VDO -- REQUIRED REFERENCES.
The current Board rules applicable to the practice setting must also be made readily available to VDTs and other employees of the VDO for reference purposes. (3-21-12)

673. VDO STAFFING.

01. Sufficient Staffing. VDOs must employ sufficient VDTs to ensure that one (1) VDT is on duty at all times the establishment is open to the public for business. (3-21-12)

02. Notification of Personnel Changes. Notification of VDT personnel changes must be provided to the Board within ten (10) days of the change and must include the names and addresses of both the resigning and the newly hired VDTs. (3-21-12)

674. VDO -- DRUG PRODUCT INVENTORY AND MANAGEMENT.

01. Authorized Prescription Drugs. VDOs are authorized to stock, and VDTs are authorized to prepare and deliver, prescription veterinary drugs except the following: (3-21-12)

a. Controlled substances listed in Schedules I through V of either the state or federal Controlled Substances Acts; (3-21-12)

b. Euthanasia drugs or products; (3-21-12)

c. Tranquilizer drugs or products; (3-21-12)

d. Curare, succinylcholine, or other neuromuscular paralyzing drugs; and (3-21-12)

e. General anesthesia drugs or products. (3-21-12)

Illinois Department of Financial & Professional Regulation

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- **IDFPR and the Drug Enforcement Administration warn against "Doctor Shopping" in letter to health care professionals**
- **IMPORTANT NOTICE for Advanced Practice Nurse (APN) Controlled Substance / Schedule II**

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Joint Committee on Administrative Rules

ADMINISTRATIVE CODE

TITLE 68: PROFESSIONS AND OCCUPATIONS
CHAPTER VII: DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION
SUBCHAPTER b: PROFESSIONS AND OCCUPATIONS
PART 1330 PHARMACY PRACTICE ACT
SECTION 1330.520 OFFSITE INSTITUTIONAL PHARMACY SERVICES

Section 1330.520 Offsite Institutional Pharmacy Services

a) Pharmacies that are not located in the facilities they serve and whose primary purpose is to provide services to patients or residents of facilities licensed under the Nursing Home Care Act, the Hospital Licensing Act, or the University of Illinois Hospital Act shall, in addition to any other requirements of the Act and this Part, comply with this Section.

b) Recordkeeping Requirements for Dispensing Prescriptions or Orders

1) Every prescription or order dispensed shall be documented with the name, initials or other unique identifies of the pharmacist (and pharmacy technician if one is used) authorized to practice pharmacy under the provisions of the Act who dispenses the prescription or order. For purposes of the Act, an authorized person is:

A) A pharmacist licensed in the State of Illinois; or

B) A registered pharmacy technician, certified pharmacy technician or student pharmacist under the supervision of a pharmacist.

2) Each pharmacy must maintain records for 5 years that contains the information in subsection (b)(3). This information shall be readily retrievable and in a format that provides enforcement agents a concise, accurate and comprehensive method of monitoring drug distribution via an audit trail. This system may require two or more documents that, when read together, will provide all the information required by federal (e.g., the regulations of the Drug Enforcement Administration (21 CFR 1300 et seq.; 1998)) and State (e.g., the Pharmacy Practice Act and the Illinois Controlled Substances Act [720 ILCS 570]) statute.

3) In addition to the record keeping requirements of subsection (b)(2), a uniformly maintained, readily retrievable hard copy record or back-up documentation of each prescription or order dispensed shall be maintained by the pharmacy for 5 years and shall include:

A) Name of resident;

B) Date of order;

C) Name, strength and dosage form of drug, or description of the medical device ordered;

D) Quantity dispensed (a separate record should be maintained when the quantity billed differs from the quantity dispensed, e.g., unit dose transfer systems);

E) Directions for use;

F) Quantity billed;

G) Prescriber's name;

H) Prescriber's signature and/or DEA number when required for controlled substances; and

I) The drug name and identification code or the manufacturer in case of a generically ordered medication or a generic interchange.

4) No prescription may be filled or refilled for a period in excess of one year from the date of the original issuance of the prescription or order by the prescriber.

5) Subject to Section 18 of the Act, any information required to be kept pursuant to this Section may be recorded and stored in a:

A) computerized pharmaceutical information system that meets the standards of performance required by the regulations of the Drug Enforcement Administration (21 CFR 1306; 1998) and shall include the capability to:

i) Retrieve the original medication order information for those medication orders that are currently authorized;

ii) Retrieve the current history of medication orders that shall, at a minimum, include the name of drug, the date of filling, the quantity dispensed, the name and identification code of manufacturer in the case of a generically written prescription or a generic interchange, for each filling, and the total number of refills when read in conjunction with any off-line hard copy of the history of medication orders dispensed to date; and

iii) Supply documentation of the correctness of filling information entered into a system must be provided by the pharmacist using the system by way of a hard copy printout of each day's filling data that has been verified, dated and signed by the dispensing pharmacist; or

B) bound log book, or separate file, in which each individual pharmacist involved in dispensing shall sign a statement each day attesting to the fact that the refill information entered into the computer that day has been reviewed by him/her and is correct as shown. The book or file must be maintained at the pharmacy employing the system for a period of 5 years after the date of dispensing the appropriately authorized refill.

c) In the event the long term care facility changes pharmacy provider services, their new provider must obtain the orders from the long term care facility and verify the authenticity and accuracy of the orders with the prescriber.

d) Staffing of the Pharmacy. When the pharmacy is closed, the public and any employees not registered under the Act are to be prohibited access to the filling and dispensing area.

e) Labeling Requirements

1) Medications for Future Use

A) Parenteral solutions to which a drug or diluent has been added or that are not in their original manufacturer's packaging shall contain the following information on the outer label:

i) Name, concentration and volume of the base parenteral solution;

ii) Name and strength of drugs added;

iii) Beyond use date and date of the admixture. Beyond use date, unless otherwise specified in the individual compendia monograph shall be not later than the beyond use date on the manufacturer's container or one year from the date the drug is repackaged, whichever is earlier; and

iv) Reference code to identify source and lot number of drugs added.

B) Non-parenterals repackaged for future use shall be identified with the following information:

i) Brand and/or generic name;

ii) Strength (if applicable);

iii) Beyond use date. Unless otherwise specified in the individual monograph, the beyond use date shall be not later than the beyond use date on the manufacturer's container or one year from the date the drug is repackaged, whichever is earlier; and

iv) Reference code to identify source and lot number.

2) Medications Prepared for Immediate Use

A) All medications prepared by the pharmacy for immediate dispensing to a specific resident or patient in the facility shall be dispensed in a container identified with:

i) Name of the resident;

ii) Resident's room and bed number;

iii) Dispensing date;

iv) Name, strength and dosage form of drug, or description of the medical device ordered;

v) Quantity dispensed;

vi) Directions for use;

vii) Prescriber's name; and

viii) Beyond use date if less than 60 days from date of dispensing.

B) Pharmacies dispensing medications to a specific resident or patient in the facility via unit dose shall label each order with the following information:

i) Name of the resident;

ii) Resident's room and bed number;

iii) Date of order;

iv) Name, strength and dosage form of drug, or description of the medical device ordered;

v) Directions for use; and

vi) Prescriber's name.

f) Pharmacies that compound and dispense sterile products shall comply with Sections 1330.640 and 1330.670.

Joint Committee on Administrative Rules

ADMINISTRATIVE CODE

TITLE 68: PROFESSIONS AND OCCUPATIONS
CHAPTER VII: DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION
SUBCHAPTER b: PROFESSIONS AND OCCUPATIONS
PART 1330 PHARMACY PRACTICE ACT
SECTION 1330.530 ONSITE INSTITUTIONAL PHARMACY SERVICES

Section 1330.530 Onsite Institutional Pharmacy Services

a) Pharmacies located in facilities licensed under the Nursing Home Care Act, the Hospital Licensing Act, or the University of Illinois Hospital Act, or that are operated by the Department of Human Services or the Department of Corrections, and that provide pharmacy services to residents, patients, employees, prescribers and students of these facilities, shall, in addition to other requirements of the Act and this Part, comply with this Section.

b) Recordkeeping Requirements

1) Every prescription or medication order filled or refilled shall contain the name, initials or other unique identifier of the pharmacist (and pharmacy technician if one is used) who fills or refills the prescription or medication order, or the name, initials or other unique identifier may be recorded on another appropriate, uniformly maintained and readily retrievable record that indicates, at least, the following information:

A) The name and dosage form of the drug;

B) The date of filling or refilling; and

C) The quantity dispensed.

2) No prescription may be dispensed for a period in excess of one year from the date of the original issuance of the prescription by the prescriber.

3) The pharmacist-in-charge shall maintain or have access to the following records for at least 5 years or as otherwise required by law:

A) Records of medication orders and medication administration to patients;

B) Procurement records for controlled substances;

C) Records of packaging, bulk compounding or manufacturing; and

D) Records of actions taken pursuant to drug recalls.

c) Labeling Requirements

1) All medication repackaged by the pharmacy for future use inside the institution or facility and not intended for immediate dispensing to a specific patient shall be identified as follows:

A) Single dose or multi-dose drugs, except sterile solutions to which a drug has been added, shall be labeled with:

i) Brand and/or generic name;

ii) Strength (if applicable);

iii) Beyond use date; and

iv) Reference code to identify source and lot number.

B) Sterile solutions to which drugs have been added shall contain on the outer label:

i) Name, concentration and volume of the base sterile solution;

ii) Name and strength of drugs added;

iii) Beyond use date and time of the admixture; and

iv) Reference code to identify source and lot number of drugs added.

2) All medication prepared by the pharmacy for immediate dispensing to a specific patient or resident in the institution or facility shall be identified as follows:

A) Single dose or multi-dose drugs, except parenteral solutions to which a drug has been added, shall be identified with:

i) Brand and/or generic name; and

ii) Strength (if applicable).

B) Sterile solutions to which drugs have been added shall be identified with:

i) Name, concentration and volume of the base sterile solution;

ii) Name and strength of drugs added; and

iii) Beyond use date and time of the admixture.

C) All medication dispensed to a specific patient in the institution shall be dispensed in a container identified with the name of the patient and the patient's location. Those institutions or facilities utilizing a unit-dose and medication cart system may identify the name of the patient and the patient's location on the outside of the bin of the medication cart, when those carts are filled by the pharmacy.

3) Labels on all medications dispensed by the pharmacy for immediate dispensing to a patient being discharged, emergency room patient and/or employee shall contain the following:

A) The name and dosage form of the drug;

B) The date filled; and

C) The quantity dispensed.

4) Investigational new drugs, authorized by the U.S. Food and Drug Administration, shall be dispensed pursuant to a valid prescription order of the principal physician-investigator or his authorized clinician. All investigational drugs shall be stored in and dispensed from the pharmacy and shall be identified with the following information:

A) Name of drug and strength (if applicable);

B) Beyond use date;

C) Reference code to identify source and lot number;

D) A label indicating "For Investigational Use Only"; and

E) Name and location of the patient. Those institutions or facilities utilizing a unit-dose and medication cart system may identify the name of the patient and the patient's location on the outside of the bin of the medication cart, when those carts are filled by the pharmacy.

5) A pharmacist providing a copy of a prescription to an ultimate consumer for the purpose of transfer or any other purpose shall cancel the face of the original prescription and record the date the copy is issued, to whom issued, and the pharmacist's signature on the face of the original prescription. Copies of prescriptions shall be marked "For Information Purposes Only" and require prescriber authorization to fill.

d) Staffing of the Pharmacy

1) The responsibilities of the pharmacist-in-charge shall include:

A) Supervision of all the activities of all employees as they relate to the practice of pharmacy;

B) Establishment and supervision of the method and manner for storage,

dispensing and safekeeping of pharmaceuticals in all areas of the institution or facility, including maintenance of security provisions to be used when the pharmacy is closed. The following security provisions shall be utilized:

i) The pharmacy shall be staffed at all times by a registered pharmacist during open hours; and

ii) Only registrants and licensees shall have access to the pharmacy, except as provided in Section 1330.530(e)(1);

C) Establishment and supervision of the recordkeeping system for the purchase, sale, delivery, possession, storage and safekeeping of drugs;

D) The development and implementation of a procedure to be utilized in the event of a drug recall that can be readily activated to assure that all drugs included on the recall are returned to the pharmacy for proper disposition;

E) Establishment of specifications for the procurement of all drugs that will be dispensed by the pharmacy; and

F) Establishment and supervision of a method of documenting an oral prescription from a licensed physician to a pharmacist and for transmission of that information to the appropriate members of the nursing staff of the institution or facility.

2) The operations of the pharmacy and the maintenance of security provisions are the responsibility of the pharmacist-in-charge whether the owner is a sole proprietor, partnership, association, corporation or any other entity.

3) Within 30 days after the change of a pharmacist-in-charge, the Division shall be notified in writing by the departing pharmacist-in-charge.

4) The departing pharmacist-in-charge shall, on the effective date of the change, inventory the following controlled substances:

A) All Schedule II drugs, as defined in the Illinois Controlled Substances Act, by actual physical count; and

B) All other scheduled drugs, as defined in the Illinois Controlled Substances Act, by estimated count.

5) The inventory shall constitute, for the purpose of this Section, the closing inventory of the departing pharmacist-in-charge and the initial inventory of the incoming pharmacist-in-charge. This inventory record shall be preserved in the pharmacy for a period of 5 years. An affidavit attesting to the completion and preservation of the inventory record bearing the date of the inventory and the signatures of the departing and incoming pharmacist-in-charge shall be submitted to the Division, at its principal office, within 30

days after the change in the pharmacist-in-charge.

6) Failure on the part of a registrant to provide the affidavit required in subsections (d)(4) and (5) shall be grounds for denying an application or renewal application for a pharmacy license or for disciplinary action against a registrant. Denial shall be based on the recommendation of the Board.

7) In the event the departing pharmacist-in-charge refuses to complete the inventory as provided for in subsection (d)(4), or that pharmacist-in-charge is incapacitated or deceased, the initial inventory for the incoming pharmacist-in-charge shall be the inventory as completed by the incoming pharmacist-in-charge. The incoming pharmacist-in-charge will not be responsible for any discrepancy that may exist in the inventory prior to his or her initial inventory.

8) When the accuracy, relevance or completeness of any submitted documentation is reasonably questioned by the Division because of lack of information, discrepancies or conflicts in information given, or a need for clarification, the registrant will be required to:

   A) Provide information as may be necessary; and/or

   B) Appear for an interview before the Board to explain the relevance or sufficiency, clarify information given or clear up any discrepancies or conflicts in information.

9) Pharmacists and pharmacies are prohibited from accepting from patients or their agents for reuse, reissue or resale dispensed medications, chemicals, poisons or medical devices, except for:

   A) Medical devices that can be properly sanitized prior to reuse, resale or re-rent; and

   B) Medications that are dispensed and stored under conditions defined and supervised by the pharmacist and are unopened in sealed, intact and unaltered containers that meet the standards for light, moisture and air permeation as defined by a current United States Pharmacopoeia/National Formulary published by the United States Pharmacopoeial Convention, Inc.

e) Medication Dispensing in the Absence of a Pharmacist. The availability of necessary medications for immediate therapeutic use during those hours when the institutional pharmacy is not open shall be met in the following manner:

1) An after-hour cabinet, which is a locked cabinet or other enclosure located outside of the pharmacy area containing a minimal supply of the most frequently required medication, may be utilized provided that only personnel specifically authorized by the institution in which the pharmacy is located may obtain access and it is sufficiently secure to deny access to unauthorized persons. After-hour cabinets shall only be used in the absence of a pharmacist. When medication is removed from the cabinet or enclosure,

written physician's orders authorizing the removal of the medication shall be placed in the cabinet or enclosure. A log shall be maintained within the cabinet or enclosure and authorized personnel removing medication shall indicate on the log the signature of the authorized personnel removing the medication, name of the medication removed, the strength (if applicable), the quantity removed and the time of removal.

2) Emergency kits containing those drugs that may be required to meet the immediate therapeutic needs of the patient, and that are not available from any other source in sufficient time to prevent risk of harm to patients by delay resulting from obtaining the drugs from the other source, may be utilized. Emergency kits shall be supplied and maintained under the supervision of a pharmacist. Drugs shall be removed from emergency kits only by authorized pharmacy personnel, persons authorized to administer medication pursuant to a valid physician's order of a physician licensed to practice medicine in all of its branches in Illinois. Emergency kits shall be sealed in some manner that will indicate when the kit has been opened. A label shall be affixed to the outside of the emergency kit indicating the beyond use date of the emergency kit. The beyond use date of the emergency kit shall be the earliest beyond use date of any drug contained in the kit. After an emergency kit has been used or upon discovery that the seal has been broken or upon the occurrence of the beyond use date, the kit shall be secured and returned to the pharmacy to be checked and/or restocked by the last authorized user. If the pharmacy is closed at such time, the kit shall be returned when it opens.

3) Whenever any drug is not available from night cabinets or emergency kits, and the drug is required to treat the immediate needs of a patient, the drug may be obtained from the pharmacy in sufficient quantity to meet the immediate need by an authorized nurse. When medication is removed from the pharmacy by an authorized nurse, a copy of the physician's order authorizing the removal of the medication shall be conspicuously placed in the pharmacy with the container from which the drug was removed so that it will be found by a pharmacist and checked promptly. A form shall be available in the pharmacy upon which shall be recorded the signature of the authorized nurse who removed the medication, the name, strength (if applicable) and quantity of medication removed.

4) Drugs may be dispensed from the emergency room only by a practitioner licensed to prescribe and dispense, and only to patients treated in the institution. This shall occur only during hours in which outpatient institutional pharmacy services are not available. The quantity dispensed should be limited to no more than a 72 hour supply, except for antimicrobial drugs and unit of use packages (e.g., inhalers, ophthalmic, otics, etc., or as provided for in Section 1330.510(b)(3)) to meet the immediate needs of the patient until pharmacy services are available. Drugs dispensed in this manner must meet all labeling requirements pertaining to community pharmacies as specified in Section 1330.500. There shall be written policies and procedures, approved by the medical staff, regarding the dispensing of drugs from the emergency room.

f) Pharmacies that compound and dispense sterile products shall comply with Sections 1330.640 and 1330.670 of this Part.

g) Pharmacies that utilize automated dispensing and storage systems shall comply with Section 1330.680 of this Part.

Information Maintained by the Office of Code Revision Indiana Legislative Services Agency

IC 25-26-13-17
Classes of pharmacy permits

Sec. 17.

(a) The board shall establish classes of pharmacy permits as follows:
Category I. A retail permit for a pharmacy that provides pharmaceutical care to the general public by the dispensing of a drug or device.
Category II. An institutional permit for hospitals, clinics, health care facilities, sanitariums, nursing homes, or dispensaries that offer pharmaceutical care by dispensing a drug product to an inpatient under a drug order or to an outpatient of the institution under a prescription.
Category III. A permit for a pharmacy that provides closed door, central fill, mail order, or other processing operations that are not open to the general public but include:
(A) traditional pharmacy functions; or
(B) nontraditional pharmacy functions, such as infusion, nuclear pharmacy, or sterile compounding.

(b) The board may approve a remote or mobile location for Category I, II, or III permits. Pharmacy practice in a mobile or remote location may include, but is not limited to, telepharmacy, automated dispensing, or delivery of cognitive services.

(c) A hospital or hospital system holding a Category II permit may offer drugs or devices:
(1) to:
(A) an employee, student, or volunteer of the hospital or hospital system;
(B) a retiree who is participating in a retirement, pension, or benefit program administered by the hospital or hospital system;
(C) an independent contractor who has an exclusive relationship with the hospital or hospital system;
(D) a member of the hospital's or hospital system's governing board; or
(E) a member of the hospital's or hospital system's medical staff; and
(2) to dependents of the individuals listed in subdivision (1); for their own use.

(d) Hospitals holding a Category II permit may operate remote locations within a reasonable distance of the licensed area, as determined by the board, after:
(1) filing an application on a form prepared by the board;
(2) having each location inspected by the board; and
(3) obtaining approval from the board.

(e) Any applicable rule governing the practice of pharmacy in Indiana shall apply to all permits under this section.

(f) After June 30, 2012, a person with:

(1) a Type I permit shall be treated as holding a Category I permit;

(2) a Type II permit shall be treated as holding a Category II permit; and

(3) a Type III, IV, V, or VI permit shall be treated as holding a Category III permit.

The change in the name of the permit does not change the expiration date of the permit.

(g) After June 30, 2012, a reference in any rule or other document to:

(1) a Type I permit shall be treated as a reference to a Category I permit;

(2) a Type II permit shall be treated as a reference to a Category II permit; or

(3) a Type III, IV, V, or VI permit shall be treated as a reference to a Category III permit.

As added by Acts 1977, P.L.276, SEC.1. Amended by P.L.149-1987,

SEC.76; P.L.147-1991, SEC.4; P.L.98-2006, SEC.9; P.L.159-2012, SEC.4; P.L.152-2012, SEC.10.

856 IAC 1-21-1 Resale of returned substances

Authority: IC 25-26-13-4
Affected: IC 25-26-13-25

Sec. 1. (a) This section implements and interprets IC 25-26-13-25(h) concerning the resale or redistribution of medications.

(b) For a medication to have been properly stored and securely maintained according to sound pharmacy practices, the storage and administration of medications in the institutional facility must be under the immediate control of licensed nursing personnel.

(c) If the medication was originally packaged by the dispensing pharmacy, it cannot be resold or redistributed unless:

(1) the medication has been repackaged into unit-dose packaging using packaging materials that meets Class A or Class B standards, found in the United States Pharmacopeia (U.S.P.), page 1574, published by the United States Pharmacopeia, 22nd Revision, January 1, 1990, United States Pharmacopeia Convention, Inc., 12601 Twinbrook Parkway, Rockville, Maryland 20852, which standards are incorporated herein by reference; and

(2) the repackaging process complies with the standards as found in the "Proper Treatment of Products Subjected to Additional Manipulations, Section 1191" of the United States Pharmacopeia, page 1705, 22nd Revision, 1990, which section is incorporated herein by reference.

(d) A medication repackaged under the provisions of subsection (c) shall be labeled with an expiration date of not greater than one (1) year until the manufacturer's expiration date, whichever is earlier.

(Indiana Board of Pharmacy; Reg 21, Sec 1; filed Jun 18, 1962, 10:00 a.m.: Rules and Regs. 1963, p. 128; filed Mar 31, 1992, 5:00 p.m.: 15 IR 1391; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1334; readopted filed Sep 26, 2008, 10:55 a.m.: 20081015-IR-856080346RFA)

Rule 22. Narcotics—Defined *(Repealed)*

(Repealed by Indiana Board of Pharmacy; filed Dec 3, 1985, 3:02 pm: 9 IR 771)

Rule 23. Dispensing of Dangerous Drugs

856 IAC 1-23-1 Dispensing of dangerous drugs

Authority: IC 25-26-13-4
Affected: IC 16-42-22; IC 25-26-13-4; IC 25-26-13-11

Sec. 1. In the sale or dispensing of any prescription drug or narcotic, the pharmacist shall be required to affix to the immediate container in which such prescription drug or narcotic is delivered a label bearing the following information:

(1) The name, address, and telephone number of the establishment from which such drug was sold.

(2) The date on which the prescription for such drug was filled.

(3) The number of such prescription as filed in the prescription files of the pharmacy where the prescription was filled.

(4) The name of the practitioner who prescribed such drug.

(5) The name of the patient, and if such drug was prescribed for an animal, a statement of the species of the animal and the owner's name.

(6) The directions for use of the drug as contained in the prescription.

(7) The name of the drug (trade or generic, or both) in compliance with the Generic Drug Law found in IC 16-42-22.

(Indiana Board of Pharmacy; Reg 23,Sec 1; filed Jun 18, 1962, 10:00 a.m.: Rules and Regs. 1963, p. 129; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1335; readopted filed Sep 26, 2008, 10:55 a.m.: 20081015-IR-856080346RFA)

Rule 24. Hospital Pharmacies *(Repealed)*

(Repealed by Indiana Board of Pharmacy; filed Jun 8, 1982, 10:04 am: 5 IR 1420)

Rule 25. Internship for Apprentice Pharmacists *(Repealed)*

(Repealed by Indiana Board of Pharmacy; filed Dec 3, 1985, 3:02 pm: 9 IR 771)

Rule 26. Continuing Professional Education

856 IAC 1-26-1 Continuing professional education; general requirements; definitions

Authority: IC 25-26-13-4
Affected: IC 25-1-9-3; IC 25-26-13-14

Sec. 1. (a) The following definitions apply throughout this rule:

(1) "Continuing professional education" or "continuing education" means accredited postlicensure professional educational experience derived from participation in postgraduate studies, institutes, seminars, lectures, conferences, workshops, and such other forms of educational experiences so as to maintain the professional competency of the practice of pharmacy, improve pharmacy professional skills, and preserve pharmaceutical standards for the purpose of the protection of the health and welfare of the citizens of Indiana.

(2) "Hours" means measurement of value applied to a particular accredited continuing pharmacy educational activity as assigned by the Indiana board of pharmacy (board) relative to maintaining the competency of a pharmacist.

(3) "Contact hour" means not less than fifty (50) nor more than sixty (60) minutes of clock time participating in a continuing education program.

(4) "Continuing education unit" or "CEU" means ten (10) contact hours of continuing education credit.

(4) Earn one and one-fourth (1.25) hours of continuing education credit for each month or part of a month from date of licensure until the end of the biennium in which licensure originates if the pharmacist becomes licensed during the biennium. However, a pharmacist who becomes newly licensed for the first time in any state in the last six (6) months of the biennium shall not be required to complete any continuing education for the biennium.

(5) Continuing education hours may be transferred from another state to Indiana if the transfer state recognizes Indiana continuing education hours.

(g) Failure to comply with any one (1) or all of the provisions of this rule while continuing to hold a license as a pharmacist in Indiana shall constitute professional incompetence by failing to keep abreast of current professional theory or practice under IC 25-1-9-3(a)(4)(B) and the pharmacist is subject to discipline under IC 25-1-9.

(Indiana Board of Pharmacy; Reg 29; filed Mar 1, 1974, 3:05 p.m.: Rules and Regs. 1975, p. 516; filed Oct 26, 1984, 3:26 p.m.: 8 IR 212; filed Jan 21, 1994, 3:00 p.m.: 17 IR 1096, eff Jan 1, 1994 [IC 4-22-2-36 suspends the effectiveness of a rule document for thirty (30) days after filing with the secretary of state. LSA Document #93-152 was filed Jan 21, 1994.]; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1335; readopted filed Sep 26, 2008, 10:55 a.m.: 20081015-IR-856080346RFA)

Rule 27. Fee Structure

856 IAC 1-27-1 Fees

Authority: IC 25-1-8-2; IC 25-26-13-4
Affected: IC 25-26-13

Sec. 1. (a) The following fees apply to an applicant for licensure to practice as a pharmacist:

(1) Application for examination for a pharmacist's license	$100
(2) Reexamination of the jurisprudence examination	$25
(3) Reexamination of the practical examination	$25
(4) Licensure by reciprocity (license transfer)	$100
(5) Application for the renewal of a biennial license	$160
(6) Certification of qualifications, grades, or registration to another state	$10
(7) Wall certificate	$10
(8) Duplicate pharmacist pocket license	No Fee
(9) Compilation of pharmacy laws	$10

(b) The following fees apply to an applicant for permission to operate, maintain, open, or establish a pharmacy:

(1) Initial application	$100
(2) Application for renewal of biennial license	$200
(3) Application for change of ownership	$50
(4) Application for change of location	$50
(5) Application for remodel	$50
(6) Duplicate pharmacy permit	No Fee
(7) Nonresident pharmacy initial application	$100
(8) Application for renewal of nonresident pharmacy biennial license	$200

(c) The following fees apply to applicants for permits or certifications authorized by the board:

(1) Intern/extern initial application	$10
(2) Intern/extern annual renewal	$10
(3) Pharmacy technician initial application	$25
(4) Pharmacy technician biennial renewal	$25

(Indiana Board of Pharmacy; Reg 29; filed Aug 30, 1977, 8:25 a.m.: Rules and Regs. 1978, p. 660; filed Mar 5, 1985, 2:42 p.m.: 8 IR 802; filed Nov 13, 1985, 3:08 p.m.: 9 IR 772; filed Apr 30, 1986, 9:43 a.m.: 9 IR 2204; filed Sep 8, 1987, 2:30 p.m.: 11 IR 95; filed Jul 24, 1991, 2:45 p.m.: 14 IR 2238; filed Jun 6, 1996, 9:00 a.m.: 19 IR 3106; filed May 29, 1998, 11:56 a.m.: 21 IR 3931; filed Aug 5, 1998, 3:48 p.m.: 21 IR 4535; filed Apr 16, 2002, 9:03 a.m.: 25 IR 2739; filed Dec 12, 2003, 10:45 a.m.: 27 IR 1574) NOTE: Renumbered Reg 30 by 1978 Amendment.

Rule 28. Institutional Pharmacies *(Repealed)*

(Repealed by Indiana Board of Pharmacy; filed Dec 26, 2001, 2:44 p.m.: 25 IR 1643)

Rule 28.1. Institutional Pharmacies and Pharmacy Services

856 IAC 1-28.1-1 Definitions

Authority: IC 25-26-13-4
Affected: IC 16-42-19-5; IC 25-6-3-7; IC 25-26-13

Sec. 1. In addition to the definitions in IC 25-26-13-2 and for purposes of this rule, the following definitions apply throughout this rule:

(1) "Cabinet" includes a mechanical storage device for dispensing drugs. The term means a locked or secured enclosure located outside the pharmacy licensed area:

(A) to which only specifically authorized personnel may obtain access by key or combination available only to those authorized persons by:

(i) security code;

(ii) password; or
(iii) other method of positively identifying an individual; and
(B) that is sufficiently secure to deny access to unauthorized persons.

(2) "Cognitive services" means those acts and operations related to a patient's drug therapy that are judgmental in nature, based on knowledge, and derived from empirical factual information.

(3) "Consultant pharmacist" means a pharmacist licensed pursuant to IC 25-26-13-11 and who engages in the practice of pharmacy in or for long term care facility or other residential patients, other than as a supplying pharmacist.

(4) "Consulting" means the provision of nonsupply related cognitive services that include, but are not necessarily limited to, the following:
(A) Drug regimen review as defined in IC 25-26-13-2.
(B) Provision of advice and counsel on drugs, the selection and use thereof to the facility, the patients therein, the health care providers of the facility regarding the appropriateness, use, storage, handling, administration, and disposal of drugs within the facility.
(C) Participation in the development of policies and procedures for drug therapy within the institution, including storage, handling, administration, and disposing of drugs and devices.
(D) Assuring the compliance with all applicable laws, rules, and regulations.
(E) Provision of educational and drug information sources for the education and training of the facility health care professionals.
(F) Accepting responsibility for the implementation and performance of review of quality-related or sentinel events as defined in this rule.

(5) "Emergency drugs" means those drugs that:
(A) may be required to meet the immediate therapeutic needs of patients; and
(B) are not available from any other authorized source in sufficient time to prevent risk of harm to patients by delay resulting from obtaining such drugs from other sources.

(6) "Institutional facility" means any health care facility whose primary purpose is to provide a physical environment for patients to obtain health care services, except those places where practitioners, as defined by IC 16-42-19-5, who are duly licensed, engage in private practice and pharmacies licensed under IC 25-26-13-17.

(7) "Institutional pharmacy" means that portion of an institutional facility where pharmacy is practiced and is:
(A) the location of the selection, compounding, production, sale, storage, and distribution of drugs, devices, and investigational or new drugs used in the diagnosis and treatment of injury, illness, and disease pursuant to drug orders and prescriptions by practitioners; and
(B) licensed with the board under IC 25-6-3-7.

(8) "Performance improvement program" means a continuous, systematic review of key medication use processes to identify, evaluate, and improve medication use and patient care.

(9) "Pharmacist in charge" (by whatever title, for example, "pharmacy manager", "pharmacy director", or "director of pharmacy") means the pharmacist who directs the activities of the institutional pharmacy and who is, as such, responsible for:
(A) all activities of the institutional pharmacy; and
(B) meeting the requirements of:
(i) IC 25-26-13;
(ii) the rules of the board; and
(iii) any federal requirements pertaining to institutional pharmacies.

The qualifying pharmacist may, depending on the circumstances, also be the pharmacist in charge, though the pharmacist in charge is not required to be the qualifying pharmacist.

(10) "Policy and procedure manual" means a written document containing the agreed-to institutional rules of operation and methodology for the effective delivery of pharmacy services.

(11) "Qualifying pharmacist" means the pharmacist who accepts responsibility for the operation of a pharmacy as defined in IC 25-26-13-2 and whose name is listed on the pharmacy permit granted under IC 25-26-13-17.

(12) "Quality-related event" means the inappropriate provision of pharmaceutical services whether or not resulting in an adverse health incident, including the following:
(A) A variation from the practitioner's order, including, but not limited to, the following:
(i) Dispensing an incorrect drug.
(ii) Dispensing an incorrect drug strength.
(iii) Dispensing an incorrect dosage form.
(iv) Dispensing a drug to a wrong patient.
(v) Providing inadequate or incorrect packaging, labeling, or directions.
(vi) Failing to provide an ordered drug.
(B) A failure to identify and manage:
(i) overutilization or underutilization;
(ii) therapeutic duplication;
(iii) drug-disease contraindications;
(iv) drug-drug interactions;
(v) incorrect drug dosage or duration of therapy;
(vi) drug-allergy interactions; or
(vii) clinical abuse and/or misuse.

(13) "Reversible condition" means a condition that requires intervention to resolve in a reasonable time.

(14) "Sentinel event" means an unexpected occurrence involving serious adverse effect, such as disability, life threatening condition, prolonged hospitalization, or death in a patient resulting from medication use.

(15) "Supplying pharmacist" means that pharmacist licensed in the state where the pharmacist is practicing and who is practicing in a supplying pharmacy (as defined in this rule) and who accepts responsibility for all aspects the drugs and devices sold (as defined in IC 25-26-13-2) or dispensed to a facility.

(16) "Supplying pharmacy" means a pharmacy licensed in the state where the pharmacy is located and which provides drugs and devices to patients in long term care or other facilities where patients reside.

(17) "Temporary condition" means a condition that resolves in a reasonable time without intervention.

(Indiana Board of Pharmacy; 856 IAC 1-28.1-1; filed Dec 26, 2001, 2:44 p.m.: 25 IR 1636; readopted filed Sep 26, 2008, 10:55 a.m.: 20081015-IR-856080346RFA)

856 IAC 1-28.1-2 Purpose

Authority: IC 25-26-13-4
Affected: IC 25-26-13-17

Sec. 2. The purpose of this rule is to set forth the responsibilities of pharmacists and pharmacies serving institutional and home health care patients.

(Indiana Board of Pharmacy; 856 IAC 1-28.1-2; filed Dec 26, 2001, 2:44 p.m.: 25 IR 1637; readopted filed Sep 26, 2008, 10:55 a.m.: 20081015-IR-856080346RFA)

856 IAC 1-28.1-3 Applicability

Authority: IC 25-26-13-4
Affected: IC 25-26-13-17

Sec. 3. This rule is applicable to pharmacies located:

(1) within institutional facilities as defined in section 1 of this rule and classified as Type II pharmacies in IC 25-26-13-17; and

(2) outside institutional facilities that serve institutionalized patients who are classified as Type III and Type VI pharmacies as in IC 25-26-13-17.

(Indiana Board of Pharmacy; 856 IAC 1-28.1-3; filed Dec 26, 2001, 2:44 p.m.: 25 IR 1637; readopted filed Sep 26, 2008, 10:55 a.m.: 20081015-IR-856080346RFA)

856 IAC 1-28.1-4 Pharmacist in charge; responsibilities

Authority: IC 25-26-13-4
Affected: IC 25-26-13-17

Sec. 4. The pharmacist in charge or an appropriate designee shall:

(1) be responsible for establishing and carrying out a performance improvement program as defined in section 1 of this rule; and

(2) develop or be responsible for development of a policies and procedures manual that shall be of sufficient scope and detail that pharmacists practicing in the institutional pharmacy will be able to practice effectively and safely.

(Indiana Board of Pharmacy; 856 IAC 1-28.1-4; filed Dec 26, 2001, 2:44 p.m.: 25 IR 1637; readopted filed Sep 26, 2008, 10:55 a.m.: 20081015-IR-856080346RF)

856 IAC 1-28.1-5 Policies and procedures manual

Authority: IC 25-26-13-4
Affected: IC 25-26-13-17

Sec. 5. (a) The pharmacist in charge shall develop or be responsible for the development of a policies and procedures manual that shall be of sufficient scope and detail that pharmacists practicing in the institutional pharmacy will be able to practice effectively and safely.

(b) The manual required in this section shall be available for inspection by a member of the board or its representative.

(c) The policies and procedures manual shall contain, at a minimum, the following:

(1) Provisions for a continuous quality improvement committee that shall be comprised of staff members of the pharmacy, including, but not necessarily limited to, the following:

(A) Pharmacists.
(B) Pharmacist interns or externs.
(C) Pharmacy technicians.
(D) Clerical or support staff.
(E) Other persons deemed necessary by the qualifying pharmacist.

(2) Provisions for the pharmacist in charge or designee to ensure that the committee conducts a review of quality related events at least every three (3) months.

(3) A process to record, measure, assess, and improve quality of patient care.

(4) The procedure for reviewing quality related or sentinel events.

(Indiana Board of Pharmacy; 856 IAC 1-28.1-5; filed Dec 26, 2001, 2:44 p.m.: 25 IR 1637; readopted filed Sep 26, 2008, 10:55 a.m.: 20081015-IR-856080346RF)

856 IAC 1-28.1-6 Personnel

Authority: IC 25-26-13-4
Affected: IC 25-26-13-17

Sec. 6. The qualifying pharmacist and/or the pharmacist in charge shall develop and implement, or cause to be developed and implemented, policies and procedures that specify duties to be performed by pharmacy technicians and other ancillary personnel. *(Indiana Board of Pharmacy; 856 IAC 1-28.1-6; filed Dec 26, 2001, 2:44 p.m.: 25 IR 1638; readopted filed Sep 26, 2008, 10:55 a.m.: 20081015-IR-856080346RFA)*

856 IAC 1-28.1-7 Pharmacist's duties

Authority: IC 25-26-13-4
Affected: IC 16-42-19-3; IC 25-26-13-2; IC 25-26-13-31; IC 25-26-16

Sec. 7. (a) Pursuant to authority granted in IC 25-26-13-2 and IC 25-26-13-31, the duties of the pharmacists practicing in the institutional pharmacy include, but are not limited to, the requirements in this section.

(b) The pharmacist practicing in an institutional pharmacy shall, at a minimum, do the following:

(1) Obtain and maintain patient drug histories and drug profiles.

(2) Perform drug evaluations, drug utilization review, drug regimen review, and drug therapy management under protocol approved by the medical staff of the institution and authorized by IC 25-26-16.

(3) Interpret the drug order written by a practitioner in or transmitted to an institutional facility and either received in or subsequently transmitted to the pharmacy.

(4) Be responsible for checking all drug orders within a maximum of twenty-four (24) hours, including those written during periods when the pharmacy is closed and orders are filled from sources, including emergency kits, drug cabinets, or the pharmacy as authorized under section 8(c) of this rule.

(5) Be responsible for drug product selection of the item that will be used to fill the drug order that may be established either by policy or formulary pursuant to the institution's pharmacy and therapeutics committee or related committee.

(6) Be responsible for determining the legality, completeness, and appropriateness of the drug order and product pursuant to IC 16-42-19-3.

(7) Participate in drug or drug-related research.

(8) Provide counseling, advising, and education of patients, patients' care givers, and health care providers and professionals on issues regarding drugs or drug therapy.

(9) Compound, label, administer, and dispense drugs or devices.

(10) Assess, record, and report quality related events as defined in this rule.

(11) Be responsible for storage and distribution of drugs and devices.

(12) Provide documentation in the medical record of the recommendations made related to the patient's therapeutic response to medication.

(13) Any other duties that shall from time to time be necessary for the proper operation of the institutional pharmacy.

(c) The consultant pharmacist shall, in addition to the duties in subsection (b), provide cognitive services as defined in this rule, including, at a minimum, the following:

(1) Drug regimen reviews as defined in IC 25-26-13-2.

(2) Offer advice and counsel to other health care providers as deemed appropriate regarding the pharmaceutical care of the patient.

(3) Develop or assist in the development of policies and procedures for the legal, safe, and effective means of handling, storing, and disposing of drugs and devices.

(4) Be responsible for assuring the safe and appropriate receipt, labeling, storage, and disposal of all drugs placed outside the pharmacy licensed area in emergency drug kits or other storage devices as authorized by law or rule.

(Indiana Board of Pharmacy; 856 IAC 1-28.1-7; filed Dec 26, 2001, 2:44 p.m.: 25 IR 1638; readopted filed Sep 26, 2008, 10:55 a.m.: 20081015-IR-856080346RFA)

856 IAC 1-28.1-8 Absence of pharmacist

Authority: IC 25-26-13-4
Affected: IC 25-26-13-17

Sec. 8. (a) During such times as an institutional pharmacy is closed and unattended by a pharmacist, the drugs may be obtained for patient use as outlined in this section.

(b) Cabinets, including mechanical storage devices for dispensing drugs, are locked or secured enclosures located outside the pharmacy licensed area, to which only specifically authorized personnel may obtain access by key, combination, or security code, password, or other method of positively identifying an individual, and are sufficiently secure to deny access to unauthorized persons. The qualifying pharmacist and/or pharmacist in charge shall, in conjunction with the appropriate committee of the institutional facility, develop inventory listings of the drugs to be included in such cabinets and shall ensure the following:

(1) Such listed drugs, properly labeled, are available therein.

(2) Only prepackaged drugs (meaning that no repackaging is required at the time of removal for an individual patient's use) are available therein, in amounts sufficient for immediate therapeutic requirements for a period not to exceed twenty-four (24) hours.

(3) When drugs are used, a record is made to include a written physician's order or accountability record.

(4) All drugs therein are reviewed by a pharmacist upon return to duty, not to exceed twenty-four (24) hours.

(5) There are written policies, procedures, and forms established to implement the requirements of this subsection.

(c) Whenever any drug is not available from floor supplies or cabinets, as defined in this section, and such drug is required to treat the immediate needs of a patient, such drug may be obtained from the pharmacy in accordance with the requirements of this subsection. One (1) supervisory licensed nurse in any given shift may have access to the pharmacy and may remove drugs there from. The qualifying pharmacist shall require that the removal of any drug from the pharmacy by an authorized nurse be recorded on a suitable form, which includes the name of the drug, strength, amount, date, time, and signature of nurse, and that a copy of the order shall be left with the form.

(d) Requirements for hospital emergency drug boxes, drug carts, emergency kits, emergency drug kits, crash carts, drug kits, or other storage method for emergency drugs are as follows:

(1) Pharmacy policy and procedures shall assure the:

(A) availability;

(B) control; and

(C) security;

of emergency drug carts, drug kits, or drug boxes in the pharmacy and patient care areas.

(2) Procedures shall include the following:

(A) Determination of drugs and quantities of drugs to be included.

(B) Labeling for expiration date.

(C) Process for restocking the cart, kit, or box.

(D) Security measures to prevent unauthorized access.

(Indiana Board of Pharmacy; 856 IAC 1-28.1-8; filed Dec 26, 2001, 2:44 p.m.: 25 IR 1638; readopted filed Sep 26, 2008, 10:55 a.m.: 20081015-IR-856080346RFA)

856 IAC 1-28.1-9 Emergency drug kits from Type III and Type VI pharmacies

Authority: IC 25-26-13-4

Affected: IC 25-26-13-17; IC 35-38

Sec. 9. (a) Emergency drug kits supplied by pharmacies with a Type III or Type VI permit shall be in compliance with this section.

(b) All drugs in the emergency kit shall be provided and owned by a single supplying pharmacy.

(c) All drugs in the emergency drug kit shall be selected and approved by a committee whose membership includes, at a minimum, the following:

(1) The facility's consultant pharmacist.

(2) A licensed nurse.

(3) A physician (medical doctor or doctor of osteopathy).

(4) The facility administrator.

(d) The selection process must identify drugs and quantities thereof in the emergency drug kit.

(e) The lists of drugs and quantities included in the emergency drug kit shall be reviewed as required periodically, but no less often than yearly.

(f) Labeling as follows:

(1) The exterior labeling of the emergency drug kit as described in this subsection shall contain, at a minimum, the following:

(A) Drug name (trade name, generic name, or active ingredients).

(B) Drug strength or size, if any.

(C) Quantity included therein.

(D) Expiration date of the kit as defined in this section.

(2) All drugs contained in the emergency drug kit as described in this section shall be labeled, at a minimum, with the following:

(A) Drug name (trade name, generic name, or active ingredients).

(B) Drug strength or size, if applicable.

(C) Name of the manufacturer, packer, or distributor.

(D) Lot number.

(E) Expiration date.

(g) The expiration date of the emergency drug kit, as required in subsection (f)(1)(D) shall be the earliest date of expiration of any of the drugs included in the kit at any time.

(h) All emergency kits subject to this subsection:

(1) shall be stored in a secure area, suitable for the prevention of unauthorized access to or diversion of the drugs therein;

(2) if controlled substances, as defined in IC 35-38, are stored in such a manner as to facilitate periodic reconciliation by the facility nursing staff, that reconciliation shall be recorded in an appropriate manner as determined by the committee described under this section; and

(3) all controlled substances contained in emergency drug kits shall remain the property of the supplying pharmacy and as such shall be included in the pharmacy's biennial inventory as required by 21 CFR 1303.04 and 21 CFR 1301.11.

(i) The nurse responsible for removing drugs from an emergency drug kit shall record or cause to be recorded, in a manner designated under subsection (h)(2), the following minimum information:

(1) Name of the patient.

(2) Name of the drug.

(3) Strength of the drug.

(4) Quantity removed.

(5) Date of removal.

(6) Time of removal.

(j) Removal of a controlled substance in Schedule II pursuant to an oral authorization from a practitioner shall be documented, and the nurse accepting such authorization is responsible for compliance with 856 IAC 2-6-7 regarding prescription requirements for controlled substances in Schedule II.

(k) Removal of a controlled substance in Schedule III, IV, or V, pursuant to an oral authorization from a practitioner, shall be documented, and the nurse accepting such authorization is responsible for compliance with 856 IAC 2-6-12.

(l) Whenever an emergency kit is opened, for any reason, the supplying pharmacy shall be notified in a timely manner, and the pharmacy shall restock, if necessary, and reseal the kit promptly so as to prevent risk of harm to patients of the facility.

(Indiana Board of Pharmacy; 856 IAC 1-28.1-9; filed Dec 26, 2001, 2:44 p.m.: 25 IR 1639; readopted filed Sep 26, 2008, 10:55 a.m.: 20081015-IR-856080346RFA)

856 IAC 1-28.1-10 Security

Authority: IC 25-26-13-4
Affected: IC 25-26-13-17

Sec. 10. The pharmacy shall be capable of being secured against entry by key, combination, code, password, or other method developed that can positively identify an individual so as to prevent access by unauthorized personnel.

(Indiana Board of Pharmacy; 856 IAC 1-28.1-10; filed Dec 26, 2001, 2:44 p.m.: 25 IR 1640; readopted filed Sep 26, 2008, 10:55 a.m.: 20081015-IR-856080346RFA)

856 IAC 1-28.1-11 Performance improvement events, sentinel events, corrective and avoidance measures, review, records, and documentation

Authority: IC 25-26-13-4
Affected: IC 25-26-13-17

Sec. 11. (a) The pharmacist in charge shall, as a part of the pharmacy's performance improvement program, assure or be responsible for assuring that data are collected to:

(1) monitor the stability of existing medication use processes;
(2) identify opportunities for improvement; and
(3) identify changes that will lead to and sustain improvement.

(b) Identification of quality related or sentinel event as defined in section 1 of this rule shall be cause for:

(1) an intensive analysis of causal factors involved in the event; and
(2) plans for corrective actions.

(c) Records of all processes, analysis, and corrective measures instituted involving such pharmacy quality related or sentinel event shall be maintained for a period of not less than two (2) years.

(d) The committee created under section 5(c)(1) of this rule shall, at a minimum, consider the effects on quality of the pharmacy system due to the following:

(1) Staffing levels of both professional and technical personnel.
(2) Workflow.
(3) Use of technology.

(e) Requirements for documentation of performance improvement monitoring of medication use processes, confidentiality of records, summarization, and examination by the board shall be as follows:

(1) Each quality related or sentinel event that occurs, or is alleged to have occurred, as the result of activities involving pharmacy operations, shall be documented in a written or electronic storage record created solely for that purpose.

(2) The quality related or sentinel event shall be:

(A) initially documented by the pharmacist to whom it is first described; and
(B) recorded on the same day of its having been so described to the pharmacist.

(3) Documentation shall include a description of the event that is of sufficient detail to permit analysis of the event.
(4) The pharmacist in charge shall summarize, or cause to be summarized, efforts to improve the medication use process on a semiannual basis.
(5) No patient names or employee names shall be included in this summary report.
(6) This report shall be maintained for a period of not less than two (2) years.
(7) The records created and maintained as a component of a pharmacy performance improvement program are confidential to the extent law permits. However, to assure compliance, the board or its representative may review the policies and procedures manual and a summarization of events described in subsection (b).

(Indiana Board of Pharmacy; 856 IAC 1-28.1-11; filed Dec 26, 2001, 2:44 p.m.: 25 IR 1640; readopted filed Sep 26, 2008, 10:55 a.m.: 20081015-IR-856080346RFA)

856 IAC 1-28.1-12 Drug distribution, storage, and accountability

Authority: IC 25-26-13-4
Affected: IC 25-26-13-17

Sec. 12. (a) All drugs and devices in pharmacies located within institutions shall be obtained and used in accordance with written policies and procedures that have been prepared or approved by the qualifying pharmacist or pharmacist in charge and the medical staff who explain the:

(1) selection;
(2) distribution;
(3) storage; and
(4) safe and effective use of:
(A) drugs;
(B) new drugs;
(C) investigational new drugs; and
(D) devices;
in the facility.

(b) The pharmacist in charge of the pharmacy located within an institution shall be responsible for the following:
(1) The safe and efficient:
(A) distribution;
(B) control;
(C) storage; and
(D) accountability;
for all drugs and devices.
(2) The compliance with all applicable Indiana and federal laws and rules.

(c) Labeling requirements are as follows:
(1) All drugs, other than unit-of-use packages, dispensed by an institutional pharmacy, intended for use within the facility, shall be distributed in appropriate containers and adequately labeled so as to identify, at a minimum, the following:
(A) Patient identification.
(B) Brand name or generic name, or both.
(C) Strength, if applicable.
(D) Route of administration.
(E) Quantity.
(F) Pharmacist's initials.
(G) Location of the patient within the institution.
(2) Unit-of-use packages shall contain information to adequately label them, at a minimum, as follows:
(A) Drug name (brand or generic, or both).
(B) Strength, if applicable.
(C) Control number and/or expiration date.
(3) All drugs dispensed by an institutional pharmacy to patients about to be discharged, or temporarily discharged, from institutions with Type III or Type IV permits, shall be labeled with the following minimum information:
(A) Name, address, and telephone number of the institutional pharmacy.
(B) Date and identifying serial number.
(C) Name of patient.
(D) Name of drug and strength, if applicable.
(E) Directions for use by the patient and route of administration.
(F) Name of prescribing practitioner.
(G) Precautionary information if any contained in the prescription.

(d) Requirements for the disposition of discontinued or recalled drugs are as follows:
(1) The qualifying pharmacist or pharmacist in charge shall be responsible for the development and implementation of policies and procedures for the return to the pharmacy of drugs and containers that are:
(A) discontinued, outdated, or recalled; or
(B) in containers with worn, illegible, or missing labels;
for proper disposition.
(2) The qualifying pharmacist or pharmacist in charge or his or her designee shall make proper disposition of such drugs at the storage site.

(e) The qualifying pharmacist or pharmacist in charge shall ensure that drugs are dispensed from the institutional pharmacy only upon authorized practitioner's:
(1) written orders;
(2) direct copies;
(3) facsimiles thereof; or
(4) electronically transmitted by other means and printed or displayed appropriately.

(f) Accountability requirements are as follows:
(1) The qualifying pharmacist or pharmacist in charge of an institutional pharmacy shall ensure that policies and procedures documenting the trail of:
(A) controlled substances; and
(B) such other drugs as may be specified by the appropriate committee of the institutional facility, from ordering and receiving by the pharmacy through administration or wastage of drug at the patient level.
(2) The qualifying pharmacist or pharmacist in charge shall be responsible for review of this process on a continual basis by review of:
(A) proofs-of-use documentation; or
(B) other electronic documentation methodology.

(3) At a minimum, the documentation process shall be able to identify the following:
(A) The name of the drug.
(B) The dose.
(C) The patient's name.
(D) The date and time of administration to the patient.
(E) The identification of the individual administering.
(F) The record of aliquot portion destroyed, if any, and identification of witness.

(g) All records and reports that are required for pharmacy functions shall be maintained according to policies and procedures developed within the institution with the approval of the pharmacist in charge for a period of not less than two (2) years.

(Indiana Board of Pharmacy; 856 IAC 1-28.1-12; filed Dec 26, 2001, 2:44 p.m.: 25 IR 1641; readopted filed Sep 26, 2008, 10:55 a.m.: 20081015-IR-856080346RFA)

856 IAC 1-28.1-13 Drug self-administration

Authority: IC 25-26-13-4
Affected: IC 25-26-13-17

Sec. 13. Self-administration of drugs by patients of an institutional facility shall be permitted only if such use is specifically authorized by the treating or ordering physician and:

(1) the patient's knowledge of self-administration has been evaluated; or
(2) the patient has received training in the proper manner of self-administration:
(A) by a pharmacist; or
(B) according to hospital policy; and

there is no risk of harm to the patient.

(Indiana Board of Pharmacy; 856 IAC 1-28.1-13; filed Dec 26, 2001, 2:44 p.m.: 25 IR 1642; readopted filed Sep 26, 2008, 10:55 a.m.: 20081015-IR-856080346RF)

856 IAC 1-28.1-14 Patient's own medication

Authority: IC 25-26-13-4
Affected: IC 25-26-13-17

Sec. 14. (a) An institutional pharmacy is prohibited from accepting and dispensing drugs that are brought into the institution by the patient, even if intended for use by that same patient. However, use of the patient's own medication may be permitted if:

(1) the patient or the patient's representative may maintain the patient's own medication:
(A) at the bedside; or
(B) for drugs with special storage requirements, including, but not limited to, refrigeration in an appropriate storage area in the patient care area under control of nursing personnel for appropriate administration to that patient only; and
(2) the nurses in charge of that patient's care shall witness the administration and maintain records of such use.

(b) If the patient or the patient's representative brings in medication part or all of which is still present at such time a patient expires, those drugs shall be delivered to the institutional pharmacy for appropriate destruction. Such drugs may not be turned over to the patient's representatives. This rule shall be made clear to the parties involved prior to the permission to use such medication. Patients who are discharged shall take with them their own medications brought to the institution under the terms of this section.

(c) In the event the patient is discharged and leaves drugs brought in under this section, either deliberately or inadvertently, such drugs shall be documented and stored at the appropriate nursing location for a maximum of seven (7) calendar days. If not claimed by the patient or the patient's agent within those seven (7) calendar days, the drugs so stored shall be destroyed as described in subsection (b).

(Indiana Board of Pharmacy; 856 IAC 1-28.1-14; filed Dec 26, 2001, 2:44 p.m.: 25 IR 1642; readopted filed Sep 26, 2008, 10:55 a.m.: 20081015-IR-856080346RFA)

856 IAC 1-28.1-15 Inspections

Authority: IC 25-26-13-4
Affected: IC 16-42-3-3; IC 25-26-13-17

Sec. 15. The qualifying pharmacist or pharmacist in charge shall be responsible for the timely inspection of all areas where drugs are stored, used, or administered. The inspection can be carried out by qualified designee and appropriate records kept. The inspection shall verify, at a minimum, the following:

(1) Disinfectants and drugs solely for nontherapeutic external use are stored separately and apart from drugs for internal use or injection.
(2) Drugs requiring special storage conditions are appropriately stored to assure the drugs are not adulterated as described in IC 16-42-3-3.
(3) Drugs subject to deterioration are removed from any accessible location prior to the expiration date (manufacturer's or other such as required under 856 IAC 1-21) and disposed of appropriately.
(4) Emergency drugs designated by the institution are in adequate supply and are properly stored in the institution.
(5) All necessary and required security and storage standards are met.
(6) All pharmacy-related policies and procedures of the institution are complied with.

(Indiana Board of Pharmacy; 856 IAC 1-28.1-15; filed Dec 26, 2001, 2:44 p.m.: 25 IR 1642; readopted filed Sep 26, 2008, 10:55 a.m.: 20081015-IR-856080346RFA)

Rule 29. Electronic Data Processing of Prescriptions

856 IAC 1-29-1 Approval of electronic data processing system

Authority: IC 25-26-13-4
Affected: IC 25-26-13-25

Sec. 1. (a) No electronic data processing system may be used by a pharmacist pursuant to a Type I, Type III, and Type VI pharmacy permit as an alternative to his or her recordation of prescription information unless that system has been approved by the Indiana board of pharmacy (board).

(b) No electronic data processing system may be used by a pharmacist as an alternative to his recordation of information directly on the original prescription pursuant to IC 25-26-13-25(c), without the approval of the board, and such an electronic data processing system does not qualify for approval unless it satisfies at a minimum the requirements found in this rule. Any such system must be approved by the board before initial installation in Indiana. Any pharmacy installing such a system must make a written request to the board for approval. Approval is subject to withdrawal for cause so that the pharmacist must in such a case discontinue use of the system as an alternative.

(Indiana Board of Pharmacy; 856 IAC 1-29-1; filed Aug 16, 1984, 3:55 p.m.: 7 IR 2543; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1337; readopted filed Oct 4, 2007, 3:33 p.m.: 20071031-IR-856070060RFA)

856 IAC 1-29-2 On-line retrieval and printout capabilities; data requirements; discontinuance of system

Authority: IC 25-26-13-4
Affected: IC 25-26-13-25

Sec. 2. (a) Any such proposed computerized system must provide on-line retrieval (via visual display device or hard-copy printout) of original prescription order information for those prescription orders which are currently authorized for refilling. This shall include:

(1) prescription number;
(2) date of issuance of the original prescription order by the prescriber;
(3) full name and address of the patient;
(4) name and address of prescriber;
(5) DEA number of prescriber when drug prescribed is controlled substance;
(6) the name, strength (if applicable), dosage form, and quantity of medication originally dispensed;
(7) total number of refills authorized by prescriber.

(b) In addition to the information contained in subsection (a) above, the following information shall be maintained for each filling:

(1) date dispensed;
(2) quantity dispensed, if different from the quantity prescribed;
(3) identification of dispensing pharmacist;
(4) adequate information to determine the number of authorized refills remaining.

(c) The system shall be able to produce a complete printout of current prescription status that would provide all necessary refill information for use in the event that the pharmacy wishes to discontinue use of the computer system. The report shall list all currently refillable prescriptions in sequence by prescription number. The following information shall be included:

(1) prescription number;
(2) date dispensed, quantity, and pharmacist's identification;
(3) the number of refills presently remaining and the amount owed, if any, from any partial refills.

(Indiana Board of Pharmacy; 856 IAC 1-29-2; filed Aug 16, 1984, 3:55 pm: 7 IR 2544; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330; readopted filed Oct 4, 2007, 3:33 p.m.: 20071031-IR-856070060RFA)

856 IAC 1-29-3 Hard-copy of daily dispensing; verification and retention; back-up capability

Authority: IC 25-26-13-4
Affected: IC 25-26-13-25

Sec. 3. (a) A pharmacy using an electronic data processing system must provide a separate hard-copy printout of prescription order and refill data for each day's dispensing or other board approved uniformly maintained readily retrievable system. This hard-copy printout or other board approved system shall include the following:

(1) prescription number;
(2) date of dispensing;
(3) patient name;
(4) drug and strength (if applicable);
(5) quantity dispensed;
(6) prescriber identification;
(7) pharmacist identification;
(8) refill status;

Statutory Law
Administrative Rules
Court Rules
Chamber Rules
Constitution

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CHAPTER 7
HOSPITAL PHARMACY PRACTICE
[Prior to 2/10/88, see Pharmacy Examiners[620] Ch 12]

657—7.1(155A) Purpose and scope. Hospital pharmacy means and includes a pharmacy licensed by the board and located within any hospital, health system, institution, or establishment which maintains and operates organized facilities for the diagnosis, care, and treatment of illnesses to which patients may or may not be admitted for overnight stay at the facility. A hospital is a facility licensed pursuant to Iowa Code chapter 135B. This chapter does not apply to a pharmacy located within such a facility for the purpose of providing outpatient prescriptions. A pharmacy providing outpatient prescriptions is and shall be licensed as a general pharmacy subject to the requirements of 657—Chapter 6. The requirements of these rules for hospital pharmacy practice apply to all hospitals, regardless of size or type, and are in addition to the requirements of 657—Chapter 8 and other rules of the board relating to services provided by the pharmacy.
[ARC 9911B, IAB 12/14/11, effective 1/18/12]

657—7.2(155A) Pharmacist in charge. One professionally competent, legally qualified pharmacist in charge in each pharmacy shall be responsible for, at a minimum, the items identified in this rule. A part-time pharmacist in charge has the same obligations and responsibilities as a full-time pharmacist in charge. Where 24-hour operation of the pharmacy is not feasible, a pharmacist shall be available on an "on call" basis. The pharmacist in charge, at a minimum, shall be responsible for:

1. Ensuring that the pharmacy utilizes an ongoing, systematic program for achieving performance improvement and ensuring the quality of pharmaceutical services.
2. Ensuring that the pharmacy employs an adequate number of qualified personnel commensurate with the size and scope of services provided by the pharmacy and sufficient to ensure adequate levels of quality patient care services. Drug dispensing by nonpharmacists shall be minimized and eliminated wherever possible.
3. Ensuring the availability of any equipment and references necessary for the particular practice of pharmacy.
4. Ensuring that a pharmacist performs therapeutic drug monitoring and drug use evaluation.
5. Ensuring that a pharmacist provides drug information to other health professionals and to patients.
6. Dispensing drugs to patients, including the packaging, preparation, compounding, and labeling functions performed by pharmacy personnel.
7. Delivering drugs to the patient or the patient's agent.
8. Ensuring that patient medication records are maintained as specified in rule 657—7.10(124,155A).
9. Training pharmacy technicians and pharmacy support persons.
10. Ensuring adequate and appropriate pharmacist oversight and supervision of pharmacy technicians and pharmacy support persons.
11. Procuring and storing prescription drugs and devices and other products dispensed from the pharmacy.
12. Distributing and disposing of drugs from the pharmacy.
13. Maintaining records of all transactions of the pharmacy necessary to maintain accurate control over and accountability for all drugs as required by applicable state and federal laws, rules, and regulations.
14. Establishing and maintaining effective controls against the theft or diversion of prescription drugs, controlled substances, and records for such drugs.
15. Preparing a written operations manual governing pharmacy functions; periodically reviewing and revising those policies and procedures to reflect changes in processes, organization, and other pharmacy functions; and ensuring that all pharmacy personnel are familiar with the contents of the manual.

16. Ensuring the legal operation of the pharmacy, including meeting all inspection and other requirements of state and federal laws, rules, and regulations governing the practice of pharmacy.
[ARC 8673B, IAB 4/7/10, effective 6/1/10]

657—7.3(155A) Reference library. References may be printed or computer-accessed. A reference library shall be maintained which includes, as a minimum, one current reference from each of the following categories, including access to current periodic updates.

1. The Iowa Pharmacy Law and Information Manual.
2. A patient information reference that includes or provides patient information in compliance with rule 657—6.14(155A).
3. A reference on drug interactions.
4. A general information reference.
5. A drug equivalency reference.
6. An injectable-drug compatibility reference.
7. A drug identification reference to enable identification of drugs brought into the facility by patients.
8. The readily accessible telephone number of a poison control center that serves the area.
9. Additional references as may be necessary for the pharmacist to adequately meet the needs of the patients served. For example, the treatment of pediatric patients and oncology patients would require additional references unique to those specialties.

657—7.4 and **7.5** Reserved.

657—7.6(124,155A) Security. The pharmacy shall be located in an area or areas that facilitate the provision of services to patients and shall be integrated with the facility's communication and transportation systems. The following conditions must be met to ensure appropriate control over drugs and chemicals in the pharmacy:

7.6(1) *Pharmacist responsibility.* Each pharmacist, while on duty, shall be responsible for the security of the pharmacy area, 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 as provided in 657—Chapter 21. Policies and procedures shall identify the minimum amount of time that a pharmacist is available at the hospital pharmacy.

7.6(2) *Access when pharmacist absent.* When the pharmacist is absent from the facility, the pharmacy is closed. Policies and procedures shall be established that identify who will have access to the pharmacy when the pharmacy is closed and the procedures to be followed for obtaining drugs, devices, and chemicals to fill an emergent need during the pharmacist's absence.

a. The pharmacist in charge may designate pharmacy technicians or pharmacy support persons who may be present in the pharmacy to perform technical or nontechnical functions, respectively, designated by the pharmacist in charge. Activities identified in paragraph *"d"* of this subrule may not be performed when the pharmacy is closed.

b. If the pharmacist in charge has authorized the presence in the pharmacy of a pharmacy technician or a pharmacy support person to perform designated functions when the pharmacy is closed, only a certified pharmacy technician may assist another authorized, licensed health care professional to locate a drug or device pursuant to an emergent need. The pharmacy technician or the pharmacy support person may not dispense or deliver the drug, chemical, or device to the licensed health care professional. The licensed health care professional shall comply with established policies and procedures for obtaining drugs, devices, and chemicals when the pharmacy is closed. The licensed health care professional shall not ask or expect the pharmacy technician or the pharmacy support person to verify that the appropriate drug, chemical, or device has been obtained from the pharmacy.

c. A pharmacy technician or a pharmacy support person who is present in the pharmacy when the pharmacy is closed shall prepare and maintain in the pharmacy a log identifying each period of time that the pharmacy technician or pharmacy support person worked in the pharmacy while the pharmacy was

closed and identifying each activity performed during that time period. Each entry shall be dated and each daily record shall be signed by the pharmacy technician or pharmacy support person who prepared the record. The log shall be periodically reviewed by the pharmacist in charge.

d. Activities which shall not be performed by a pharmacy technician or a pharmacy support person when the pharmacist is absent from the facility include:

(1) Dispensing, delivering, or distributing any prescription drugs or devices to patients or others, including health care professionals, prior to pharmacist verification. Verification by a nurse or other licensed health care professional shall not supplant verification by a pharmacist.

(2) Providing the final verification for the accuracy, validity, completeness, or appropriateness of a filled prescription or medication order.

(3) Conducting prospective drug use review or evaluating a patient's medication record for purposes identified in rule 657—8.21(155A).

(4) Providing patient counseling, consultation, or drug information.

(5) Making decisions that require a pharmacist's professional judgment such as interpreting or applying information.

(6) Preparing compounded drug products for immediate administration by other hospital staff or health care professionals without verification by a pharmacist.

7.6(3) *Locked areas.* All pharmacy areas where drugs or devices are maintained or stored and where a pharmacist is not continually present shall be locked.

7.6(4) *Verification by pharmacist.* When the pharmacy is open, patient-specific drugs or devices shall not be distributed prior to the pharmacist's final verification and approval.

7.6(5) *Drugs or devices in patient care areas.* Drugs or devices maintained or stored in patient care areas shall be in locked storage unless the patient care unit is staffed by health care personnel and the medication area is visible to staff at all times.

[ARC 8673B, IAB 4/7/10, effective 6/1/10; **ARC 9408B**, IAB 3/9/11, effective 4/13/11]

657—7.7(155A) Verification by pharmacist when pharmacy is closed. A hospital pharmacy may contract with another pharmacy for remote pharmacist preview and verification of patient-specific drugs or devices ordered for a patient when the hospital pharmacy is closed. Contracted services may include pharmacist order entry pursuant to subrule 7.8(3). Pharmacies entering into a contract or agreement pursuant to this rule shall comply with the following requirements:

7.7(1) *Nonsupplanting service.* A contract or agreement for remote pharmacist services shall not relieve the hospital pharmacy from employing or contracting with a pharmacist to provide routine pharmacy services within the facility. The activities authorized by this rule are intended to supplement hospital pharmacy services when the pharmacy is closed and are not intended to eliminate the need for an on-site hospital pharmacy or pharmacist.

7.7(2) *Hospital-staff pharmacist.* Nothing in this rule shall prohibit a pharmacist employed by or contracting with a hospital pharmacy for on-site services from also providing remote preview and verification of patient-specific drugs or devices ordered for a patient when the hospital pharmacy is closed. A pharmacist previewing and verifying drug or device orders from a remote location shall have access to patient information pursuant to subrule 7.7(4) or 7.7(5), shall have access to the prescriber as provided in subrule 7.7(6), and shall be identified on the drug or device order as provided in subrule 7.7(7).

7.7(3) *Licenses required.* A pharmacy contracting with a hospital pharmacy to provide services pursuant to this rule shall maintain with the board a current Iowa pharmacy license. A remote pharmacist providing pharmacy services as an employee or agent of a contracting pharmacy pursuant to this rule shall be licensed to practice pharmacy in Iowa.

7.7(4) *Electronic access to patient information.* The remote pharmacist shall have secure electronic access to the hospital pharmacy's patient information system and to all other electronic systems that the on-site pharmacist has access to when the pharmacy is open. The remote pharmacist shall receive training in the use of the hospital's electronic systems.

7.7(5) *Nonelectronic patient information.* If a hospital's patient information is not maintained in an electronic data system or if the hospital pharmacy is not able to provide remote electronic access to the patient information system, the hospital pharmacy may petition for a waiver of subrule 7.7(4) pursuant to 657—Chapter 34 and this subrule. In addition to the information required pursuant to 657—Chapter 34, the petition for waiver shall identify the hospital pharmacy's alternative to the electronic sharing of patient information, shall explain in detail how the alternative method will ensure timely provision of patient information necessary for the remote pharmacist to effectively review the patient's drug regimen and history, and shall detail the processes involved in the alternative proposal including identification of all individuals involved in each of those processes.

7.7(6) *Access to prescriber.* The remote pharmacist shall be able to contact the prescriber to discuss any concerns identified during the pharmacist's review of the patient's information.

7.7(7) *Pharmacist identified.* The record of each patient-specific drug or device order processed pursuant to this rule shall identify, by name or other unique identifier, each pharmacist involved in the preview and verification of the order. The record of each patient-specific drug or device visually verified pursuant to this rule shall identify, by name or other unique identifier, each pharmacist involved in the visual verification of the product.

[ARC 9408B, IAB 3/9/11, effective 4/13/11]

657—7.8(124,126,155A) Drug distribution and control. Policies and procedures governing drug distribution and control shall be developed by the pharmacist in charge with input from other involved hospital staff such as physicians and nurses, 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) *Drug preparation.* The pharmacist shall institute the control procedures needed to ensure that patients receive the correct drugs at the proper times. Adequate quality assurance procedures shall be developed.

a. Hospitals shall utilize a unit dose dispensing system pursuant to rule 657—22.1(155A). All drugs dispensed by the pharmacist for administration to patients shall be in single unit or unit dose packages if practicable unless the dosage form or drug delivery device makes it impracticable to package the drug in a unit dose or single unit package.

(1) The pharmacist in charge shall establish policies and procedures that identify situations when drugs may be dispensed in other than unit dose or single unit packages outside the unit dose dispensing system.

(2) The need for nurses to manipulate drugs prior to their administration shall be minimized.

b. Pharmacy personnel shall, except as specified in policies and procedures, prepare all sterile products in conformance with 657—Chapter 13.

c. Pharmacy personnel shall compound or prepare drug formulations, strengths, dosage forms, and packages useful in the care of patients.

7.8(2) *Drug formulary.* The pharmacist in charge shall maintain a current formulary of drug products approved for use in the institution and shall be responsible for specifications for those drug products and for selecting their source of supply.

7.8(3) *Medication orders.* Except as provided in subrule 7.8(14) or this subrule, a pharmacist shall receive a copy of an original written medication order for review except when the prescriber directly enters the medication order into an electronic medical record system or when the prescriber issues a verbal medication order directly to a registered nurse or pharmacist who then enters the order into an electronic medical record system.

a. *Verbal order.* The use of verbal orders shall be minimized. All verbal orders shall be read back to the prescriber, and the read back shall be documented with or on the order.

b. *Written order not entered by prescriber.* If an individual other than the prescriber enters a medication order into an electronic medical record system from an original written medication

order, the pharmacist shall review and verify the entry against the original written order before the drug is dispensed except for emergency use, when the pharmacy is closed, or as provided in rule 657—7.7(155A).

c. *Order entered when pharmacy closed.* When the pharmacy is closed, a registered nurse or pharmacist may enter a medication order into an electronic medical record system for the purpose of creating an electronic medication administration record and a pharmacist shall verify the entry against the original written medication order, if such written order exists, as soon as practicable.

d. *System security.* Hospitalwide and pharmacy stand-alone computer systems shall be secure against unauthorized entry. System login or access credentials issued to an authorized system user shall not be shared or disclosed to any other individual.

e. *Abbreviations and chemical symbols on orders.* The use of abbreviations and chemical symbols on medication orders shall be discouraged but, if used, shall be limited to abbreviations and chemical symbols approved by the appropriate patient care committee.

7.8(4) *Stop order.* A written policy or other system concerning stop orders shall be established to ensure that medication orders are not inappropriately continued.

7.8(5) *Emergency drug supplies and floor stock.* Supplies of drugs for use in medical emergencies shall be immediately available at each nursing unit or service area as specified in policies and procedures. Authorized stocks shall be periodically reviewed in a multidisciplinary manner. All drug storage areas within the hospital shall be routinely inspected to ensure that no outdated or unusable items are present and that all stock items are properly labeled and stored.

7.8(6) *Disaster services.* The pharmacy shall be prepared to provide drugs and pharmaceutical services in the event of a disaster affecting the availability of drugs or internal access to drugs or access to the pharmacy.

7.8(7) *Drugs brought into the institution.* The pharmacist in charge shall determine those circumstances when patient-owned drugs brought into the institution may be administered to a hospital patient and shall establish policies and procedures governing the use and security of drugs brought into the institution. Procedures shall address identification of the drug and methods for ensuring the integrity of the product prior to permitting its use by the patient. The use of patient-owned drugs shall be minimized to the greatest extent possible.

7.8(8) *Samples.* The use of drug samples within the institution shall be eliminated to the extent possible. Sample use is prohibited for hospital inpatient use. If the use of drug samples is permitted for hospital outpatients, that use of samples shall be controlled and the samples shall be distributed through the pharmacy or through a process developed in cooperation with the pharmacy and the institution's appropriate patient care committee, subject to oversight by the pharmacy.

7.8(9) *Investigational drugs.* If investigational drugs are used in the institution:

a. A pharmacist shall be a member of the institutional review board.

b. The pharmacy shall be responsible, in cooperation with the principal investigator, for providing information about investigational drugs used in the institution and for the distribution and control of those drugs.

7.8(10) *Hazardous drugs and chemicals.* The pharmacist, in cooperation with other hospital staff, shall establish policies and procedures for handling drugs and chemicals that are known occupational hazards. The procedures shall maintain the integrity of the drug or chemical and protect hospital personnel.

7.8(11) *Leave meds.* Labeling of prescription drugs for a patient on leave from the facility for a period in excess of 24 hours shall comply with 657—subrule 6.10(1). The dispensing pharmacy shall be responsible for packaging and labeling leave meds in compliance with this subrule.

7.8(12) *Discharge meds.* Drugs authorized for a patient being discharged from the facility shall be labeled in compliance with 657—subrule 6.10(1) before the patient removes those drugs from the facility premises. The dispensing pharmacy shall be responsible for packaging and labeling discharge meds in compliance with this subrule.

7.8(13) *Own-use outpatient prescriptions.* If the hospital pharmacy dispenses own-use outpatient prescriptions, the pharmacy shall comply with all requirements of 657—Chapter 6 except rule 657—6.1(155A).

7.8(14) *Influenza and pneumococcal vaccines.* As authorized by federal law, a written or verbal patient-specific medication administration order shall not be required prior to administration to an adult patient of influenza and pneumococcal polysaccharide vaccines pursuant to physician-approved hospital policy and after the patient has been assessed for contraindications. Administration shall be recorded in the patient's medical record.

[**ARC 8170B**, IAB 9/23/09, effective 10/28/09; **ARC 9911B**, IAB 12/14/11, effective 1/18/12]

657—7.9(124,155A) Drug information. The pharmacy is responsible for providing the institution's staff and patients with accurate, comprehensive information about drugs and their use and shall serve as its center for drug information.

7.9(1) *Staff education.* The pharmacist shall keep the institution's staff well informed about the drugs used in the institution and their various dosage forms and packagings.

7.9(2) *Patient education.* The pharmacist shall help ensure that all patients are given adequate information about the drugs that they receive. This is particularly important for ambulatory, home care, and discharged patients. These patient education activities shall be coordinated with the nursing and medical staffs and patient education department, if any.

657—7.10(124,155A) Ensuring rational drug therapy. An important aspect of pharmaceutical services is that of maximizing rational drug use. The pharmacist, in concert with the medical staff, shall develop policies and procedures for ensuring the quality of drug therapy.

7.10(1) *Patient profile.* Sufficient patient information shall be collected, maintained, and reviewed by the pharmacist to ensure meaningful and effective participation in patient care. This requires that a drug profile be maintained for each patient receiving care at the hospital. A pharmacist-conducted drug history from patients may be useful in this regard.

a. Appropriate clinical information about patients shall be available and accessible to the pharmacist for use in daily practice.

b. The pharmacist shall review each patient's current drug regimen and directly communicate any suggested changes to the prescriber.

7.10(2) *Adverse drug events.* The pharmacist, in cooperation with the appropriate patient care committee, shall develop a mechanism for the reporting and review, by the committee or other appropriate medical group, of adverse drug events. The pharmacist shall be informed of all reported adverse drug events occurring in the facility. Adverse drug events include but need not be limited to adverse drug reactions and medication errors.

657—7.11(124,126,155A) Outpatient services. No prescription drugs shall be dispensed to patients in a hospital outpatient setting. If a need is established for the dispensing of a prescription drug to an outpatient, a prescription drug order shall be provided to the patient to be filled at a pharmacy of the patient's choice.

7.11(1) *Definitions.* For the purposes of this rule, the following definitions shall apply:

"Emergency department patient" means an individual who is examined and evaluated in the emergency department.

"Outpatient" means an individual examined and evaluated by a prescriber who determined the individual's need for the administration of a drug or device, which individual presents to the hospital outpatient setting with a prescription or order for administration of a drug or device. "Outpatient" does not include an emergency department patient.

"Outpatient medication order" means a written order from a prescriber or an oral or electronic order from a prescriber or the prescriber's authorized agent for administration of a drug or device. An outpatient medication order may authorize continued or periodic administration of a drug or device for

a period of time and frequency determined by the prescriber or by hospital policy, not to exceed legal limits for the refilling of a prescription drug order.

7.11(2) *Administration in the outpatient setting.* Drugs shall be administered only to outpatients who have been examined and evaluated by a prescriber who determined the patient's need for the drug therapy ordered.

a. *Accountability.* A system of drug control and accountability shall be developed and supervised by the pharmacist in charge and the facility's outpatient services committee, or a similar group or person responsible for policy in the outpatient setting. The system shall ensure accountability of drugs incidental to outpatient nonemergency therapy or treatment. Drugs shall be administered only in accordance with the system.

b. *Controlled substances.* Controlled substances maintained in the outpatient setting are kept for use by or at the direction of prescribers for the nonemergency therapy or treatment of outpatients. In order to receive a controlled substance, a patient shall be examined in the outpatient setting or in an alternate practice setting or office by a prescriber who shall determine the patient's need for the drug. If the patient is examined in a setting outside the outpatient setting, the prescriber shall provide the patient with a written prescription or order to be presented at the hospital outpatient setting.

c. *Outpatient medication orders.* A prescriber may authorize, by outpatient medication order, the periodic administration of a drug to an outpatient.

(1) Schedule II controlled substance. An outpatient medication order for administration of a Schedule II controlled substance shall be written and, except as provided in rule 657—10.25(124) regarding the issuance of multiple Schedule II prescriptions, shall authorize a single administration of the prescribed substance.

(2) Schedule III, IV, or V controlled substance. An outpatient medication order for administration of a Schedule III, IV, or V controlled substance shall be written and may be authorized for a period not to exceed six months from the date ordered.

(3) Noncontrolled substance. An outpatient medication order for administration of a noncontrolled prescription drug may be authorized for a period not to exceed 18 months from the date ordered.

[ARC 8909B, IAB 6/30/10, effective 8/4/10]

657—7.12(124,126,155A) Drugs in the emergency department. Drugs maintained in the emergency department are kept for use by or at the direction of prescribers in the emergency department. Drugs shall be administered or dispensed only to emergency department patients. For the purposes of this rule, "emergency department patient" means an individual who is examined and evaluated in the emergency department.

7.12(1) *Accountability.* A system of drug control and accountability shall be developed and supervised by the pharmacist in charge and the facility's emergency department committee, or a similar group or person responsible for policy in the emergency department. The system shall identify drugs of the nature and type to meet the immediate needs of emergency department patients. Drugs shall be administered or dispensed only in accordance with the system.

7.12(2) *Controlled substances.* Controlled substances maintained in the emergency department are kept for use by or at the direction of prescribers in the emergency department.

a. In order to receive a controlled substance, a patient shall be examined in the emergency department by a prescriber who shall determine the need for the drug. It is not permissible under state and federal regulations for a prescriber to see a patient outside the emergency department setting, or talk to the patient on the telephone, and then proceed to call the emergency department and order the administration of a stocked controlled substance upon the patient's arrival at the emergency department except as provided in paragraph 7.12(2)*"c"* or *"d."*

b. A prescriber may authorize, without again examining the patient, the administration of additional doses of a previously authorized drug to a patient presenting to the emergency department within 24 hours of the patient's examination and treatment in the emergency department.

c. In an emergency situation when a health care practitioner authorized to prescribe controlled substances is not available on site, and regardless of the provisions of paragraph 7.12(2)*"a,"* the

emergency department nurse may examine the patient in the emergency department and contact the on-call prescriber. The on-call prescriber may then authorize the nurse to administer a controlled substance to the patient pending the arrival of the prescriber at the emergency department. As soon as possible, the prescriber shall examine the patient in the emergency department and determine the patient's further treatment needs.

d. In an emergency situation when a health care practitioner authorized to prescribe controlled substances examines a patient in the prescriber's office and determines a need for the administration of a controlled substance, and regardless of the provisions of paragraph 7.12(2)*"a,"* the prescriber may direct the patient to present to the emergency department, with a valid written prescription or order for the administration of the controlled substance. As soon as possible, the prescriber shall examine the patient in the emergency department and determine the patient's further treatment needs.

7.12(3) *Drug dispensing.* In those facilities with 24-hour pharmacy services, only a pharmacist or prescriber may dispense any drugs to an emergency department patient. In those facilities located in an area of the state where 24-hour outpatient or 24-hour on-call pharmacy services are not available within 15 miles of the hospital, and which facilities are without 24-hour outpatient pharmacy services, the provisions of this rule shall apply.

a. Pharmacist in charge responsibility. The pharmacist in charge is responsible for maintaining accurate records of dispensing of drugs from the emergency department and for ensuring the accuracy of prepackaged drugs and the complete and accurate labeling of prepackaged drugs pursuant to this paragraph.

(1) Prepackaging. Except as provided in subrule 7.12(4), drugs dispensed to an emergency department patient in greater than a 24-hour supply may be dispensed only in prepackaged quantities not to exceed a 72-hour supply or the minimum prepackaged quantity in suitable containers, except that a seven-day supply of doxycycline provided through the department of public health pursuant to the crime victim compensation program of the Iowa department of justice may be dispensed for the treatment of a victim of sexual assault. Prepackaged drugs shall be prepared pursuant to the requirements of rule 657—22.3(126).

(2) Labeling. Drugs dispensed pursuant to this paragraph shall be appropriately labeled as required in paragraph 7.12(3)*"b,"* including necessary auxiliary labels.

b. Prescriber responsibility. Except as provided in subrule 7.12(4), a prescriber who authorizes dispensing of a prescription drug to an emergency department patient is responsible for the accuracy of the dispensed drug and for the accurate completion of label information pursuant to this paragraph.

(1) Labeling. Except as provided in subrule 7.12(4), at the time of delivery of the drug the prescriber shall appropriately complete the label such that the dispensing container bears a label with at least the following information:

1. Name and address of the hospital;
2. Date dispensed;
3. Name of prescriber;
4. Name of patient;
5. Directions for use;
6. Name and strength of drug.

(2) Delivery of drug to patient. Except as provided in subrule 7.12(4), the prescriber, or a licensed nurse under the supervision of the prescriber, shall give the appropriately labeled, prepackaged drug to the patient or patient's caregiver. The prescriber, or a licensed nurse under the supervision of the prescriber, shall explain the correct use of the drug and shall explain to the patient that the dispensing is for an emergency or starter supply of the drug. If additional quantities of the drug are required to complete the needed course of treatment, the prescriber shall provide the patient with a prescription for the additional quantities.

7.12(4) *Use of InstyMeds dispensing system.* A hospital located in an area of the state where 24-hour outpatient pharmacy services are not available within 15 miles of the hospital may implement the InstyMeds dispensing system in the hospital emergency department only as provided by this subrule.

a. Persons with access to the dispensing machine for the purposes of stocking, inventory, and monitoring shall be limited to pharmacists, pharmacy technicians, and pharmacist-interns.

b. The InstyMeds dispensing system shall be used only in the hospital emergency department for the benefit of patients examined or treated in the emergency department.

c. The dispensing machine shall be located in a secure and professionally appropriate environment.

d. The stock of drugs maintained and dispensed utilizing the InstyMeds dispensing system shall be limited to acute care drugs provided in appropriate quantities for a 72-hour supply or the minimum commercially available package size, except that antimicrobials may be dispensed in a quantity to provide the full course of therapy.

e. Drugs dispensed utilizing the InstyMeds dispensing system shall be appropriately labeled as provided in 657—subrule 6.10(1), paragraphs *"a"* through *"g."*

f. Prior to authorizing the dispensing of a drug utilizing the InstyMeds dispensing system, the prescriber shall offer the patient the option of being provided a prescription that may be filled at the pharmacy of the patient's choice.

g. When appropriate for an acute condition, the prescriber shall provide to the patient or the patient's caregiver a prescription for the remainder of drug therapy beyond the supply available utilizing the InstyMeds dispensing system. During consultation with the patient or the patient's caregiver, the prescriber shall clearly explain the appropriate use of the drug supplied, the need to have a prescription for any additional supply of the drug filled at a pharmacy of the patient's choice, and the need to complete the full course of drug therapy.

h. The pharmacy shall, in conjunction with the hospital emergency department, implement policies and procedures to ensure that a patient utilizing the InstyMeds dispensing system has been positively identified.

i. The hospital pharmacist shall review the printout of drugs provided utilizing the InstyMeds dispensing system within 24 hours unless the pharmacy is closed, in which case the printout shall be reviewed during the first day the pharmacy is open following the provision of the drugs. The purpose of the review is to identify any dispensing errors, to determine dosage appropriateness, and to complete a retrospective drug use review of any antimicrobials dispensed in a quantity greater than a 72-hour supply. Any discrepancies found shall be addressed by the pharmacy's continuous quality improvement program.

[**ARC 8909B**, IAB 6/30/10, effective 8/4/10]

657—7.13(124,155A) Records. Every inventory or other record required to be kept under this chapter or other board rules or under Iowa Code chapters 124 and 155A shall be kept by the pharmacy and be available for inspection and copying by the board or its representative for at least two years from the date of such inventory or record unless a longer retention period is specified for the particular inventory or record.

7.13(1) *Medication order information.* Each original medication order contained in inpatient records shall bear the following information:

a. Patient name and identification number;

b. Drug name, strength, and dosage form;

c. Directions for use;

d. Date ordered;

e. Practitioner's signature or electronic signature or that of the practitioner's authorized agent.

7.13(2) *Medication order maintained.* The original medication order shall be maintained with the medication administration record in the medical records of the patient following discharge.

7.13(3) *Documentation of drug administration.* Each dose of medication administered shall be properly recorded in the patient's medical record.

These rules are intended to implement Iowa Code sections 124.301, 124.303, 124.306, 126.10, 126.11, 155A.6, 155A.13, 155A.27, 155A.28, 155A.31, and 155A.33 through 155A.36.

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[Filed ARC 8909B (Notice ARC 8413B, IAB 12/30/09), IAB 6/30/10, effective 8/4/10]
[Filed ARC 9408B (Notice ARC 9183B, IAB 11/3/10), IAB 3/9/11, effective 4/13/11]
[Filed ARC 9911B (Notice ARC 9788B, IAB 10/5/11), IAB 12/14/11, effective 1/18/12]

◊ Two or more ARCs

KANSAS STATE BOARD OF PHARMACY LAWS AND REGULATIONS

UPDATED January 2012

The law book listed below contains the current "unofficial" * pharmacy law and rules.

* The permanent statutes of the Kansas State Board of Pharmacy have been codified at Chapter 65 of the Kansas Statutes Annotated. The KSA's are published by the Secretary of State's Office and contain all of the "official" agency laws. Chapter 68 of the Kansas Administrative Rules contains all "official" agency rules and are published by the Secretary of State's Office. The KAR's contain the "official" agency rules and regulations.

65-1615, 65-1616.
History: L. 1887, ch. 174, §§ 6, 7; R.S. 1923, 65-1615, 65-1616; Repealed, L. 1953, ch. 290, § 38; July 1.

65-1617.
History: L. 1887, ch. 174, § 8; R.S. 1923, 65-1617; Repealed, L. 1943, ch. 269, § 28; June 30.

65-1618.
History: L. 1887, ch. 174, § 9; R.S. 1923, 65-1618; Repealed, L. 1953, ch. 290, § 38; July 1.

65-1619.
History: L. 1885, ch. 150, § 13; R.S. 1923, 65-1619; Repealed, L. 1953, ch. 290, § 38; July 1.

65-1620.
History: L. 1897, ch. 164, § 1; L. 1921, ch. 270, § 1; R.S. 1923, 65-1620; Repealed, L. 1953, ch. 290, § 38; July 1.

65-1621 to 65-1623.
History: L. 1933, ch. 87, §§ 1 to 3 (Special Session); Repealed, L. 1953, ch. 290, § 38; July 1.

65-1624.
History: L. 1953, ch. 290, § 1; Repealed, L. 1975, ch. 319, § 47; July 1.

65-1625. Title of act. This act shall be known and may be cited as the pharmacy act of the state of Kansas.
History: L. 1953, ch. 290, § 2; L. 1975, ch. 319, § 1; July 1.

65-1626. Definitions. [See Revisor's Note] For the purposes of this act:
(a) "Administer" means the direct application of a drug, whether by injection, inhalation, ingestion or any other means, to the body of a patient or research subject by:
(1) A practitioner or pursuant to the lawful direction of a practitioner;
(2) the patient or research subject at the direction and in the presence of the practitioner; or
(3) a pharmacist as authorized in K.S.A. 65-1635a and amendments thereto.
(b) "Agent" means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor or dispenser but shall not include a common carrier, public warehouseman or employee of the carrier or warehouseman when acting in the usual and lawful course of the carrier's or warehouseman's business.
(c) "Authorized distributor of record" means a wholesale distributor with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's prescription drug. An ongoing relationship is deemed to exist between such wholesale distributor and a manufacturer when the wholesale distributor, including any affiliated group of the wholesale distributor, as defined in section 1504 of the internal revenue code, complies with any one of the following:
(1) The wholesale distributor has a written agreement currently in effect with the manufacturer evidencing such ongoing relationship; and
(2) the wholesale distributor is listed on the manufacturer's current list of authorized distributors of record, which is updated by the manufacturer on no less than a monthly basis.

synthesis and includes any packaging or repackaging of the drug or labeling or relabeling of its container, except that this term shall not include the preparation or compounding of a drug by an individual for the individual's own use or the preparation, compounding, packaging or labeling of a drug by:

(1) A practitioner or a practitioner's authorized agent incident to such practitioner's administering or dispensing of a drug in the course of the practitioner's professional practice;

(2) a practitioner, by a practitioner's authorized agent or under a practitioner's supervision for the purpose of, or as an incident to, research, teaching or chemical analysis and not for sale; or

(3) a pharmacist or the pharmacist's authorized agent acting under the direct supervision of the pharmacist for the purpose of, or incident to, the dispensing of a drug by the pharmacist.

(y) "Manufacturer" means a person licensed or approved by the FDA to engage in the manufacture of drugs and devices.

(z) "Normal distribution channel" means a chain of custody for a prescription-only drug that goes from a manufacturer of the prescription-only drug, from that manufacturer to that manufacturer's co-licensed partner, from that manufacturer to that manufacturer's third-party logistics provider, or from that manufacturer to that manufacturer's exclusive distributor, directly or by drop shipment, to:

(1) A pharmacy to a patient or to other designated persons authorized by law to dispense or administer such drug to a patient;

(2) a wholesale distributor to a pharmacy to a patient or other designated persons authorized by law to dispense or administer such drug to a patient;

(3) a wholesale distributor to a chain pharmacy warehouse to that chain pharmacy warehouse's intracompany pharmacy to a patient or other designated persons authorized by law to dispense or administer such drug to a patient; or

(4) a chain pharmacy warehouse to the chain pharmacy warehouse's intracompany pharmacy to a patient or other designated persons authorized by law to dispense or administer such drug to a patient.

(aa) "Person" means individual, corporation, government, governmental subdivision or agency, partnership, association or any other legal entity.

(bb) "Pharmacist" means any natural person licensed under this act to practice pharmacy.

(cc) "Pharmacist in charge" means the pharmacist who is responsible to the board for a registered establishment's compliance with the laws and regulations of this state pertaining to the practice of pharmacy, manufacturing of drugs and the distribution of drugs. The pharmacist in charge shall supervise such establishment on a full-time or a part-time basis and perform such other duties relating to supervision of a registered establishment as may be prescribed by the board by rules and regulations. Nothing in this definition shall relieve other pharmacists or persons from their responsibility to comply with state and federal laws and regulations.

(dd) "Pharmacy," "drug store" or "apothecary" means premises, laboratory, area or other place:

(1) Where drugs are offered for sale where the profession of pharmacy is practiced and where prescriptions are compounded and dispensed; or

(2) which has displayed upon it or within it the words "pharmacist," "pharmaceutical chemist," "pharmacy," "apothecary," "drugstore," "druggist," "drugs," "drug sundries" or any of these words or combinations of these words or words of similar import either in English or any sign containing any of these words; or

(3) where the characteristic symbols of pharmacy or the characteristic prescription sign "Rx" may be exhibited. As used in this subsection, premises refers only to the portion of any building

or structure leased, used or controlled by the licensee in the conduct of the business registered by the board at the address for which the registration was issued.
(ee) "Pharmacy student" means an individual, registered with the board of pharmacy, enrolled in an accredited school of pharmacy.
(ff) "Pharmacy technician" means an individual who, under the direct supervision and control of a pharmacist, may perform packaging, manipulative, repetitive or other nondiscretionary tasks related to the processing of a prescription or medication order and who assists the pharmacist in the performance of pharmacy related duties, but who does not perform duties restricted to a pharmacist.
(gg) "Practitioner" means a person licensed to practice medicine and surgery, dentist, podiatrist, veterinarian, optometrist or scientific investigator or other person authorized by law to use a prescription-only drug in teaching or chemical analysis or to conduct research with respect to a prescription-only drug.
(hh) "Preceptor" means a licensed pharmacist who possesses at least two years' experience as a pharmacist and who supervises students obtaining the pharmaceutical experience required by law as a condition to taking the examination for licensure as a pharmacist.
(ii) "Prescription" means, according to the context, either a prescription order or a prescription medication.
(jj) "Prescription medication" means any drug, including label and container according to context, which is dispensed pursuant to a prescription order.
(kk) "Prescription-only drug" means any drug whether intended for use by man or animal, required by federal or state law (including 21 U.S.C. § 353, as amended) to be dispensed only pursuant to a written or oral prescription or order of a practitioner or is restricted to use by practitioners only.
(ll) "Prescription order" means: (1) An order to be filled by a pharmacist for prescription medication issued and signed by a practitioner or a mid-level practitioner in the authorized course of professional practice; or (2) an order transmitted to a pharmacist through word of mouth, note, telephone or other means of communication directed by such practitioner or mid-level practitioner.
(mm) "Probation" means the practice or operation under a temporary license, registration or permit or a conditional license, registration or permit of a business or profession for which a license, registration or permit is granted by the board under the provisions of the pharmacy act of the state of Kansas requiring certain actions to be accomplished or certain actions not to occur before a regular license, registration or permit is issued.
(nn) "Professional incompetency" means:
(1) One or more instances involving failure to adhere to the applicable standard of pharmaceutical care to a degree which constitutes gross negligence, as determined by the board;
(2) repeated instances involving failure to adhere to the applicable standard of pharmaceutical care to a degree which constitutes ordinary negligence, as determined by the board; or
(3) a pattern of pharmacy practice or other behavior which demonstrates a manifest incapacity or incompetence to practice pharmacy.
(oo) "Retail dealer" means a person selling at retail nonprescription drugs which are prepackaged, fully prepared by the manufacturer or distributor for use by the consumer and labeled in accordance with the requirements of the state and federal food, drug and cosmetic acts. Such nonprescription drugs shall not include:
(1) A controlled substance;

(e) If a prescription order contains a statement that during any particular time the prescription may be refilled at will, there shall be no limitation as to the number of times that such prescription may be refilled except that it may not be refilled after the expiration of the time specified or one year after the prescription was originally issued, whichever occurs first.
(f) Any pharmacist who exercises brand exchange and dispenses a less expensive drug product shall not charge the purchaser more than the regular and customary retail price for the dispensed drug.
Nothing contained in this section shall be construed as preventing a pharmacist from refusing to fill or refill any prescription if in the pharmacist's professional judgment and discretion such pharmacist is of the opinion that it should not be filled or refilled.
History: L. 1953, ch. 290, § 23; L. 1975, ch. 319, § 23; L. 1978, ch. 242, § 2; L. 1979, ch. 194, § 1; L. 1986, ch. 231, § 25; L. 1991, ch. 188, § 1; L. 1994, ch. 247, § 3; L. 1998, ch. 87, § 1; L. 2005, ch. 88, § 1; L. 2007, ch. 19, § 1; March 29.

65-1637a. Institutional drug rooms; supervision and record-keeping; rules and regulations.
(a) An institutional drug room shall be under the supervision of a pharmacist or a practitioner, who may be retained on a part-time basis and who shall be responsible for recordkeeping and storage of drugs by such drug room. For the purposes of this section, "practitioner" means any person licensed to practice medicine and surgery.
(b) The board shall adopt such rules and regulations relating to record-keeping and storage of drugs by institutional drug rooms as necessary for proper control of drugs by such drug rooms.
(c) This section shall be part of and supplemental to the pharmacy act of the state of Kansas.
History: L. 1979, ch. 193, § 5; L. 1986, ch. 231, § 26; June 1.

65-1638. Sale of drugs and poisons by registered pharmacist. A pharmacist shall have the right to keep and sell, subject to such restrictions as may be provided by law, all drugs and poisons listed in the national formulary, the United States pharmacopoeia and other standard pharmaceutical and medical works of recognized utility, but nothing in the pharmacy act of the state of Kansas shall be construed to protect any pharmacist who violates or in any way abuses this trust from the penalties for violations of the laws relating to the sale or distribution of drugs. Nothing in the pharmacy act of the state of Kansas shall prohibit pharmacists from repackaging poisons according to applicable state and federal packaging and labeling laws. The sale of poisons shall conform to applicable state and federal laws.
History: L. 1953, ch. 290, § 24; L. 1965, ch. 506, § 29; L. 1975, ch. 319, § 24; L. 1979, ch. 194, § 2; L. 1986, ch. 231, § 27; June 1.

65-1639.
History: L. 1953, ch. 290, § 25; L. 1975, ch. 319, § 25; Repealed, L. 1979, ch. 194, § 4; July 1.

65-1640. Act not applicable to manufacture or to certain sales of poisons. Nothing contained in the pharmacy act of the state of Kansas shall prevent the manufacture by any person of any poisons, nor shall anything in such act prevent the sale by any person of any poisons when the poison is sold in unbroken packages and is labeled as required by law.
History: L. 1953, ch. 290, § 26; L. 1975, ch. 319, § 26; L. 1979, ch. 194, § 3; July 1.

KENTUCKY PHARMACY LAWS

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UNOFFICIAL TEXT OF STATUTES AND ADMINISTRATIVE REGULATIONS
FOR INFORMATION ONLY
REVISED FEBRUARY 2012

315.010 Definitions for chapter.

As used in this chapter, unless the context requires otherwise:

(1) "Administer" means the direct application of a drug to a patient or research subject by injection, inhalation, or ingestion, whether topically or by any other means;

(2) "Association" means the Kentucky Pharmacists Association;

(3) "Board" means the Kentucky Board of Pharmacy;

(4) "Collaborative care agreement" means a written agreement between a specifically identified individual practitioner and a pharmacist who is specifically identified, whereby the practitioner outlines a plan of cooperative management of a specifically identified individual patient's drug-related health care needs that fall within the practitioner's statutory scope of practice. The agreement shall be limited to specification of the drug-related regimen to be provided and any tests which may be necessarily incident to its provisions; stipulated conditions for initiating, continuing, or discontinuing drug therapy; directions concerning the monitoring of drug therapy and stipulated conditions which warrant modifications to dose, dosage regimen, dosage form, or route of administration;

(5) "Compound" or "compounding" means the preparation or labeling of a drug pursuant to or in anticipation of a valid prescription drug order including, but not limited to, packaging, intravenous admixture or manual combination of drug ingredients. "Compounding," as used in this chapter, shall not preclude simple reconstitution, mixing, or modification of drug products prior to administration by nonpharmacists;

(6) "Confidential information" means information which is accessed or maintained by a pharmacist in a patient's record, or communicated to a patient as part of patient counseling, whether it is preserved on paper, microfilm, magnetic media, electronic media, or any other form;

(7) "Continuing education unit" means ten (10) contact hours of board approved continuing pharmacy education. A "contact hour" means fifty (50) continuous minutes without a break period;

(8) "Dispense" or "dispensing" means to deliver one (1) or more doses of a prescription drug in a suitable container, appropriately labeled for subsequent administration to or use by a patient or other individual entitled to receive the prescription drug;

(9) "Drug" means any of the following:

(a) Articles recognized as drugs or drug products in any official compendium or supplement thereto;

(b) Articles, other than food, intended to affect the structure or function of the body of man or other animals;

(c) Articles, including radioactive substances, intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals; or

(d) Articles intended for use as a component of any articles specified in paragraphs (a) to (c) of this subsection;

(c) A qualified applicant awaiting examination for licensure as a pharmacist or the results of an examination for licensure as a pharmacist; or

(d) An individual participating in a residency or fellowship program approved by the board for internship credit;

(17) "Pharmacy" means every place where:

(a) Drugs are dispensed under the direction of a pharmacist;

(b) Prescription drug orders are compounded under the direction of a pharmacist; or

(c) A registered pharmacist maintains patient records and other information for the purpose of engaging in the practice of pharmacy, whether or not prescription drug orders are being dispensed;

(18) "Pharmacy technician" means a natural person who works under the immediate supervision, or general supervision if otherwise provided for by statute or administrative regulation, of a pharmacist for the purpose of assisting a pharmacist with the practice of pharmacy;

(19) "Practice of pharmacy" means interpretation, evaluation, and implementation of medical orders and prescription drug orders; responsibility for dispensing prescription drug orders, including radioactive substances; participation in drug and drug-related device selection; administration of medications or biologics in the course of dispensing or maintaining a prescription drug order; the administration of adult immunizations pursuant to prescriber-approved protocols; the administration of influenza vaccines to individuals nine (9) to thirteen (13) years of age pursuant to prescriber-approved protocols with the consent of a parent or guardian; the administration of immunizations to individuals fourteen (14) to seventeen (17) years of age pursuant to prescriber-approved protocols with the consent of a parent or guardian; the administration of immunizations to a child as defined in KRS 214.032, pursuant to protocols as authorized by KRS 315.500; drug evaluation, utilization, or regimen review; maintenance of patient pharmacy records; and provision of patient counseling and those professional acts, professional decisions, or professional services necessary to maintain and manage all areas of a patient's pharmacy-related care, including pharmacy-related primary care as defined in this section;

(20) "Practitioner" has the same meaning given in KRS 217.015(35);

(21) "Prescription drug" means a drug which:

(a) Under federal law is required to be labeled with either of the following statements:

1. "Caution: Federal law prohibits dispensing without prescription";

2. "Caution: Federal law restricts this drug to use by, or on the order of, a licensed veterinarian";

3. "Rx Only"; or

4. "Rx"; or

(b) Is required by any applicable federal or state law or administrative regulation

315.035 Permit required for operation of a pharmacy -- Application -- Fee -- Issuance -- Fee for failure to renew -- Premises covered by permit -- Rules and regulations -- Requirements for in-state pharmacy doing business through the Internet -- Board may waive permit requirements for out-of-state pharmacy -- Temporary operation of pharmacy during state of emergency.

(1) No person shall operate a pharmacy within this Commonwealth, physically or by means of the Internet, facsimile, phone, mail, or any other means, without having first obtained a permit as provided for in KRS Chapter 315. An application for a permit to operate a pharmacy shall be made to the board upon forms provided by it and shall contain such information as the board requires, which may include affirmative evidence of ability to comply with such reasonable standards and rules and regulations as may be prescribed by the board. Each application shall be accompanied by a reasonable permit fee to be set by administrative regulation promulgated by the board pursuant to KRS Chapter 13A, not to exceed two hundred fifty dollars ($250).

(2) Upon receipt of an application of a permit to operate a pharmacy, accompanied by the permit fee not to exceed two hundred fifty dollars ($250), the board shall issue a permit if the pharmacy meets the standards and requirements of KRS Chapter 315 and the rules and regulations of the board. The board shall refuse to renew any permit to operate unless the pharmacy meets the standards and requirements of KRS Chapter 315 and the rules and regulations of the board. The board shall act upon an application for a permit to operate within thirty (30) days after the receipt thereof; provided, however, that the board may issue a temporary permit to operate in any instance where it considers additional time necessary for investigation and consideration before taking final action upon the application. In such event, the temporary permit shall be valid for a period of thirty (30) days, unless extended.

(3) A separate permit to operate shall be required for each pharmacy.

(4) Each permit to operate a pharmacy, unless sooner suspended or revoked, shall expire on June 30 following its date of issuance and be renewable annually thereafter upon proper application accompanied by such reasonable renewal fee as may be set by administrative regulation of the board, not to exceed two hundred fifty dollars ($250) nor to increase more than twenty-five dollars ($25) per year. An additional fee not to exceed the annual renewal fee may be assessed and set by administrative regulation as a delinquent renewal penalty for failure to renew by June 30 of each year.

(5) Permits to operate shall be issued only for the premises and persons named in the application and shall not be transferable; provided however, that a buyer may operate the pharmacy under the permit of the seller pending a decision by the board of an application which shall be filed by the buyer with the board at least five (5) days prior to the date of sale.

(6) The board may promulgate rules and regulations to assure that proper equipment and reference material is on hand considering the nature of the pharmaceutical practice conducted at the particular pharmacy and to assure reasonable health and sanitation standards for areas within pharmacies which are not subject to health and

sanitation standards promulgated by the Kentucky Cabinet for Health and Family Services or a local health department.

(7) Each pharmacy shall comply with KRS 218A.202.

(8) Any pharmacy within the Commonwealth that dispenses more than twenty-five percent (25%) of its total prescription volume as a result of an original prescription order received or solicited by use of the Internet, including but not limited to electronic mail, shall, prior to obtaining a permit, receive and display in every medium in which it advertises itself a seal of approval for the National Association of Boards of Pharmacy certifying that it is a Verified Internet Pharmacy Practice Site (VIPPS) or a seal certifying approval of a substantially similar program approved by the Kentucky Board of Pharmacy. VIPPS, or any other substantially similar program approved by the Kentucky Board of Pharmacy, accreditation shall be maintained and remain current.

(9) Any pharmacy within the Commonwealth doing business by use of the Internet shall certify the percentage of its annual business conducted via the Internet and submit such supporting documentation as requested by the board, and in a form or application required by the board, when it applies for permit or renewal.

(10) A pharmacist may temporarily operate a pharmacy in an area not designated on the permit as authorized in KRS 315.500.

Effective: July 15, 2010

History: Amended 2010 Ky. Acts ch. 22, sec. 6, effective July 15, 2010. -- Amended 2007 Ky. Acts ch. 124, sec. 9, effective June 26, 2007. -- Amended 2005 Ky. Acts ch. 150, sec. 19, effective June 20, 2005; ch. 61, sec. 1, effective June 20, 2005; and ch. 99, sec. 597, effective June 20, 2005. -- Amended 1998 Ky. Acts ch. 426, sec. 548, effective July 15, 1998. -- Amended 1996 Ky. Acts ch. 257, sec. 5, effective July 15, 1996. -- Amended 1982 Ky. Acts ch. 191, sec. 4, effective July 15, 1982. -- Amended 1974 Ky. Acts ch. 310, sec. 1. -- Created 1966 Ky. Acts ch. 260, sec. 6.

NECESSITY, FUNCTION, AND CONFORMITY: By the authority of KRS 315.191(2) the Board of Pharmacy is responsible to control all matters relating to pharmacies and pharmacists with respect to drugs sold by prescriptions only. This administrative regulation assures the public that a registered pharmacist is present and that prescription drugs distribution is curtailed.

Section 1. No pharmacist shall fill and dispense prescriptions obtained from an establishment or place which offers to the public, in any manner, its services as a "pickup station" or "intermediary" for the purpose of having prescriptions filled or delivered unless such establishment or place has a registered pharmacist in full charge of such services.
(Rx-7; 1 Ky.R. 10; eff. 9-11-74.)

201 KAR 2:074. Pharmacy services in hospitals or other organized health care facilities.
RELATES TO: KRS 315.010, 315.020, 315.030, 315.121
STATUTORY AUTHORITY: KRS 315.191(1)
NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1) requires the Kentucky Board of Pharmacy to establish requirements to regulate and control pharmacies. KRS 315.002 and 315.005 require standards of practice in all settings where drugs are handled and requires the board to insure the safety of all drug products provided to the citizens of Kentucky. This administrative regulation establishes requirements for pharmacy services in hospitals or other organized health care facilities.

Section 1.

(1) "Institutional pharmacy" means that portion of an acute care hospital licensed under 902 KAR 20:016 or a pharmacy serving another organized health care facility which is engaged in the manufacture, production, sale or distribution of drugs, medications, devices or other materials used in the diagnosis or treatment of injury, illness, or disease.

(2) "Investigational drug" means any drug which has not been approved for use in the United States, but for which an investigational drug application has been approved by the FDA.

(3) "Other organized health care facility" means a facility:

(a) Whose primary purpose is to provide medical care and treatment to inpatients; and

1. An intermediate care facility;
2. A skilled nursing facility;
3. A hospital other than an acute care hospital licensed under 902 KAR 20:016;
4. A licensed personal care home;
5. A licensed family care home;
6. A nursing home;
7. A nursing facility;
8. An intermediate care facility for mental retardation; or
9. An Alzheimer's nursing home.

(4) "Unit dose distribution" means a system in which drug therapy profiles are maintained in the pharmacy and doses are scheduled, prepared, and delivered in a ready-to-administer form to the patient care area as they are needed.

Section 2. Pharmacy Administration.

(1) General. The pharmacy, organized as a separate department or service, shall be directed by a professionally competent, legally qualified pharmacist. The director of pharmacy services shall be responsible for departmental management and the development and implementation of goals and objectives to meet the needs of the institution.

(2) Director of pharmacy.

(a) The director of pharmacy services shall be thoroughly knowledgeable about institutional pharmacy practice and management.

(b) If the director of pharmacy services is not employed full time, the institution shall establish an ongoing arrangement in writing with an appropriately qualified pharmacist to provide services required by this administrative regulation and KRS 315.020(1). The director of pharmacy services shall be responsible to the chief executive officer of the institution or his designee.

(c) If a hospital pharmacy is decentralized, each decentralized section or separate organizational element shall be under the immediate supervision of a pharmacist responsible to the director.

(3) Pharmacy personnel.

(a) The institutional pharmacy shall maintain additional pharmacists in cooperation with the institution's administration, either full time or part time, as they are required to operate safely and effectively to meet the needs of the patients.

(b) If nonpharmacist personnel are employed, they shall perform all duties under the supervision of a pharmacist and they shall not be assigned, nor shall they perform, duties that are to be performed only by pharmacists.

(4) Responsibilities.

(a) Lines of authority and areas of responsibility within the pharmacy shall be clearly defined. Written job descriptions for all categories of pharmacy personnel shall be prepared and revised as necessary.

(b) There shall be policies and procedures to provide for selection of drugs as well as a distribution system to serve the needs of the patient. Provision for procurement of drugs in an emergency situation shall be provided for.

(5) Supportive personnel.

(a) Sufficient supportive personnel (technical, clerical, and other) shall be available in order to optimize the participation of pharmacists in activities requiring professional judgment.

(b) The training and supervision of supportive personnel shall be the responsibility of the pharmacist.

(6) Availability.

(a) The services of a pharmacist shall be available at all times. However, if around-the-clock operation of the pharmacy is not feasible, the pharmacist shall be available on an on-call basis and an adequate night drug cabinet shall be established. The pharmacy itself shall not be designated as the night drug cabinet.

(b) Hospitals not having a full-time pharmacist, but in which drugs are prepackaged or relabeled or transferred from one container to another, shall obtain a pharmacy permit and have at least a part-time pharmacist designated to perform those functions or to provide personal supervision of those functions.

Section 3. Physical Facility.

(1) The institutional pharmacy shall have adequate space, equipment, and supplies sufficient to provide for safe and efficient drug storage, preparation and distribution, patient education and consultation, drug information services, and proper management of the department.

(2) Legal requirements. The physical facility shall meet state and federal regulations and shall be accessible by key by authorized pharmacy personnel only.

(3) (a) A currently licensed hospital shall be exempt from the provisions of subsection (2) of this section if it:

1. Is authorized by the Department for Health and Human Services to provide pharmacy services; and
2. Does not currently possess a pharmacy permit.

(b) A currently licensed hospital exempt from the provisions of subsection (2) of this section shall permit access by authorized personnel only.

(4) Location. Locked storage or locked medication carts shall be provided for use in each nursing unit or service area.

(5) Reference materials. The pharmacy shall have current pharmaceutical reference materials in accordance with 201 KAR 2:090. References related to the following subjects shall also be available:

(a) Drug identification;
(b) Toxicology;
(c) Drug interactions;
(d) Parenteral drug compatibility; and
(e) Microbiology.

Section 4. Drug Distribution and Control.

(1) General. The institutional pharmacy shall be responsible for the procurement, distribution and control of all drugs and parenteral solutions used within the institution. Policies and procedures governing these functions shall be developed by the pharmacist with input from other involved hospital or other organized health care facility staff (e.g., nurses) and committees (e.g., pharmacy and therapeutics committee and patient care committee).

(2) Dispensing. The pharmacist shall dispense medications only on the order of a licensed practitioner.

(3) Prescriber's order. The pharmacist shall review the medication order within a reasonable amount of time.

(4) Recordkeeping. The pharmacist shall maintain appropriate records of each medication order. The records shall be retained for the time and in the manner prescribed by state and federal law.

(5) Patient medication profile. A medication profile shall be maintained for all inpatients and for those ambulatory patients routinely receiving care at the institution. The pharmacist shall utilize this profile to properly review, schedule, prepare, and distribute medications except in emergency situations.

(6) Labeling and packaging.

(a) All licensees shall comply with U.S.P. Standards established pursuant to federal law and all state and federal laws and regulations regarding labeling and packaging.

(b) Labeling and packaging of medications used for outpatients shall meet the requirements of state and federal law.

(7) Dispensing. The pharmacist shall dispense medications by the unit dose distribution system if feasible. If the unit dose distribution system is not utilized, adequate safeguards shall be in place to protect patients.

(8) Stop orders. There shall be established written stop order policies or other methods of assuring that drug orders are not continued inappropriately in accordance with the status of the patient.

(9) Administration. Drugs shall be administered only upon order of a licensed practitioner. The institutional pharmacy shall participate in the establishment of policies and procedures regarding the administration of medications. Specific procedures shall be developed in cooperation with appropriate hospital or other health care facility personnel regarding and shall include personnel authorized to schedule, prepare and administer medications.

(10) Unused medication. The institutional pharmacy shall establish policies and procedures for the disposition of patients' unused medications. Medication in unit dose form may be reissued if package integrity has been maintained and the product is still in date.

(11) Hospital floor stocks.

(a) Floor stocks of drugs shall be kept as small as possible. The pharmacist in charge shall be responsible for authenticating the need for floor stock.

(b) A pharmacist shall review all orders distributed through floor stock within a reasonable amount of time.

(c) The pharmacist in charge shall be responsible for defining those areas of the hospital requiring floor stock (e.g., emergency room, surgery, critical care, or medical or surgical wards).

(d) All drug storage areas within the hospital shall be routinely inspected by pharmacy personnel at least monthly and documentation maintained to insure that no unusable items are present and that all stock items are properly labeled and stored.

(e) This subsection shall not apply to other organized health care facilities.

(12) Drug recall. There shall be a system for removing from use any drugs subjected to a recall.

(13) Sample medications. The institutional pharmacy shall establish policies and procedures regarding medical representatives and the obtaining, storage, and dispensing of complimentary packages of medications.

(14) Emergency drugs.

(a) The institutional pharmacy shall establish policies and procedures for supplying emergency drugs.

(b) For expediency and efficiency, emergency drugs shall be limited in number to include only those whose prompt use and immediate availability are generally regarded by physicians as essential in the proper treatment of sudden and unforeseen patient emergencies.

(c) Emergency stocks shall be routinely inspected by pharmacy personnel on a monthly basis and documentation maintained to determine if contents have become outdated and if the stocks are being maintained at adequate levels.

(15) Investigational drugs.

(a) Policies and procedures controlling the use of investigational drugs (if used in the institution) shall be developed and followed.
(b) The pharmacy shall be responsible for storing, packaging, labeling, distributing, maintaining inventory records (including lot numbers and expiration date) and providing information about investigational drugs (including proper disposal).
(16) Controlled substances. All permit holders shall comply with state and federal laws regarding controlled substances.

Section 5. Assuring Rational Drug Therapy.
(1) Appropriate clinical information about patients shall be available and accessible to the pharmacist for use in his daily practice activities.
(2) The pharmacist shall be a member of the pharmacy and therapeutics committee and any other committees where input concerning the use of drugs is required.
(3) The pharmacist shall provide a means to insure that patients receive adequate information about the drugs they receive. Patient education activities shall be in coordination with the nursing and medical staffs and patient education department, if any.
(16 Ky.R. 1713; Am. 2150; 17 Ky.R. 2175; eff. 12-13-90; 30 Ky.R. 75; 577; eff. 8-20-2003.)

201 KAR 2:076. Parenteral pharmaceutical compounding.
RELATES TO: KRS 315.020
STATUTORY AUTHORITY: KRS 315.020(1), (2), 315.065(1), (2), 315.191(1)
NECESSITY, FUNCTION, AND CONFORMITY: The Kentucky Board of Pharmacy is responsible to insure minimum standards of practice of parenteral compounding by pharmacies. The board is also responsible to insure the safety of all products provided to the citizens of the Commonwealth.

Section 1. A policy and procedure manual for parenteral pharmaceutical compounding shall be available at a pharmacy for inspection purposes. The manual shall include policies and procedures for:
(1) Oncology drugs;
(2) Disposal of unused supplies and medications;
(3) Drug destruction and return;
(4) Drug dispensing;
(5) Drug labeling;
(6) Storage;
(7) Duties and qualifications for staff;
(8) Equipment;
(9) Handling of hazardous wastes;
(10) Investigation drug protocol;
(11) Safety;
(12) Recordkeeping;
(13) Reference material;
(14) Sanitation;
(15) Security;
(16) Transportation; and
(17) Quality assurance, as relates to:

Louisiana Revised Statutes of 1950

Title 37 – Professions and Occupations

Chapter 14 – Pharmacy Practice Act

*[**Editor's Note**: The Louisiana Pharmacy Practice Act was substantially revised and reorganized under the authority of Act 767 of the 1999 Louisiana Legislature. Subsequent amendments are noted herein.]*

Part A. General Provisions

§1161. Short title

This Chapter shall be known as the "Louisiana Pharmacy Practice Act".

§1162. Legislative declaration

The practice of pharmacy in the state of Louisiana is declared a professional practice affecting the public health, safety, and welfare and is subject to regulation and control in the public interest. Therefore, any rule or regulation adopted relative to pharmacists and the operations of pharmacies, including any amendment, modification, or repeal thereof, shall be adopted as provided by the Administrative Procedure Act and shall be effective only upon approval by the respective oversight committees having jurisdiction over matters relative to pharmacists and the operation of pharmacies. It is further declared to be a matter of public interest and concern that the practice of pharmacy, as defined in this Chapter, merit and receive the confidence of the public and that only qualified persons be permitted to engage in the practice of pharmacy. This Chapter shall be liberally construed to carry out these objectives and purposes.

§1163. Statement of purpose

It is the purpose of this Chapter to promote, preserve, and protect the public health, safety, and welfare by and through the effective control and regulation of the practice of pharmacy; the licensure of pharmacists; and the licensure, permitting, certification, registration, control, and regulation of all persons or sites, in or out of this state that sell drugs or devices to consumers and/or patients or assist in the practice of pharmacy, within the state.

§1164. Definitions

As used in this Chapter, the following terms have the meaning ascribed to them by this Section:

(1) *"Administer"* or *"administration"* means the direct application of a drug to the body of a patient or research subject by injection, inhalation, ingestion, or any other means.

(2) *"Approved college of pharmacy"* means:

(a) A college or school of pharmacy which is accredited by the Accreditation Council for Pharmacy Education.

(b) World Health Organization's "World Directory of School of Pharmacy" or other board recognized foreign college or school of pharmacy graduate who has attained equivalency status approved by the board.

(*Amended by Act 164 of 2006 Louisiana Legislature, effective August 15, 2006*)

(3) *"Automated medication system"* includes, but is not limited to, a mechanical system that perform operations or activities, other than compounding or administration, relative to the storage, packaging, or delivery of medications, and which collects, controls, and maintains all transaction information. An automated medication system may be profile driven, non-profile driven, or a combination of both.

(a) *"Profile driven"* system requires that medication orders/prescriptions be reviewed by the pharmacist for appropriateness, dosage, and contraindications prior to, or concomitantly with, being entered into the system, and before access is allowed into the system for medication administration.

(b)(i) *"Non-profile driven"* system does not require prior or concomitant pharmacist review of medication orders/prescriptions in order to gain access to the system for medication administration. A non-profile driven system may include, but is not limited to, a night drug cabinet, emergency drug kit, or floor stock/first dose cabinet.

(ii) *"Floor stock/first dose cabinet"* is a medication storage device, which shall be used by personnel, authorized by a protocol established by the pharmacist-in-charge, to gain access to doses as needed and first doses in patient-care areas. In addition, a floor stock/first dose cabinet may be used to store medications in such specialty areas including, but not limited to, an emergency room, surgery suite, and endoscopy suite.

(4) *"Board"* means the Louisiana Board of Pharmacy.

(5) *"Compounding"* means the preparation, mixing, assembling, packaging, or labeling of a drug or device by a pharmacist for his patient as the result of a practitioner's prescription drug order or initiative based on the

practitioner/patient/pharmacist relationship in the course of professional practice, or including the preparation of drugs or devices in anticipation of prescription drug orders to be received by the compounding pharmacist based on routine, regularly observed prescribing patterns. Compounding does not include the compounding of drug products that are essentially copies of a commercially available product.

(6) *"Confidential information"* means information accessed, maintained by, or transmitted to a pharmacist in the patient's records or which is communicated to the patient as part of patient counseling, which is privileged and may be released only to the patient or, to those practitioners, other authorized health care professionals, and other pharmacists when, in a pharmacist's professional judgment, such release is necessary to protect the patient's health and well being; and to such other persons or agencies authorized by law to receive such confidential information regardless of whether such information is in the form of paper, preserved on microfilm, or is stored on electronic media.

(7) *"Costs"* is a monetary amount assessed to cover administrative expenses, including but not limited to licensure, permitting, certification, registration, and the investigation and prosecution of a disciplinary action.

(8) *"Deliver"* or *"delivery"* means the actual, constructive, or attempted transfer of a drug or device from one person to another, whether or not for a consideration.

(9) *"Device"* means an instrument, apparatus, implement, machine, contrivance, implant, or other similar or related article, including any component part or accessory, which is required under federal law to bear the label, "Caution: Federal or State law requires dispensing by or on the order of a physician" and/or "Rx Only", or any other designation required under federal law.

(10) *"Dispense"* or *"dispensing"* means the interpretation, evaluation, and implementation of a prescription drug order, including the preparation and delivery of a drug or device to a patient or patient's agent in a suitable container appropriately labeled for subsequent administration to, or use by, a patient. "Dispense" necessarily includes a transfer of possession of a drug or device to the patient or the patient's agent.

(11) *"Distribute"* or *"distribution"* means the delivery of a drug or device other than by administering or dispensing.

(12) *"Drug"* means: (a) any substance recognized as a drug in the official compendium, or supplement thereto, designated by the board for use in the diagnosis, cure, mitigation, treatment or prevention of diseases in humans or animals, (b) any substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals, or (c) any substance other than food intended to affect the structure or any function of the body of humans or other animals.

(13) *"Drug regimen review"* means and includes, but is not limited to, the following activities: (a) Review of the prescription drug order and patient record for: [i] known allergies, [ii] therapy contraindications, [iii] dose and route of administration, and [iv] directions for use, (b) Review of the prescription drug order and patient record for duplication of therapy, (c) Review of the prescription drug order and patient record for interactions, and (d) Review of the prescription drug order and patient record for proper utilization including over- or under- utilization, and optimum therapeutic outcomes.

(14) *"Electronic transmission"* means transmission of information in electronic form or the transmission of the exact visual image of a document by way of electronic equipment.

(15) *"Emergency drug kit (EDK)"* for long-term care facilities (LTCF) or other board approved sites, other than a hospital, means a drug kit containing designated drugs which may be required to meet the immediate therapeutic emergency needs of a resident or patient.

(16) *"Equivalent drug product"* means a drug product that has been rated as a pharmaceutical equivalent by the federal food and drug administration (FDA) and has the same established name, active ingredients, strength or concentration, dosage form, and route of administration and which is formulated to contain the same amount of active ingredients in the same dosage form and to meet the same compendial or other applicable standards such as strength, quality, purity, and identity, but which may differ in characteristics such as shape, scoring, configuration, packaging, excipients including colors, flavors, preservatives, and expiration time.

(17) *"Final checks of work"* is the requirement that only a pharmacist supervises and releases the completed product prepared by a pharmacy technician.

(18) *"Hospital pharmacy"* means a pharmacy department located in a hospital licensed under R.S. 40:2100 et seq. For the purposes of this Chapter a hospital pharmacy is one example of a primary care treatment modality pharmacy.

(19) *"Infusion pharmacy"* means a pharmacy that provides prepared solutions for direct administration to a patient in a private residence, long term care facility, or hospice setting by means of irrigation, enteral, parenteral, intravenous, intramuscular, subcutaneous, or intraspinal infusion.

(20) *"Institutional facility"* means any organization whose primary purpose is to provide a physical environment for a patient to obtain health care services, including but not limited to a:

(a) Hospital pharmacy.

(b) Convalescent home.

(c) Nursing home.

(d) Extended care facility.
(e) Mental health facility.
(f) Rehabilitation center.
(g) Psychiatric center.
(h) Developmental disability center.
(i) Drug abuse treatment center.
(j) Family planning clinic.
(k) Penal institution.
(l) Hospice.
(m) Public health facility.
(n) Athletic facility.

(21) *"Institutional pharmacy"* means that physical portion of an institutional facility where drugs, devices, and other materials used in the diagnosis and treatment of injury, illness, and disease are dispensed, compounded, and distributed and pharmacy primary care is provided; and is permitted by the board and is devoted exclusively to providing professional services to a patient in that institutional setting other than a hospital.

(22) *"Labeling"* means the process of preparing and affixing a label to any drug container exclusive, however, of the labeling by a manufacturer, packer, or distributor of a non-prescription drug or commercially packaged legend drug or device. Any such label shall include all information required by federal and state law or regulation.

(23) *"Long term care facility"* means a nursing home, retirement care, mental care, or other facility or institution that provides extended health care to a residential patient, including but not limited to health care facilities licensed by the Department of Health and Hospitals.

(24) *"Manufacturer"* means a person who manufactures drugs and includes a labeler, primary distributor, or person who prepares drugs in dosage form by mixing.

(25) *"Manufacturing"* means the production, preparation, propagation, conversion, or processing of a drug or device, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical or biological synthesis, and includes any packaging or repackaging of the substance or labeling or relabeling of its container, and the promotion and marketing of such drugs or devices. Manufacturing also includes the preparation and promotion of commercially available products from bulk compounds for resale by pharmacies, practitioners, or other persons.

(26) *"Medical order"* means a lawful order of a practitioner that may or may not include a prescription.

(27) *"Non-prescription drug"* means a drug that may be sold without a prescription and that is labeled for use by the consumer in accordance with the federal and state laws and regulations.

(28) *"Out-of-state pharmacy"* means a pharmacy located outside this state.

(29) *"On-site facility"* means and refers to the location of a building that houses a board permitted pharmacy.

(30) *"Off-site facility"* means and refers to the location of a building that houses a licensee of the Department of Health and Hospitals, but which does not house a board permitted pharmacy.

(31) *"Patient counseling"* means the communication by a pharmacist of information, as defined by the regulations of the board, to the patient or caregiver, in order to ensure proper use of drugs and devices.

(32) *"Permit"* means the grant of authority by the board to any person authorizing the practice of pharmacy at a site.

(33) *"Person"* means an individual, corporation, partnership, association, or any other legal entity, including government.

(34) *"Pharmacist"* means an individual currently licensed by the board to engage in the practice of pharmacy in the state.

(35) *"Pharmacist-in-charge"* means a pharmacist currently licensed by the board who accepts responsibility for the operation of a pharmacy in conformance with all laws and regulations pertinent to the practice of pharmacy and the distribution of drugs, and who is personally in full and actual charge of such pharmacy and personnel.

(36) *"Pharmacy"* means any place located within this state where drugs are dispensed and pharmacy primary care is provided, and any place outside of this state where drugs are dispensed and pharmacy primary care is provided to residents of this state.

(37)(a) *"Pharmacy collaborative drug therapy management"* means that practice whereby a pharmacist or pharmacists have, on a voluntary basis, agreed to manage the disease-specific drug therapy of a patient under written protocol, working in conjunction with a physician licensed to practice medicine by the Louisiana State Board of Medical Examiners. Pharmacy collaborative drug therapy management does not include the substitution by the pharmacist of a product that is not an equivalent drug product to the product originally prescribed by the physician or practitioner without the explicit consent of the physician or practitioner. Any pharmacy collaborative drug therapy management protocol shall adhere to rules and regulations promulgated by the board.

(b)(i) The Louisiana State Board of Medical Examiners and the Louisiana Board of Pharmacy shall initiate

the rulemaking process in accordance with the provisions of the Administrative Procedure Act by publishing their respective notices of intent no later than one hundred twenty days following the effective date of this Subparagraph.

(ii) If both boards have not initiated the rulemaking process in accordance with the provisions of the Administrative Procedure Act by publishing their respective notices of intent by one hundred twenty days following the effective date of this Subparagraph, then the boards shall appoint a committee composed of three physicians and three pharmacists, the physicians by the Louisiana State Board of Medical Examiners and the pharmacists by the Louisiana Board of Pharmacy. This committee shall complete the drafting process no later than one hundred eighty days following the effective date of this Subparagraph.

(iii) If the boards have not initiated the rulemaking process in accordance with the provisions of the Administrative Procedure Act by publishing their respective notices of intent by one hundred eighty days following the effective date of this Subparagraph, then the Louisiana Board of Pharmacy shall have the authority to promulgate the rule required in R.S. 37:1164(37) independently of the Louisiana State Board of Medical Examiners.
(*Amended by Act 627 of 2006 Louisiana Legislature, effective August 15, 2006*)

(38) *"Pharmacy primary care"* means bringing health care as close as possible to where people live and work and may constitute a portal of entry into the continuing health care process in an effort to enhance optimum therapeutic outcomes.

(39) *"Pharmacy intern"* means an individual who is:
(a) Engaged in the practice of pharmacy while under the direct and immediate supervision of a pharmacist for the purpose of obtaining practical experience for licensure as a pharmacist and is satisfactorily progressing in a board-approved college of pharmacy.
(b) A graduate of a board-approved college of pharmacy or a graduate who has established educational equivalency through a program approved by the board.
(c) A qualified applicant awaiting examination for licensure.
(d) An individual participating in a residency or fellowship.

(40) *"Pharmacy technician"* means an individual who assists in the practice of pharmacy under the direct and immediate supervision of a licensed pharmacist and is certified to do so by the board.

(41) *"Practice of pharmacy"* or *"practice of the profession of pharmacy"* means and includes the compounding, filling, dispensing, exchanging, giving, offering for sale, or selling, drugs, medicines, or poisons, pursuant to prescriptions or orders of physicians, dentists, veterinarians, or other licensed practitioners, or any other act, service operation or transaction incidental to or forming a part of any of the foregoing acts, requiring, involving or employing the science or art of any branch of the pharmacy profession, study or training.

(42) *"Practitioner"* means an individual currently licensed, registered, or otherwise authorized by the appropriate licensing board to prescribe and administer drugs in the course of professional practice.

(43) *"Preceptor"* means an individual who is currently licensed as a pharmacist by the board, meets certain qualifications as a preceptor as established by the board, and participates in the instructional training of pharmacy interns.

(44) *"Prescription"* or *"prescription drug order"* means an order from a practitioner authorized by law to prescribe for a drug or device that is patient specific and is communicated by any means to a pharmacist in a permitted pharmacy, and is to be preserved on file as required by law or regulation.

(45) *"Prescription drug"* or *"legend drug"* means a drug that is required by any applicable federal or state law or regulation to be dispensed or delivered pursuant only to a prescription drug order, or is restricted to use by practitioners only.

(46) *"Probation"* means a restriction of pharmacy practice for a specified period of time.

(47) *"Reciprocity"* means the acknowledgment and licensure of a pharmacist from another state or jurisdiction pursuant to procedures established by the board.

(48) *"Reprimand"* means a formal reproof of a person for violation of this Chapter or rules and regulations of the board.

(49) *"Reverse drug distributor"* means a person that receives and handles drugs that are expired, discontinued, adulterated, or misbranded, for the purposes of destruction or other final disposition or for return to the original manufacturer of a drug.

(50) *"Revocation"* is the withdrawal of the license, permit, certification, or registration authorized under this Chapter and means that a person under active revocation no longer has the privilege to practice in the state.

(51) *"Significant adverse drug reaction"* means any drug-related incident that may result in serious harm, injury, or death to the patient.

(52) *"Summary suspension"* means the suspension of a license, permit, certification, or registration that requires a person to cease practice immediately pending the results of a hearing.

(53) *"Suspension"* means the withdrawal of the license, permit, certification, or registration to practice pharmacy in the state for a period of time.

(54) *"Warning"* means a written notice issued to a person addressing possible aberrant conduct.

(55) *"Wholesale drug distribution"* means distribution of legend drugs to other than the consumer or patient, including but not limited to distribution by manufacturers, repackers, own label distributors, jobbers and wholesale drug distributors.

(56) *"Wholesale drug distributor"* means any person who sells legend drugs to other than the consumer or the patient, including but not limited to manufacturers, repackers, own label distributors, jobbers, brokers, agents, and pharmacies.

(end of Part A)

Part D. Permit Requirements

§1221. Unlawful operation

A. No person shall open, establish, operate, or maintain a pharmacy, located within this state, unless the pharmacy is issued a permit by the board.

B. No out-of-state pharmacy providing pharmacy services to residents of this state shall open, establish, operate, or maintain a pharmacy, located out-of-state, unless the pharmacy is issued a permit by the board.

C. No permit to operate a pharmacy shall be granted or renewed unless evidence satisfactory to the board ensures that a pharmacist in the state where the permit is issued and pharmacy is located will be on duty during normal hours as administratively defined.

§1222. Qualifications

A. A person applying for a permit to open, establish, operate, or maintain a pharmacy, within or outside of this state, shall complete an application in such form and contain such data as the board may require, and complete such other requirements as deemed necessary by the board, including but not limited to designation and identification of a pharmacist-in-charge.

B. Each pharmacy shall ensure accessibility to pharmacy primary care for the public as defined by the board.

C. Each pharmacy permitted by the board may designate a registered agent in this state for service of process.

D. Any such person who does not so designate a registered agent shall be deemed to have designated the secretary of state to be its agent, upon whom may be served all legal process in any action or proceeding against such pharmacy.

E. A permit to operate a pharmacy shall not be transferable.

§1223. Classifications

A. The board shall determine the permit classifications of all persons permitted under this Part, and establish minimum standards for such persons.

B. The board shall establish the criteria that each permit holder must meet to qualify for a permit in each classification. The board may issue a permit with varying restrictions to such persons where the board deems it necessary.

§1224. Compounding and filling of prescriptions; absence of pharmacist

A. In each pharmacy there shall be a pharmacist on duty at all times. The filling, compounding and dispensing of prescriptions shall be limited to pharmacists and pharmacy technicians acting under the supervision of a pharmacist.

B. If the pharmacist should find it necessary to be temporarily absent, leaving the prescription department unattended either by a pharmacist or a pharmacy technician, then the prescription department shall be closed.

C. The board shall establish criteria for the temporary absence of a pharmacist from the prescription department.

D. Notwithstanding any provision of law to the contrary, after the pharmacist or pharmacy technician has complied with all duties imposed upon him by law regarding a prescription, a cashier or other clerical person may lawfully deliver the drug or device and collect payment therefor.

E. A prescription may be filled, compounded, and dispensed at the permitted pharmacy which first received the prescription or at any other permitted pharmacy to which the prescription is properly transferred from the originating pharmacy. A prescription may be properly transferred through the transfer of prescription information from one pharmacy to another manually or through an electronic transfer using an electronic file updated on a real-time on-line basis and shared by two or more pharmacies. Electronic transfers of prescriptions shall be permitted regardless of whether or not the pharmacy from which the prescription is transferred is open for business.

F. (*Repealed by Act 83 of the 2000 Louisiana Legislature, effective June 6, 2000.)*

§1224.1. Filling of additional refills in anticipation of authorization

Notwithstanding any provision of law to the contrary, when all refills authorized on an original prescription have been dispensed, additional prescription refills may be added to the original prescription and compounded, filled,

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Title 46 – Professional and Occupational Standards

Part LIII: Pharmacists

Chapter 15. Hospital Pharmacy

§1501. Cross References

A. For all regulations that apply to permitted hospital pharmacies concerning pharmacy practices not specifically stated in this chapter, refer to Chapter 11.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:808 (October 1988), effective January 1, 1989, amended LR 29:2093 (October 2003), effective January 1, 2004.

§1503. Definitions

A. As used in this chapter, the following terms shall have the meaning ascribed to them in this Section:
Hospital Pharmacy – a pharmacy department permitted by the board and located in a hospital licensed pursuant to R.S. 40:2100 et seq. For the purposes of this chapter, a hospital pharmacy is one example of a primary care treatment modality pharmacy.
Registered Patient – A person receiving health care services within a hospital facility.
Remote Processing Services – the processing of a medical order or prescription by one pharmacy on behalf of another pharmacy, including:
a. receiving, interpreting, or clarifying a medical order;
b. entering data and transferring medical order information;
c. interpreting clinical data;
d. performing therapeutic intervention relative to medication therapy; and
e. providing drug information concerning a patient's drug therapy; provided, however, that remote processing does not include the physical preparation or physical transfer of drugs.
Remote Processor – a permitted hospital pharmacy in Louisiana which provides remote processing services for another permitted hospital pharmacy in Louisiana.
Unit Dose – the packaging of individual prescription doses in a suitable container that have been properly labeled as to the identity of the generic, chemical, or trade name of the drug; strength; lot number; and expiration date. All unit doses qualify as "prepackaging" as used in this chapter. However, all prepackaging is not necessarily in "unit dose" packaging.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2093 (October 2003), effective January 1, 2004, amended LR 33:1132 (June 2007).

§1505. Hospital Pharmacy Permit

A. A hospital pharmacy permit shall be required to operate a pharmacy department located within a hospital for registered patients in a hospital. The permit shall be applied for, and renewed, in the manner prescribed by the board in Chapter 11 of these regulations.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2093 (October 2003), effective January 1, 2004, amended LR 33:1132 (June 2007).

§1507. Pharmacist-in-Charge

A. The pharmacist-in-charge of a hospital pharmacy permit shall have had at least two years of experience as a licensed and practicing pharmacist prior to accepting the appointment.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2093 (October 2003), effective January 1, 2004.

§1509. Drug Distribution Control

A. The hospital pharmacist-in-charge shall be responsible for the safe and efficient procurement, receipt, distribution, control, accountability, and patient administration and management of drugs. The staff of the hospital facility shall cooperate with the pharmacist-in-charge in meeting drug control requirements in ordering, administering, and accounting for pharmaceuticals.

1. Procedure Manual. The pharmacist-in-charge shall maintain written procedures for the safe and efficient distribution of pharmaceutical products and delivery of pharmacy care. An updated copy shall be available for board inspection upon request.
2. Inventories. The pharmacist-in-charge shall:
    a. perform an annual inventory on all controlled dangerous substances; and
    b. maintain a perpetual inventory of Schedule I and II controlled dangerous substances.
3. Records. The pharmacist-in-charge shall maintain adequate records regarding the use and accountability of controlled dangerous substances. Proof of use records for controlled dangerous substances shall be maintained separately and in such a manner as to be readily retrievable. These records shall specify the following minimum information:
    a. drug name, strength, and quantity;
    b. dose;
    c. full name of patient;
    d. date and time of administration; and
    e. name of person administering the drug.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2093 (October 2003), effective January 1, 2004.

§1511. Prescription Drug Orders

A. The pharmacist shall review the practitioner's medical order prior to dispensing the initial dose of medication, except in cases of emergency.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2093 (October 2003), effective January 1, 2004.

§1513. Labeling

A. All drugs dispensed by a hospital pharmacy, intended for use within the facility, shall be dispensed in appropriate containers and adequately labeled as to identify patient name and location, drug name(s) and strength, and medication dose(s). Additionally, compounded preparations and sterile preparations shall be labeled with the expiration or beyond-use date, initials of the preparer, and the pharmacist performing the final check.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2093 (October 2003), effective January 1, 2004.

§1515. Ambulance Service Drugs

A. Hospital pharmacies that supply prescription drugs, including any controlled dangerous substances, to any authorized ambulance service or emergency medical service shall maintain proper records to ensure control, proper utilization, inventory, and accountability.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2093 (October 2003), effective January 1, 2004.

§1517. Pharmacist Absence/Drug Cabinet

A. Pharmacist Absence. In the absence of a licensed pharmacist, admittance to the pharmacy by unauthorized persons is prohibited. When the pharmacy is closed, a pharmacist shall be on emergency call.

B. Drug Cabinets. In the absence of a licensed pharmacist, arrangements shall have been formulated in advance by the pharmacist-in-charge to provide drugs for the patients by the use of drug cabinets.

1. Emergency Use. A drug cabinet is solely intended for the proper and safe storage of needed drugs when the pharmacy is closed and shall be available for emergency use by authorized hospital personnel only.
2. Security. The drug cabinet shall be a securely constructed and locked enclosure located outside the permitted pharmacy ensuring access to authorized personnel only.
3. Inventory. The pharmacist-in-charge shall be responsible for the selection and quantity of the drugs to be maintained in the drug cabinet and shall maintain a perpetual inventory of any controlled dangerous substances stored in the drug cabinet.
4. Labeling. Medications stored in a drug cabinet shall be properly labeled.
5. Quantities. Prepackaged drugs shall be available in amounts sufficient for immediate therapeutic or emergency requirements.
6. Accessibility. Written medical practitioner's orders and proof of use, if applicable, shall be provided when a drug cabinet inventory is utilized.
7. Inspection. Medications stored in a drug cabinet shall be inspected every thirty days.
8. Policy Manual. A policy and procedure manual shall be maintained to implement the drug cabinet requirements and is to be made available to the board upon request for inspection and approval.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2093 (October 2003), effective January 1, 2004.

§1519. Drug Returns

A. In a hospital with a permitted hospital pharmacy on site, drugs may be returned to the pharmacy in accordance with good professional practice standards.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2094 (October 2003), effective January 1, 2004.

§1521. Off-Site Pharmacy Services

A. Availability. Pharmacy services may be procured contractually from outside the hospital for inpatient administration.

B. Contractual agreements shall provide for:

1. emergency – the pharmacy provider shall be available for on-call for emergency pharmacy services.
2. storage – adequate drug storage facilities shall be provided to the pharmacy provider.
3. labeling – prescription drugs supplied to hospital inpatients shall be properly labeled to ensure that adequate control, supervision, and recall of medication are monitored.
4. contractual pharmacy service – off-site contractual pharmacy services rendered to the hospital shall be in accordance with federal and state laws, rules, and regulations.

C. A pharmacy providing off-site contractual pharmacy services to a hospital shall not be considered a hospital pharmacy.

D. Medications. Prescription medications independently supplied to registered patients shall comply with all appropriate board regulations and statutes and/or hospital rules, regulations, and policies.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2094 (October 2003), effective January 1, 2004.

§1523. Outpatient Pharmacy Dispensing

A. Hospital outpatient dispensing shall require a separate pharmacy permit for the specialty classification(s) under these regulations. All records including the annual inventory of controlled dangerous substances for the outpatient pharmacy shall be maintained and kept separate and apart from that of the inpatient pharmacy, as the outpatient pharmacy may not acquire drugs through the hospital pharmacy permit under the provisions of the Robinson-Patman Act, 15 U.S.C. §13(c).

B. Nothing in this section shall prohibit the dispensing of certain prescriptions from the hospital pharmacy, as allowed under the Robinson-Patman Act, 15 U.S.C. §13, including:
   1. dispensing to the hospital inpatient for use in his treatment at the hospital;
   2. dispensing to the patient admitted to the hospital's emergency facility for use in the patient's treatment at that location;
   3. dispensing to the hospital outpatient for personal use on the hospital premises;
   4. dispensing in the context of a genuine take-home prescription, intended for a limited and reasonable time as a continuation of, or supplement to, the treatment that was administered at the hospital to the recipient while an inpatient, an outpatient, or an emergency facility patient if the patient needs that treatment; or
   5. dispensing to the hospital's physicians, employees, or its students for their personal use or for the personal use of their dependents.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2094 (October 2003), effective January 1, 2004.

§1525. Remote Processing of Medical Orders

A. General Requirements
   1. A hospital pharmacy may obtain remote processing services from a remote processor provided the pharmacies:
      a. have the same owner or have entered into a written contract or agreement that outlines the services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with federal and state laws, rules, and regulations; and
      b. share a common electronic file or have appropriate technology to allow access to sufficient information necessary or required to provide the requested services.
   2. A contract or agreement for remote processing services shall not relieve the hospital pharmacy from employing or contracting with a pharmacist to provide routine pharmacy services within the facility. The activities authorized by this Section are intended to supplement hospital pharmacy services when the pharmacy is not operating and are not intended to eliminate the need for an on-site hospital pharmacy or pharmacist.

B. Access to Patient Information
   1. The remote pharmacist shall have secure electronic access to the hospital pharmacy's patient information system and to all other electronic systems that the hospital pharmacist has access to when the pharmacy is operating. The remote pharmacist shall receive training in the use of the hospital's electronic systems.
   2. If a hospital pharmacy is not able to provide remote electronic access to the patient information system, both pharmacies shall have appropriate technology to allow access to the required patient information.

C. Policies and Procedures
   1. Hospital pharmacies and remote processors engaging in the acquisition or provision of remote processing services shall maintain a policy and procedure manual for reference by all personnel; it shall also be available for inspection and copying by the board.
   2. At a minimum, the manual shall include policies and procedures for:
      a. identification of the responsibilities of each of the pharmacies;
      b. protection of the integrity and confidentiality of patient information; and
      c. maintenance of appropriate records to identify the name, initials, or unique identification code of each pharmacist performing processing functions, the specific services performed, and the date of such services.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 33:1132 (June 2007).

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Louisiana Administrative Code

Title 46 – Professional and Occupational Standards

Part LIII: Pharmacists

Chapter 17. Institutional Pharmacy

Subchapter A. General Requirements

§1701. Cross References

A. For all regulations that apply to permitted institutional pharmacies concerning pharmacy practices not specifically stated in this chapter, refer to Chapter 11.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2094 (October 2003), effective January 1, 2004.

§1703. Definitions

A. As used in this Chapter, the following terms shall have the meaning ascribed to them in this section:

Institutional Facility – any organization whose primary purpose is to provide a physical environment for a patient to obtain health care services, including but not limited to a(n):

a. convalescent home;
b. nursing home;
c. extended care facility;
d. mental health facility;
e. rehabilitation center;
f. psychiatric center;
g. developmental disability center;
h. drug abuse treatment center;
i. family planning clinic;
j. penal institution;
k. hospice;
l. public health facility;
m. athletic facility.

Institutional Pharmacy – that physical portion of an institutional facility where drugs, devices, and other materials used in the diagnosis and treatment of an injury, illness, and disease are dispensed, compounded, and distributed and pharmacy primary care is provided, and is permitted by the board and is devoted exclusively to providing professional services to a patient in that institutional setting, other than a hospital.

Long Term Care Facility – a nursing home, retirement center, mental care, or other facility or institution that provides extended health care to a residential patient, including but not limited to health care facilities licensed by the Department of Health and Hospitals.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2094 (October 2003), effective January 1, 2004.

§1705. Institutional Pharmacy Permit

A. An institutional pharmacy permit shall be required to operate a pharmacy department located within an institutional facility, other than a hospital, for residents or patients of that institutional facility. The permit shall be applied for, and renewed, in the manner prescribed by the board in Chapter 11 of these regulations.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2095 (October 2003), effective January 1, 2004.

§1707. Drug Cabinet

A. In the absence of a licensed pharmacist, arrangements shall have been formulated in advance by the pharmacist-in-charge to provide drugs for the residents/patients by the use of drug cabinets. When the pharmacy is closed, a pharmacist shall be on emergency call.

1. Emergency Use. A drug cabinet is solely intended for the proper and safe storage of needed drugs when the pharmacy is closed and shall be available for emergency use by authorized facility personnel only.
2. Security. The drug cabinet shall be a securely constructed and locked enclosure located outside the permitted pharmacy area ensuring access by authorized personnel only.
3. Inventory. The pharmacist-in-charge shall be responsible for the selection and quantity of drugs to be maintained in the drug cabinet and shall maintain a perpetual inventory of any controlled dangerous substances. Medications shall be available in quantities sufficient only for immediate therapeutic needs.
4. Labeling. Medications stored in a drug cabinet shall bear a label with the following minimum information:
    a. drug name;
    b. dosage form;
    c. strength;
    d. name of manufacturer and/or distributor;
    e. manufacturer's lot or batch number;
    f. pharmacist's initials; and
    g. expiration date, according to United States Pharmacopeia guidelines.
5. Accountability. Documented medical practitioner's orders and proof of use shall be provided when any of the drug cabinet inventory is utilized.
6. Inspection. The pharmacy shall inspect medications stored in a drug cabinet every 30 days, plus or minus five days.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2095 (October 2003), effective January 1, 2004, amended LR 33:1133 (June 2007).

Subchapter B. Emergency Drug Kits

§1709. Definitions

A. As used in this Subchapter, the following terms shall have the meaning ascribed to them in this section:

Emergency Drug Kit (EDK) – for long-term care facilities or other board-approved sites, other than a hospital, means a drug kit containing designated emergency drugs which may be required to meet the immediate therapeutic needs of a resident or patient.

Emergency Drugs – those drugs which may be required to meet the immediate therapeutic needs of patients and which are not available from any other authorized source in sufficient time to prevent risk of harm to patients or residents because of delay resulting from obtaining such medications from such other source.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2095 (October 2003), effective January 1, 2004.

§1711. Emergency Drug Kit Permit

A. A long-term care facility, institutional facility without an institutional pharmacy, or other board-approved site, other than a hospital, that desires to maintain an Emergency Drug Kit shall obtain an EDK permit from the board.

B. Permit Application and Requirements. Application for an EDK permit shall be made on a form provided by the board.

1. The provider pharmacy shall apply to the board for an EDK permit. The administrator of the applicant facility shall also sign the application for said permit. Upon compliance with the required provisions, the provider pharmacy shall be issued a permit by the board for the provider pharmacy to establish and maintain an EDK in the facility.
2. The provider pharmacy shall be a Louisiana-licensed pharmacy.
3. Only one provider pharmacy shall be assigned to and be responsible for each EDK.
4. EDK permits are institutional facility-specific and not transferable.
5. A separate permit is required for each EDK.
6. The original EDK permit shall be conspicuously displayed at the provider pharmacy. A copy of the EDK permit shall be maintained in the room where the EDK is located.

C. Pharmacist-in-Charge. The pharmacist-in-charge of the provider pharmacy shall be the pharmacist-in-charge of the EDK. The maintenance of the EDK shall at all times remain the responsibility of the pharmacist-in-charge.

D. Renewal. Each EDK permit issued by the board shall be renewed annually by the provider pharmacy, at the time designated by the board. If an EDK permit is not renewed by July 1 of each year, the existing permit shall expire and become null and void.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2095 (October 2003), effective January 1, 2004.

§1713. Emergency Drug Kit Requirements

A. Emergency Use. An EDK is solely intended for the immediate therapeutic emergency needs of a resident or patient.

B. Security. The EDK shall be tamper-evident and shall be maintained in a secure enclosure located within the institutional facility and shall be available for emergency use by authorized personnel only.

C. Exterior Identification and Labeling. The EDK shall be clearly labeled to indicate that it is an emergency drug kit. In addition, the attached exterior label shall have an inventory of contents and contact information of the provider pharmacy.

D. Labeling. Medications stored in an EDK shall bear a label with the following minimum information:
1. drug name;
2. dosage form;
3. strength;
4. name of manufacturer and/or distributor;
5. manufacturer's lot or batch number; and
6. expiration date, according to United States Pharmacopeia guidelines.

E. Storage. All drugs in an EDK shall be stored to ensure a proper environment for the preservation of the drugs. If federal or state laws or regulations require adequate storage outside the EDK, documentation shall be kept with the EDK properly identifying this special storage requirement and drug(s) involved.

F. Policies and Procedures. Policies and procedures shall be maintained by the provider pharmacy and the applicant facility to implement the EDK requirements.

G. Accountability. Documented medical practitioner's orders and proof of use shall be provided when an EDK inventory is utilized. Medication administered to patients from the EDK shall be documented with the following information, in accordance with the institutional facility policy manual, that shall be immediately reduced to writing and a copy delivered to the provider pharmacy:
1. name of the resident patient;
2. drug name, strength, and quantity;
3. nature of the emergency;
4. time and date of administration;
5. name of person administering the medication; and
6. name of prescriber authorizing the medication.

H. Records. Records shall be readily retrievable and comply with applicable federal and state laws and regulations.

I. Inspection.
1. The provider pharmacy shall inspect the EDK every thirty (30) days, plus or minus five (5) days. Proper documentation of these inspections, EDK inventory, and all records of use shall be maintained and made available to the board upon request.
2. The EDK shall be available for inspection by the board.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2096 (October 2003), effective January 1, 2004.

Subchapter C. Drug Abuse Treatment Center Pharmacies

§1715. Purpose

A. The board may issue a pharmacy permit for a drug abuse treatment center operating in the state of Louisiana where drugs are dispensed and pharmacy primary care is provided.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2096 (October 2003), effective January 1, 2004.

§1717. Cross References

A. For all regulations that apply to drug abuse treatment center pharmacies concerning pharmacy practices not specifically stated in this subchapter, refer to Chapter 11.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2096 (October 2003), effective January 1, 2004.

§1719. Definitions

A. As used in this Subchapter, the following terms shall have the meaning ascribed to them in this section:

Administer or Administration – means the direct application of a drug to the body of a patient or research subject by injection, inhalation, ingestion, or any other means.

Authorized Personnel – means individuals who, within the scope of their authority granted by mutual agreement of the drug abuse treatment center's pharmacist-in-charge and director, are granted access to the drug abuse treatment center's pharmacy department as part of his duties.

Dispense or Dispensing – means the interpretation, evaluation, and implementation of a prescription drug order, including the preparation and delivery of a drug or device to a patient or patient's agent in a suitable container appropriately labeled for subsequent administration to, or use by, a patient. "Dispense" necessarily includes a transfer of possession of a drug or device to the patient or the patient's agent.

Drug Abuse Treatment Center – means any establishment, facility, or institution, public or private, whether operated for profit or not, which primarily offers, or purports to offer, maintain, or operate facilities for the residential or outpatient diagnosis, care, treatment, or rehabilitation of two or more non-related individuals, who are patients as defined herein, excluding, however, any hospital or mental hospital otherwise licensed by the Department of Health and Hospitals.

Patient or Client – means a person who is dependent on, or otherwise suffering physically or mentally from the use of, or abuse of, controlled dangerous substances and who requires continuing care of a drug abuse treatment center.

Perpetual Inventory – means a computer record of inventory kept continuously up to date by detailed entries of all incoming and outgoing items. This includes inventory on hand, purchases, and dispensing.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2096 (October 2003), effective January 1, 2004.

§1721. Drug Abuse Treatment Center Pharmacy Permit

A. A drug abuse treatment center pharmacy permit shall be required to operate a pharmacy department located within a drug abuse treatment facility for patients of that facility. The permit shall be applied for, and renewed, in the manner prescribed by the board in Chapter 11 of these regulations.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2097 (October 2003), effective January 1, 2004.

§1723. Minimum Security Controls for Drug Abuse Treatment Centers

A. Persons enrolled in a drug abuse treatment center shall wait for their prescriptions in an area physically separated from the controlled dangerous substance (CDS) storage and dispensing area. This requirement shall be enforced by the drug abuse treatment center physician(s), pharmacist(s), and employees.

B. All CDS used in a drug abuse treatment center shall be securely locked and accessible to authorized personnel within that facility only.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2097 (October 2003), effective January 1, 2004.

§1725. Records and Reports of Drug Abuse Treatment Centers

A. All persons licensed by the Department of Health and Hospitals to operate a drug abuse treatment center and who possess a Drug Enforcement Administration (DEA) registration to purchase, possess, and use CDS shall keep the following records:

1. records of CDS received by approved persons, including date of receipt, name and address of distributor, type and quantity of such drugs received, and the signature of the individual receiving the CDS. A duplicate invoice or separate itemized list furnished by the distributor will be sufficient to satisfy this record requirement, provided it includes all required information and is maintained in a separate file. In addition, duplicate copies of federal order forms for CDS listed in Schedule II must be retained; and
2. records of CDS administered or dispensed, including date of administration or dispensing, name of patient, signature of person administering or dispensing, type and quantity of drug, and such other information as may be required by state and federal laws and regulations.

B. Records of perpetual inventories shall be kept at the permitted site as prescribed by law.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2097 (October 2003), effective January 1, 2004.

Subchapter D. Drug Donations to Pharmacies in Penal Institutions

§1727. Medication Transfers

A. In facilities licensed by the Department of Health and Hospitals where United States Pharmacopeia (USP) storage requirements can be assured, prescription drugs, except controlled dangerous substances, dispensed in unit dose or in individually sealed doses may be transferred to a permitted institutional pharmacy located within a penal institution operated under the authority of the Department of Public Safety and Corrections for re-labeling and dispensing to that penal institution's patients, free of charge, pursuant to a valid prescription order.

1. The pharmacist-in-charge of the institutional pharmacy located within a penal institution shall be responsible for determination of suitability of the product for reuse.
    a. No product where integrity cannot be assured shall be accepted for re-dispensing by the pharmacist.
    b. A re-dispensed prescription medication shall be assigned the expiration date stated on the package.
    c. No product shall be re-dispensed more than one time.
2. Pursuant to a voluntary agreement between the facility licensed by the Department of Health and Hospitals and an institutional pharmacy located within a penal institution operated under the authority of the Department of Public Safety and Corrections, prescription drugs, except controlled substances, may be transferred from the facility to the pharmacy provided the following procedures are satisfied:
    a. The physical transfer shall be accomplished by an individual authorized to do so by the institutional pharmacy located within a penal institution.

b. The patient from whom the prescription medication was obtained shall document their consent for the donation; the consent shall be maintained on file in the facility.
c. The patient's name, prescription number, and any other identifying marks, shall be obliterated from the packaging prior to removal from the facility.
d. The drug name, strength, and expiration date shall remain on the medication package or label.
e. An inventory list of the drugs shall accompany the drugs being transferred. The list shall contain, at a minimum, the medication name, strength, quantity, and expiration date.
f. Expired drugs shall not be transferred. In the event expired drugs are received by an institutional pharmacy located within a penal institution, the pharmacist-in-charge shall destroy them as required by law.

B. Under no circumstances may these transferred medications be re-distributed to another location.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:1408 (July 2008).

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

392 MAINE BOARD OF PHARMACY

Chapter 3: APPLICABILITY OF RULES TO UNREGISTERED FACILITIES

Summary: This chapter provides for the applicability of the board's rules to the facilities identified in 32 M.R.S.A. §13721(1)(D).

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1. Facilities Not Registered or Licensed by the Board

Dispensaries, hospital pharmacies, extended care facilities, boarding homes, nursing homes, drug abuse treatment centers, penal institutions, family planning centers, medical clinics and all other facilities that are not registered or licensed by the board shall comply with and be bound by Chapters 1 - 7 and 14-32 of the board's rules.

STATUTORY AUTHORITY: 32 M.R.S.A. §§ 13720, 13721(1)(D), 13723

EFFECTIVE DATE:
November 8, 2004 - filing 2004-505

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02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

392 MAINE BOARD OF PHARMACY

Chapter 14: PHARMACY SERVICES AT RURAL HEALTH CENTERS

Summary: This chapter sets forth requirements for the pharmacy services provided by rural health centers licensed by the board.

1. Consulting Pharmacist; Monthly Inspection

Each rural health center must have a consulting pharmacist who inspects the rural health center on a monthly basis pursuant to a written contract between the pharmacist and the rural health center. The consulting pharmacist shall send a report of each inspection to the medical director and the administrator of the rural health center within 10 days after the inspection.

2. Limitation on Prescription Authority

No rural health center may dispense Schedule II controlled substances.

3. Recordkeeping

1. Prescription Drug Orders Filled From Inventory

A practitioner shall write all prescription drug orders in duplicate. The original shall be given to the drug outlet provider daily. The copy shall be kept at the rural health center.

2. Daily Reports

A rural health center shall provide the provider drug outlet with a daily report of each medication dispensed from inventory, the patient name, and all other information needed for the patient profile.

3. Patient Profiles and Medication Records

Patient profiles shall be maintained at the provider drug outlet. Medication records shall be kept at the rural health center.

4. Labels and Containers

A. Each rural health center shall use its own label for prescription drugs. The consulting pharmacist shall ensure that the labels used by the rural health

center contain complete and accurate directions for use. The rural health center shall provide the patient with verbal directions as to proper medication usage.

B. The consulting pharmacist shall ensure that each prescription container provided by the provider drug outlet lists the lot number, manufacturer and expiration date of the medication.

C. The consulting pharmacist shall ensure that the provider drug outlet supplies the rural health center with the latest package inserts of all medications in the formulary.

4. Storage and Security

A rural health center shall ensure the security of drugs at all times. A rural health center shall keep drugs in a locked storage area during non-business hours. A rural health center that provides pharmacy services must be protected by an alarm system.

5. Freedom of Choice

A rural health center shall advise its patients of their right to choose a source of pharmaceutical services.

STATUTORY AUTHORITY: 32 M.R.S.A. §§ 13720, 13721(1), 13722, 13723, 13762, 13763, 13764

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10.34.03.00

Title 10 DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Subtitle 34 BOARD OF PHARMACY

Chapter 03 Inpatient Institutional Pharmacy

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

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10.34.03.01

.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.

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10.34.03.02

.02 Definitions.

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

B. Terms Defined.

(1) "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 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.

(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.

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10.34.03.03

.03 Issuance of Permits.

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

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10.34.03.04

.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.

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10.34.03.05

.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.

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10.34.03.06

.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. Thedirector 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 inpatient institutional pharmacy area where prescription drugs or devices are held shall be limited to authorized personnel under a pharmacist's supervision.

D. An inpatient 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.

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10.34.03.07

.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

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10.34.03.08

.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.

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10.34.03.09

.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.

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10.34.03.10

.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.

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10.34.03.11

.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.

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10.34.03.12

.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; and

(h) Vaccination status.

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10.34.03.13

.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.

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10.34.03.14

.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.

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10.34.03.15

.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.

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10.34.03.16

.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.

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10.34.03.9999

Administrative History

Effective date: November 6, 1995 (22:22 Md. R. 1666)

Chapter revised effective October 1, 2011 (38:19 Md. R. 1147)

General Laws

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Section 37. “Drug business”, as used in the two following sections, shall mean the sale, or the keeping or exposing for sale of drugs, medicines, chemicals or poisons, except as otherwise provided in section thirty-five, also the sale or the keeping or exposing for sale of opium, morphine, heroin, codeine or other narcotics, or any salt or compound thereof, or any preparation containing the same, or cocaine, alpha or beta eucaine, or any synthetic substitute therefor, or any salt or compound thereof, or any preparation containing the same, and the said term shall also mean the compounding and dispensing of physicians’ prescriptions.

Michigan Legislative Website

PUBLIC HEALTH CODE (EXCERPT)
Act 368 of 1978

333.17707 Definitions; P.

Sec. 17707.

(1) “Personal charge” means the immediate physical presence of a pharmacist or dispensing prescriber.

(2) “Pharmacist” means an individual licensed under this article to engage in the practice of pharmacy.

(3) “Pharmacist intern” or “intern” means an individual who satisfactorily completes the requirements set forth in rules promulgated by the board and is licensed by the board for the purpose of obtaining instruction in the practice of pharmacy from a preceptor approved by the board.

(4) “Pharmacy” means a building or part of a building in which the practice of pharmacy is conducted.

(5) “Practice of pharmacy” means a health service, the clinical application of which includes the encouragement of safety and efficacy in the prescribing, dispensing, administering, and use of drugs and related articles for the prevention of illness, and the maintenance and management of health. Professional functions associated with the practice of pharmacy include:

(a) The interpretation and evaluation of the prescription.

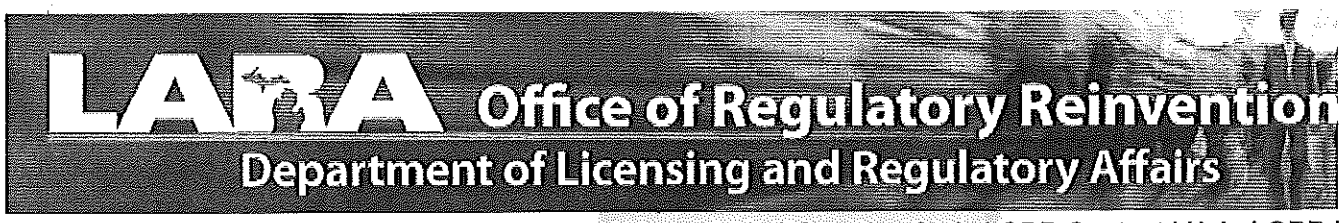
(b) Drug product selection.

(c) The compounding, dispensing, safe storage, and distribution of drugs and devices.

(d) The maintenance of legally required records.

(e) Advising the prescriber and the patient as required as to contents, therapeutic action, utilization, and possible adverse reactions or interactions of drugs.

History: 1978, Act 368, Eff. Sept. 30, 1978 ;-- Am. 1990, Act 333, Eff. Mar. 28, 1991
Popular Name: Act 368



Michigan Administrative Code

Licensing and Regulatory Affairs

Bureau of Health Professions:

Medical Marihuana	R 333.101 - 3
Board of Massage Therapy - General Rules	R 338.701 - 33
Disciplinary Proceedings	R 338.1601 - 3
Task for on Physician Assistants – General Rules	R 338.6101 -
Board of Dentistry - Dental Amalgam	R 338.11801 -
Board of Acupuncture:	
Board of Acupuncture - General Rules	R 338.13001 -
Board of Athletic Trainers:	
Board of Athletic Trainers	R 338.1301 -
Board of Audiology:	
Audiologist - General Rules	R 338.1 - 338.
Board of Chiropractic:	
Board of Chiropractic - General Rules	R 338.12001 -
Board of Counseling:	
Board of Counseling - General Rules	R 338.1751 - 3
Board of Dentistry:	
Board of Dentistry - General Rules	R 338.11101 -
Board of Marriage and Family Therapy:	
Board of Marriage and Family Therapy	R 338.7201 - 3
Board of Medicine:	
Board of Medicine - General Rules	R 338.2301 -
Board of Nursing:	
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Board of Nursing Home Administration:	
Board of Nursing Home Administrators - General Rules	R 339.14001 -
Board of Occupational Therapists:	
Board of Occupational Therapists - General Rules	R 338.1191 -
Board of Optometry:	
Board of Optometry	R 338.241 - 33
Board of Osteopathic Medicine and Surgery:	
Continuing Education	R 338.91 - 33
Board of Osteopathic Medicine and Surgery - General Rules	R 338.101 - 3
Board of Pharmacy:	
Board of Pharmacy	R 338.471 - 3
Radiopharmaceuticals	R 338.3001 -
Public Participation at Open Board Meetings	R 338.3031 -

10 square feet of free working surface. If more than 1 pharmacist is on duty at any one time, the free working space shall be increased by not less than 4 square feet for each additional pharmacist. The prescription counter shall be kept clean and orderly. The space behind the prescription counter shall be sufficient to allow free movement within the area and shall be free of obstructions.

(3) All pharmacies that occupy less than the entire area of the premises owned, leased, used, or controlled by the licensee shall be permanently enclosed by partitions from the floor to the ceiling. All partitions shall be of substantial construction and shall be securely lockable so that drugs and devices that can only be sold by a pharmacist are unobtainable during the absence of the pharmacist. Identification of this department by the use of the words "drug," "medicines," or "pharmacy" or by the use of a similar term or combination of terms shall be restricted to the area that is registered by the board. The pharmacy department shall be locked when the pharmacist is not in the establishment.

History: 1979 AC; 1980 AACS.

R 338.483 Rescinded.

History: 1979 AC; 1992 AACS.

R 338.484 Rescinded.

History: 1979 AC.

ADMINISTRATIVE HEARINGS

R 338.485 - R 338.485y Rescinded.

History: 1979 AC; 1980 AACS.

R 338.486 "Medical institution" and "pharmacy services" defined; pharmacy services in medical institutions.

Rule 16. (1) As used in this rule:

(a) "Medical institution" means a hospital, skilled nursing facility, county medical care facility, nursing home, or other health facility which is licensed or approved by the state and which directly or indirectly provides or includes pharmacy services.

(b) "Pharmacy services" means the direct and indirect patient care services associated with the practice of pharmacy.

(2) Pharmacy services shall be directed and provided by a licensed pharmacist.

(3) Pharmacy personnel who assist the pharmacist by performing delegated functions in the care of inpatients shall be supervised by a pharmacist who is on the premises of the medical institution.

(4) The pharmacist who directs the pharmacy services shall develop, implement, supervise, and coordinate all of the services provided, including, at a minimum, all of the following:

(a) Dispensing medications in a form that minimizes additional preparation before administration to the patient, including the admixture of parenterals.

(b) Obtaining the prescriber's original medication order, a direct carbonized copy, an electromechanical facsimile, or other electronic order transmission. Security measures shall be in place to ensure that system access by unauthorized individuals is not allowed.

(c) Interpreting and reviewing the prescriber's medication orders and communicating problems with these orders to the physician or nurse before administration of first doses. If the interpretation and review will cause a medically unacceptable delay, then a limited number of medications may be stocked at the patient care areas for the administration of first doses.These medications shall be provided in a manner that ensures security and immediate availability, such as sealed or secured medication kits, carts,

or treatment trays. A pharmacist shall routinely inspect the medications and, after use, shall verify the contents and replace the medications as necessary.

(d) Monitoring medication therapy to promote positive patient outcomes while evaluating clinically significant chemical and therapeutic incompatibilities.

(e) Establishing the specifications for the procurement of all pharmaceuticals and related biologicals and chemicals approved for use in the medical institution.

(f) Periodically inspecting all areas in the medical institution where medications are stored to verify compliance with the standards for the safe use and storage of the medications.

(g) Maintaining proper security for all medications stored or kept within the medical institution.

(h) Providing educational programs regarding medications and their safe use.

(i) Providing a method by which medications can be obtained during the absence of a pharmacist in a medical institution where a pharmacist is not available 24 hours a day. The method shall minimize the potential for medication error. During the absence of a pharmacist, the services of a pharmacist shall be available on an on-call basis. Only a limited number of medications that are packaged in units of use shall be available. The medications shall be approved and reviewed periodically as deemed necessary, but not less than once a year, by an appropriate interdisciplinary practitioner committee of the medical institution. The medication shall be kept in a securely locked, substantially constructed cabinet or its equivalent in an area of limited access in a centralized area outside the pharmacy. Each medication shall be labeled to include the name of the medication, the strength, the expiration date, if dated, and the lot number. A written order and a proof of removal and use document shall be obtained for each medication united removed. The order and document shall be reviewed by the pharmacist within 48 hours of removing medication from the cabinet or its equivalent. The pharmacist who directs pharmacy services in the medical institution shall designate the practitioners who are permitted to remove the medication. A pharmacist shall audit the storage locations as often as needed to guarantee control, but not less than once every 30 days.

(5) Upon recommendation of an interdisciplinary practitioners committee, the pharmacist who directs pharmacy services in the medical institution shall adopt written policies and procedures to promote safe medication practices, to conduct medication utilization review, to approve medications for the medical institution's formulary or medication list, and to promote positive patient outcomes. A pharmacist shall meet with the committee at least quarterly to conduct assigned responsibilities.

(6) A pharmacy shall ensure that every medication dispensed is identified with its name and strength labeled on the container in which it is dispensed or on each single unit package. A pharmacy that is engaged in drug distribution to medical institutions which use unit-of-use packaging shall place identification on the label of its package to allow the package to be readily traced. The name of the patient and any identifying number shall be labeled on the medication container. The container may be the individual patients' assigned medication drawer. The directions for use shall be on the label of the container if the directions are not communicated in another effective manner. If the medication is to be self-administered, then directions for use shall be on the container. The preceding provisions of this subrule are minimum labeling standards only and do not supersede other applicable laws or rules.

(7) A pharmacist shall personally supervise the destruction of unused portions of prescription medication, other than controlled substances under part 71 of the code, dispensed to patients. However, medications in single- unit packages and intravenous solutions which are designed to be tamper-evident and which show no evidence that tampering has occurred may be returned to stock. Medications that leave the medical institution or its legal affiliates may not be returned to stock for redispensing.

(8) The licensed pharmacist who directs pharmacy services in the medical institution shall make the policies, procedures, and written reports required by this rule available to the board of pharmacy, upon request.

History: 1979 AC; 1980 AACS; 1998-2000 AACS.

R 338.487 Rescinded.

History: 1979 AC.

2011 Minnesota Statutes

Resources

Topics

Chemically Dependent Persons
Crimes
Drugs and Medicine
Food and Drug Administration (u.s.)
Fraud
Gases
Health and Accident Insurance
Legislative Committees
Mental Illness, Persons with
Pharmacists and Pharmacies
Pharmacy Board
Sales
Suicide
United States Pharmacopeia and National Formulary

Recent History

2010 Subd. 1 Amended 2010 c 289 s 1
2007 Subd. 1 Amended 2007 c 123 s 124
1997 Subd. 1 Amended 1997 c 132 s 2
2003 Subd. 5 New 2003 c 66 s 8

151.06 POWERS AND DUTIES.

Subdivision 1.**Generally; rules.**

(a) Powers and duties. The Board of Pharmacy shall have the power and it shall be its duty:

(1) to regulate the practice of pharmacy;

(2) to regulate the manufacture, wholesale, and retail sale of drugs within this state;

(3) to regulate the identity, labeling, purity, and quality of all drugs and medicines dispensed in this state, using the United States Pharmacopeia and the National Formulary, or any revisions thereof, or standards adopted under the federal act as the standard;

(4) to enter and inspect by its authorized representative any and all places where drugs, medicines, medical gases, or veterinary drugs or devices are sold, vended, given away, compounded, dispensed, manufactured, wholesaled, or held; it may secure samples or specimens of any drugs, medicines, medical gases, or veterinary drugs or devices after paying or offering to pay for such sample; it shall be entitled to inspect and make copies of any and all records of shipment, purchase, manufacture, quality control, and sale of

these items provided, however, that such inspection shall not extend to financial data, sales data, or pricing data;

(5) to examine and license as pharmacists all applicants whom it shall deem qualified to be such;

(6) to license wholesale drug distributors;

(7) to deny, suspend, revoke, or refuse to renew any registration or license required under this chapter, to any applicant or registrant or licensee upon any of the following grounds:

(i) fraud or deception in connection with the securing of such license or registration;

(ii) in the case of a pharmacist, conviction in any court of a felony;

(iii) in the case of a pharmacist, conviction in any court of an offense involving moral turpitude;

(iv) habitual indulgence in the use of narcotics, stimulants, or depressant drugs; or habitual indulgence in intoxicating liquors in a manner which could cause conduct endangering public health;

(v) unprofessional conduct or conduct endangering public health;

(vi) gross immorality;

(vii) employing, assisting, or enabling in any manner an unlicensed person to practice pharmacy;

(viii) conviction of theft of drugs, or the unauthorized use, possession, or sale thereof;

(ix) violation of any of the provisions of this chapter or any of the rules of the State Board of Pharmacy;

(x) in the case of a pharmacy license, operation of such pharmacy without a pharmacist present and on duty;

(xi) in the case of a pharmacist, physical or mental disability which could cause incompetency in the practice of pharmacy;

(xii) in the case of a pharmacist, the suspension or revocation of a license to practice pharmacy in another state; or

(xiii) in the case of a pharmacist, aiding suicide or aiding attempted suicide in violation of section 609.215 as established by any of the following:

(A) a copy of the record of criminal conviction or plea of guilty for a felony in violation of section 609.215, subdivision 1 or 2;

(B) a copy of the record of a judgment of contempt of court for violating an injunction issued under section 609.215, subdivision 4;

(C) a copy of the record of a judgment assessing damages under section 609.215, subdivision 5; or

(D) a finding by the board that the person violated section 609.215, subdivision 1 or 2. The board shall investigate any complaint of a violation of section 609.215, subdivision 1 or 2;

(8) to employ necessary assistants and adopt rules for the conduct of its business;

(9) to register as pharmacy technicians all applicants who the board determines are qualified to carry out the duties of a pharmacy technician; and

(10) to perform such other duties and exercise such other powers as the provisions of the act may require.

(b) Temporary suspension. In addition to any other remedy provided by law, the board may, without a hearing, temporarily suspend a license for not more than 60 days if the board finds that a pharmacist has violated a statute or rule that the board is empowered to enforce and continued practice by the pharmacist would create an imminent risk of harm to others. The suspension shall take effect upon written notice to the pharmacist, specifying the statute or rule violated. At the time it issues the suspension notice, the board shall schedule a disciplinary hearing to be held under the Administrative Procedure Act. The pharmacist shall be provided with at least 20 days' notice of any hearing held under this subdivision.

(c) Rules. For the purposes aforesaid, it shall be the duty of the board to make and publish uniform rules not inconsistent herewith for carrying out and enforcing the provisions of this chapter. The board shall adopt rules regarding prospective drug utilization review and patient counseling by pharmacists. A pharmacist in the exercise of the pharmacist's professional judgment, upon the presentation of a new prescription by a patient or the patient's caregiver or agent, shall perform the prospective drug utilization review required by rules issued under this subdivision.

(d) Substitution; rules. If the United States Food and Drug Administration (FDA) determines that the substitution of drugs used for the treatment of epilepsy or seizures poses a health risk to patients, the board shall adopt rules in accordance with accompanying FDA interchangeability standards regarding the use of substitution for these drugs. If the board adopts a rule regarding the substitution of drugs used for the treatment of epilepsy or seizures that conflicts with the substitution requirements of section 151.21, subdivision 3, the rule shall supersede the conflicting statute. If the rule proposed by the board would increase state costs for state public health care programs, the board shall report to the chairs and ranking minority members of the senate Health and Human Services Budget Division and the house of representatives Health Care and Human Services Finance Division the proposed rule and the increased cost associated with the proposed rule before the board may adopt the rule.

Subd. 1a.**Disciplinary action.**

It shall be grounds for disciplinary action by the Board of Pharmacy against the registration of the pharmacy if the Board of Pharmacy determines that any person with supervisory responsibilities at the pharmacy sets policies that prevent a licensed pharmacist from providing drug utilization review and patient counseling as required by rules adopted under subdivision 1. The Board of Pharmacy shall follow the requirements of chapter 14 in any disciplinary actions taken under this section.

Subd. 2.**Application.**

The provisions of subdivision 1 shall apply to an individual owner or sole proprietor and shall also apply to the following:

(1) In the case of a partnership, each partner thereof;

(2) In the case of an association, each member thereof;

(3) In the case of a corporation, each officer or director thereof and each shareholder owning 30 percent or more of the voting stock of such corporation.

Subd. 2a.

[Repealed, 1988 c 550 s 20]

Subd. 3.**Application of Administrative Procedure Act.**

The board shall comply with the provisions of chapter 14, before it fails to issue, renew, suspends, or revokes any license or registration issued under this chapter.

Subd. 4.**Reinstatement.**

Any license or registration which has been suspended or revoked may be reinstated by the board provided the holder thereof shall pay all costs of the proceedings resulting in the suspension or revocation, and, in addition thereto, pay a fee set by the board.

Subd. 5.**Costs; penalties.**

The board may impose a civil penalty not exceeding $10,000 for each separate violation, the amount of the civil penalty to be fixed so as to deprive a licensee or registrant of any economic advantage gained by reason of the violation, to discourage similar violations by the licensee or registrant or any other licensee or registrant, or to reimburse the board for the cost of the investigation and proceeding, including, but not limited to, fees paid for services provided by the Office of Administrative Hearings, legal and investigative services provided by the Office of the Attorney General, court reporters, witnesses, reproduction of records, board members' per diem compensation, board staff time, and travel costs and expenses incurred by board staff and board members.

History:

(5808-6) 1937 c 354 s 6; 1941 c 78 s 1; 1955 c 847 s 16; 1969 c 933 s 8; 1973 c 722 s 2; 1975 c 136 s 30; 1976 c 222 s 81,82; 1982 c 424 s 130; 1985 c 248 s 70; 1988 c 550 s

7; 1990 c 526 s 3; 1990 c 568 art 2 s 18; 1992 c 513 art 7 s 10,11; 1992 c 577 s 5; 1997 c 132 s 2; 2003 c 66 s 8; 2007 c 123 s 124; 2010 c 289 s 1

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Minnesota Administrative Rules

CHAPTER 6800, Pharmacies and Pharmacists

Board of Pharmacy

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OPERATIONS IN HOSPITALS

6800.7100 DEFINITIONS.

Subpart 1. **Credentialed.** "Credentialed" means registered with, certified by, or similarly recognized by a health-related agency or department of the state of Minnesota.

Subp. 2. **Drug administration.** "Drug administration" means to deliver by or pursuant to the lawful order of a licensed practitioner a single dose of a drug to a patient by injection, inhalation, ingestion, or by any other immediate means and shall include:

A. preparing the individual dose from a previously dispensed, properly labeled container;

B. verifying the dose as prescribed;

C. giving the individual dose by the proper route to the correct patient at the proper time;

D. assuring that the dose is taken; and

E. promptly recording the time and dose given.

Subp. 3. **Drug dispensing.** "Drug dispensing" means to deliver one or more doses of a drug for subsequent administration to, or use by a patient or human research subject. Such drug dispensing shall be performed by the pharmacist in compliance with part 6800.3100 or 6800.3750, subparts 2 to 10, with delivery being made in a suitable container properly labeled.

Subp. 4. **Pharmaceutical service.** "Pharmaceutical service" means the control of the utilization of drugs, biologicals, and chemicals including procuring, manufacturing, compounding, dispensing, distribution, and storing of drugs, biologicals, and chemicals under the conditions prescribed by this part. The provision of drug information and related pharmaceutical care services to patients and to other health professionals is included within the meaning of pharmaceutical services.

Subp. 5. **Supervision.** "Supervision," as used in connection with parts 6800.7100 to 6800.7950, means stationed within the same work area, coupled with the ability to control and responsibility for an action.

Statutory Authority: *MS s 151.06*

History: *9 SR 1656; 18 SR 1145*

Posted: *September 21, 2011*

6800.7200 SCOPE.

The provisions of parts 6800.7100 to 6800.7950 are applicable to pharmaceutical services provided to patients in hospitals, including state hospitals, provided, however, that parts 6800.0100 to 6800.5600 and 6800.8100 to 6800.9700 shall also be applicable to such pharmaceutical services, unless specifically exempted by parts 6800.7100 to 6800.8100 or unless in direct conflict therewith, in which case parts 6800.7100 to 6800.8100 shall apply.

Statutory Authority: *MS s 151.06*

Posted: *September 21, 2011*

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6800.7300 PHARMACISTS AND SUPPORT PERSONNEL.

Pharmaceutical services in hospitals shall be organized and directed by a pharmacist. Pharmaceutical services shall be provided only by pharmacists and other personnel under a pharmacist's supervision. The use of supportive personnel shall be in accordance with the provisions of part 6800.3850.

Statutory Authority: *MS s 151.06*

History: *9 SR 1656*

Posted: *September 21, 2011*

6800.7400 HOSPITAL PHARMACIST-IN-CHARGE.

Subpart 1. **Qualifications.** The pharmacist-in-charge, regardless of title or designation, shall be a pharmacist licensed in this state.

Subp. 2. **On-site pharmacies.** A pharmacist providing pharmaceutical services to a hospital maintaining an on-site pharmacy shall be engaged by the hospital and shall provide at least part-time, five-day-per-week services.

Subp. 3. **Drug room.** A pharmacist providing pharmaceutical services from off-site to a hospital maintaining a drug room shall schedule on-premises visits on at least a weekly basis.

Subp. 4. **Responsibilities.** The responsibilities and duties of the hospital pharmacist-in-charge include at least the following specific duties in addition to the duties of the pharmacist-in-charge found in part 6800.2400:

A. the procurement, identification, security, storage, and distribution of all drugs, as well as the disposition of drugs whose effectiveness has expired or which, for other reasons, are deemed no longer usable;

B. the development, implementation, coordination, supervision, and review of pharmaceutical services in the hospital and policies related thereto;

C. the supervision of the preparation and sterilization of parenteral drugs in the hospital;

D. the supervision of bulk compounding of pharmaceuticals;

E. the establishment of specifications for procurement of drugs and chemicals for direct patient use;

F. the development of a hospital formulary system;

G. the dispensing of drugs and chemicals for direct patient use;

H. the maintaining of a stock of antidotes and emergency drugs in the hospital;

I. the maintaining of pharmaceutical service records; and

J. cooperating in the teaching and research programs of the hospital.

Subp. 5. **Span of control.** The pharmacist's span of supervision shall extend to all areas of the hospital where drugs are stored. No less than every month inspections of these areas shall be conducted and substantiated by records so as to verify at least proper drug storage, documentation of distribution and administration of controlled substances, absence of outdated drugs, and the integrity of the required emergency drug supply.

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Subp. 6. [Repealed, 18 SR 1145]

Statutory Authority: *MS s 151.06; 152.02*

History: *17 SR 1279; 18 SR 1145; 31 SR 1673*

Posted: *September 21, 2011*

HOSPITAL SERVICE POLICIES

6800.7510 PATIENT CARE.

Pharmaceutical service policies shall cover at least the following:

A. the providing of drug information to patients and health professionals;

B. the limiting of drug administration;

C. an ongoing proactive program to identify risks to patient safety and reducing errors;

D. the immediate reporting of adverse drug reactions;

E. the self-administration of drugs by patients;

F. the use of drugs brought into the hospital by or with the patient. If the drugs are not to be used while the patient is hospitalized, they shall be packaged, sealed, stored, and returned to the patient at the time of discharge;

G. the use of investigational drugs;

H. the preparation, use, and disposal of chemotherapy drugs;

I. the preparation of compounded sterile products; and

J. the preparation of compounded nonsterile products.

Statutory Authority: *MS s 151.06; 152.02*

History: *18 SR 1145; 31 SR 1673*

Posted: *September 21, 2011*

6800.7520 PHARMACEUTICAL SERVICE POLICIES.

Subpart 1. **Dispensing drugs.** Pharmaceutical service policies shall cover at least the following measures related to the control, accessibility, dispensing, and administration of drugs:

A. Developing, implementing, and maintaining a system assuring the availability of prescribed drugs at all times.

B. Dispensing of legend drugs.

C. Changing of labels or the transfer of drugs from one container to another.

D. Maintaining security and emergency access in accordance with part 6800.7530.

E. Supplying of prepackaged legend drugs which are accessible for use without entering either the pharmacy or drug room maintained for use when a pharmacist is not available. Such supply may be located in nursing units, with access limited to designated registered nurses. No hospital pharmacy shall utilize a floor stock drug distribution system of this or any other type as its primary system of drug delivery.

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F. Maintaining a supply of drugs for use in medical emergencies.

G. Specifying the maintenance of permissible supplies of nonprescription drugs in nursing service units.

H. Assuring that unused patient drugs, discontinued and outdated drugs, and containers with worn, illegible, or missing labels be returned to a pharmacist for disposition.

I. Maintaining a drug recall procedure which can be implemented no more than 24 hours after recall notification by the manufacturer.

J. Permitting the dispensing of drugs only pursuant to orders initiated by a licensed practitioner.

K. Assuring that orders for drugs are transmitted to the pharmacy by the prescriber or by an order format which produces a direct copy of the order as it is documented in the patient chart.

L. Providing for a system of accountability for inpatient dispensing meeting the intent of the certification requirement of part 6800.3100.

M. Establish a pharmacist monitoring system that reconciles a nurse prepared medication administration record (MAR) to the pharmacy profile.

N. Requiring authorization for a standing order to be noted on the patient's medical record. Standing orders shall specify the circumstances under which the drug is to be administered, the drug, dosage, route, frequency of administration, and duration.

O. Assuring that when drug therapy is not renewed on an established regular basis the therapy is limited either by the prescriber's specific indication or by automatic stop orders.

P. Assuring that precautionary measures, including quality control documentation, for the safe admixture of parenteral products are developed in writing. Admixture preparation shall be limited to pharmacists, pharmacist-interns, supportive personnel under the supervision of a pharmacist, licensed practitioners, and licensed nurses. Furthermore, sterile admixtures shall be labeled as required in part 6800.7900 and must be prepared as required in part 6800.3300, subpart 2.

Q. Assuring that investigational drug use is in accordance with state and federal law: basic information concerning the dosage form, route of administration, strength, actions, uses, side effects, adverse effects, interactions, and symptoms of toxicity of such drugs shall be available in the pharmacy (investigational drugs shall be distributed only from the pharmacy).

R. Assuring that the practice of drug reconstitution is performed only by pharmacists, licensed practitioners, licensed nurses, or hospital-authorized personnel under the supervision of licensed pharmacists, licensed practitioners, or licensed nurses.

S. Developing, implementing, and maintaining a system of controlled substance and narcotic control in accordance with subitems (1) to (7).

(1) Controlled substances must be accounted for by either:

(a) a "proof-of-use" sign-out sheet where each dose given is accounted for by the licensed health care professional who procures the drug. No controlled substance may be kept on floor stock unless it is accompanied by the sign-out sheet and each dose is documented by the licensed health care professional at the time the drug is procured from the stock. The proof-of-use sheets must include at least the date and time, the patient's name, the dose administered, and the licensed health care professional's signature;

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(b) the dispensing of the drug to a specific patient after the pharmacy receives an individual drug order; or

(c) a computer system which utilizes electronic distribution records of controlled substance transactions as long as the system complies with the following requirements:

i. allows for retrieval of all information required by this regulation for all distribution and dispensing transactions for two years;

ii. provides for at least weekly transaction printouts, except that this requirement does not have to be met if a secure daily 24-hour backup is performed which allows for restoration of required information in case of a system failure;

iii. maintains a complete online transaction file that is printable on request, or have a "lock-out" feature that prevents editing of distribution or dispensing information;

iv. allows for the printing of a report of all distribution and dispensing transactions for a minimum of two years. The system must be capable of retrieving and printing a report listing variables which include, but are not limited to: the identity of a user accessing the system; the date and time controlled substances are distributed to or removed from the automated distribution machine; the quantity of a controlled substance distributed to or removed from the automated distribution machine; drug name, strength, and dosage form; patient name; and practitioner name.

(2) Wasting of doses must be carried out by two licensed individuals who are authorized to have access to controlled substances. The wasting of doses must be documented, with the accuracy of the documentation being certified by the licensed individuals who carried out the wasting. Certification must include the signature or other unique identifier of the licensed individuals who carried out the wasting.

(3) There must be a system for reconciling the proof-of-use sheets in the pharmacy to assure accountability of all sheets sent to the various nursing stations.

(4) Controlled substances must be stored under lock on the nursing stations or other patient care area.

(5) Access to the main supply of Schedule II controlled substances in the pharmacy must be restricted to a limited number of persons in the pharmacy. The main supply of Schedule II controlled substances in the pharmacy must be kept locked when not being used.

(6) Single unit-of-use dosage forms should be used when possible.

(7) A perpetual inventory of Class II controlled substances must be accurately maintained.

T. Developing policies for the issuance of medications to patients who are going on leave from the facility. These policies may allow the preparation, by the facility's registered nurses responsible for overseeing medication administration, of a supply of medications, not to exceed a 72-hour supply, in paper envelopes or other more suitable containers for use by a patient temporarily leaving the facility at times when the facility's pharmacy is closed or cannot supply the needed medication in a timely manner. A container may hold only one medication. A label on the container shall include the date, the patient's name, the facility, the name of the medication, its strength, dose, and time of administration, and the initials of the person preparing the medication and label.

Subp. 2. **Maintenance of documents.** Pharmaceutical service policies shall cover at least the following measures related to the maintenance of documents.

A. The pharmacist-in-charge shall maintain at least the following written documents:

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(1) a statement of service philosophy and objectives;

(2) a job description for each classification of personnel;

(3) a list of pharmaceutical service committees, and other hospital committees on which the pharmaceutical service is represented, with minutes of proceedings and attendance records;

(4) procurement records for controlled substances for two years or as required by law;

(5) prescriptions or other forms initiated by the prescriber, for two years or as required by law;

(6) records of packaging, bulk compounding, or manufacturing for two years or as required by law;

(7) records of action taken pursuant to drug recalls for two years or as required by law;

(8) special reports concerning narcotics and other drugs for two years or as required by law;

(9) records of pharmacist's inspections of drug supplies maintained outside the pharmacy or drug room, as permitted under subpart 1, items E and F, for two years; and

(10) records of withdrawals by nonpharmacists of prepackaged drugs from the pharmacy or drug room, as permitted under subpart 1, item D and part 6800.7530, for two years.

B. The following documents relative to pharmaceutical services shall also be maintained:

(1) a current organization chart delineating intraservice structure and lines of authority, and describing the pharmaceutical service's relationship to the administration, organized medical staff, and other relevant hospital services;

(2) a list of all licensed and/or credentialed personnel, with verification of the present validity of those licenses or credentials;

(3) a record of the number of persons, by job description, employed full-time and part-time in the pharmaceutical services;

(4) copies of current staffing patterns and weekly work schedules for two years;

(5) receipted invoices for drugs, chemicals, and pharmaceutical service supplies purchased and received over the immediately preceding two years; and

(6) any agreement or contract between an off-premises pharmacy and the hospital.

Statutory Authority: *MS s 151.06; 152.02*

History: *18 SR 1145; 27 SR 260; 31 SR 1673; 36 SR 237*

Posted: *September 21, 2011*

6800.7530 MAINTAINING SECURITY AND EMERGENCY ACCESS.

Subpart 1. **Limited access.** Only a pharmacist may have access to the pharmacy except in the following situations and under the following conditions set forth in subparts 2 and 3.

Subp. 2. **Disaster.** In the case of disaster, the hospital administrator may allow access for purposes of emergency maintenance, disaster prevention and control, and patient safety.

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Subp. 3. **Emergencies.** For purposes of withdrawing limited doses of drugs for administration to inpatients in emergencies when the pharmacy is closed, a designated registered nurse may make emergency withdrawal of a dose required by a patient. Only a designated registered nurse in any given shift may have emergency access.

The person withdrawing from a bulk stock container the limited doses for administration shall leave in the pharmacy, on a form developed by the pharmacy, a record of the drugs withdrawn showing the patient's name, the name of the drug and dose prescribed, drug strength, the amount taken, the time and date, and the signature of nurse withdrawing drug.

The person withdrawing the drug from a bulk stock container or unit dose packaging bin shall place upon the record of withdrawal the container from which the limited doses were taken so that the withdrawal may be verified by the pharmacist.

Subp. 4. **Emergency access procedure.** The pharmacist-in-charge shall develop an emergency access procedure and may make provisions for prepackaged drugs for emergency withdrawal, provided the number of doses does not exceed the number usually required by a patient during the time the pharmacy is closed.

Statutory Authority: *MS s 151.06*

History: *18 SR 1145*

Posted: *September 21, 2011*

6800.7600 [Repealed, 23 SR 1597]

Posted: *September 21, 2011*

6800.7700 DRUG HANDLING AND STORAGE.

At least the following provisions for the safe handling and secure storing of drugs shall be observed. Storage areas shall be safeguarded by an effective security system, with the pharmacist responsible for maintaining security. Drugs shall be protected from contamination. Drugs shall be stored at temperatures recommended by the U.S.P./N.F. or by the individual drug label or package insert.

Statutory Authority: *MS s 151.06*

Posted: *September 21, 2011*

6800.7800 PHARMACEUTICAL SERVICE SPACE.

The pharmacy or drug room shall be surrounded by a continuous partition or wall extending from floor to ceiling. All doors and windows shall be securely locked when the pharmacy or drug room is closed, so as to prevent entry by unauthorized persons.

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When drugs are stored on nursing service units space shall be available at each unit for the storage, safeguarding, and preparation of medication doses, and shall include provision of at least the following:

A. A well-illuminated, locked drug cabinet or room shall be equipped with clearly labeled cubicles to ensure physical separation of individual patient prescribed medications. Medications may be stored in secured individual patient storage areas or secured portable storage carts providing separate compartments for individual patients.

B. A container or compartment that is capable of securing controlled substances with a lock or other safeguard system shall be permanently attached to storage carts or medication rooms.

Statutory Authority: *MS s 151.06*

Posted: *September 21, 2011*

6800.7900 PRESCRIPTION LABELING.

Subpart 1. **Outpatient prescriptions.** Labels for filled outpatient prescription drug orders shall comply with parts 6800.3400 and 6800.4150. Labels for outpatient nonprescription drugs shall comply with the federal regulations. Drugs originally dispensed to an inpatient shall be returned to the pharmacy for proper labeling before leaving the hospital premises.

Subp. 2. **Inpatient chart orders.** The containers of all drugs dispensed to inpatients on the basis of chart orders, other than those dispensed pursuant to part 6800.3750, shall be labeled with the following information:

A. name of patient;

B. name of drug;

C. route of administration of drug when necessary for clarification;

D. strength of drug;

E. auxiliary labels as needed;

F. expiration date, if applicable; and

G. date dispensed.

Subp. 3. **Drugs prepackaged for emergency use.** All drugs dispensed under part 6800.7520, subpart 1, item E shall be labeled with the following information:

A. identification of pharmacy or other source;

B. name of drug or list of ingredients;

C. strength of drug or amount of ingredients;

D. auxiliary labels as needed;

E. expiration date, if any;

F. usual dose; and

G. control number or date of issue.

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Subp. 4. **Supplemental label.** Whenever a drug is added to a parenteral solution, a distinctive supplemental label shall be firmly affixed to the container. The supplemental label should be placed to permit visual inspection of the infusion contents and to allow the name, type of solution, and lot number on the manufacturer's label to be read.

Subp. 5. **Intravenous admixtures.** Intravenous admixtures must be labeled with the following information:

A. name of solution and volume of solution;

B. patient's name;

C. bottle sequence number or other control number system, if appropriate;

D. name and quantity of each additive;

E. infusion or administration rate, if appropriate;

F. storage requirements if other than room temperature;

G. date and time of administration if appropriate;

H. beyond-use date; and

I. ancillary precaution labels.

Subp. 6. **Responsibility.** The hospital pharmacy service is responsible for ensuring proper labeling of all medications.

Statutory Authority: *MS s 151.06; 151.212*

History: *9 SR 1656; 18 SR 1145; 36 SR 237*

Posted: *September 21, 2011*

6800.7950 EXTENSION OF PHARMACY SERVICES UNDER LICENSE.

A licensed pharmacy in a hospital may utilize additional locations within the hospital in conformity with part 6800.0800, subpart 3, without the necessity of securing additional licenses provided, however, that the pharmacist-in-charge of the hospital pharmacy informs the board of the location of each satellite and assumes professional responsibility, in accordance with parts 6800.2400 and 6800.3850, for the practice of pharmacy and for staffing in each additional location.

Statutory Authority: *MS s 151.06*

History: *18 SR 1145*

Posted: *September 21, 2011*

OPERATION OF PARENTERAL-ENTERAL/HOME HEALTH CARE PHARMACIES

6800.8000 SCOPE AND PURPOSE.

The purpose of parts 6800.8000 to 6800.8008 is to provide standards for the preparation, labeling, and distribution of sterile products by licensed home health care pharmacies pursuant to a prescription drug order. The standards are intended to apply to sterile products compounded by the pharmacist, notwithstanding the location of the patient, such as a private home, nursing home, hospice, or doctor's office.

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Miss. Code Ann. § 73-21-73

MISSISSIPPI CODE of 1972

*** Current through the 2011 Regular Session and 1st Extraordinary Session ***

TITLE 73. PROFESSIONS AND VOCATIONS
CHAPTER 21. PHARMACISTS
MISSISSIPPI PHARMACY PRACTICE ACT

Miss. Code Ann. § 73-21-73 (2011)

§ 73-21-73. Definitions [Repealed effective July 1, 2016]

As used in this chapter, unless the context requires otherwise:

(a) "Administer" means the direct application of a prescription drug pursuant to a lawful order of a practitioner to the body of a patient by injection, inhalation, ingestion or any other means.

(b) "Board of Pharmacy," "Pharmacy Board," "MSBP" or "board" means the State Board of Pharmacy.

(c) "Compounding" means (i) the production, preparation, propagation, conversion or processing of a sterile or nonsterile drug or device either directly or indirectly by extraction from substances of natural origin or independently by means of chemical or biological synthesis or from bulk chemicals or the preparation, mixing, measuring, assembling, packaging or labeling of a drug or device as a result of a practitioner's prescription drug order or initiative based on the practitioner/patient/pharmacist relationship in the course of professional practice, or (ii) for the purpose of, as an incident to, research, teaching or chemical analysis and not for sale or dispensing. Compounding also includes the preparation of drugs or devices in anticipation of prescription drug orders based on routine regularly observed prescribing patterns.

(d) "Continuing education unit" means ten (10) clock hours of study or other such activity as may be approved by the board, including, but not limited to, all programs which have been approved by the American Council on Pharmaceutical Education.

(e) "Deliver" or "delivery" means the actual, constructive or attempted transfer in any manner of a drug or device from one person to another, whether or not for a consideration, including, but not limited to, delivery by mailing or shipping.

(f) "Device" means an instrument, apparatus, implement, machine, contrivance, implant, in

(v) "Nonprescription drugs" means nonnarcotic medicines or drugs that may be sold without a prescription and are prepackaged and labeled for use by the consumer in accordance with the requirements of the statutes and regulations of this state and the federal government.

(w) "Person" means an individual, corporation, partnership, association or any other legal entity.

(x) "Pharmacist" means an individual health care provider licensed by this state to engage in the practice of pharmacy. This recognizes a pharmacist as a learned professional who is authorized to provide patient services.

(y) "Pharmacy" means any location for which a pharmacy permit is required and in which prescription drugs are maintained, compounded and dispensed for patients by a pharmacist. This definition includes any location where pharmacy-related services are provided by a pharmacist.

(z) "Prepackaging" means the act of placing small precounted quantities of drug products in containers suitable for dispensing or administering in anticipation of prescriptions or orders.

(aa) Unlawful or unauthorized "possession" means physical holding or control by a pharmacist of a controlled substance outside the usual and lawful course of employment.

(bb) "Practice of pharmacy" means a health care service that includes, but is not limited to, the compounding, dispensing, and labeling of drugs or devices; interpreting and evaluating prescriptions; administering and distributing drugs and devices; the compounding, dispensing and labeling of drugs and devices; maintaining prescription drug records; advising and consulting concerning therapeutic values, content, hazards and uses of drugs and devices; initiating or modifying of drug therapy in accordance with written guidelines or protocols previously established and approved by the board; selecting drugs; participating in drug utilization reviews; storing prescription drugs and devices; ordering lab work in accordance with written guidelines or protocols as defined by paragraph (ll) of this section; providing pharmacotherapeutic consultations; supervising supportive personnel and such other acts, services, operations or transactions necessary or incidental to the conduct of the foregoing.

(cc) "Practitioner" means a physician, dentist, veterinarian, or other health care provider authorized by law to diagnose and prescribe drugs.

(dd) "Prescription" means a written, verbal or electronically transmitted order issued by a practitioner for a drug or device to be dispensed for a patient by a pharmacist.

(ee) "Prescription drug" or "legend drug" means a drug which is required under federal law to

Miss. Code Ann. § 73-21-105

MISSISSIPPI CODE of 1972

*** Current through the 2011 Regular Session and 1st Extraordinary Session ***

TITLE 73. PROFESSIONS AND VOCATIONS
CHAPTER 21. PHARMACISTS
MISSISSIPPI PHARMACY PRACTICE ACT

Miss. Code Ann. § 73-21-105 (2011)

§ 73-21-105. Registration of businesses where prescription drugs or devices are dispensed, sold, repackaged, manufactured, etc.; registration of reverse distributors; establishment of criteria; procedures and fees; applications; standards for operation; reports of changes of circumstances; penalties for violations; exemption of physicians, dentists, etc., from chapter [Repealed effective July 1, 2016]

(1) Every facility/business that engages in the wholesale distribution of prescription drugs, to include without limitation, manufacturing in this state, distribution into this state, or selling or offering to sell in this state, or distribution from or within this state, and every reverse distributor located in or outside of this state that conducts business with pharmacies in this state, shall register biennially with the Mississippi State Board of Pharmacy by applying for a permit on a form supplied by the board and accompanied by a fee as set by subsection (4) of this section. The Pharmacy Board shall by regulation determine the classification of permit(s) that shall be required.

(2) Every business/facility/pharmacy located in this state that engages in or proposes to engage in the dispensing and delivery of prescription drugs to consumers shall register with the Mississippi State Board of Pharmacy by applying for a permit on a form supplied by the board and accompanied by a fee as set by subsection (4) of this section. The Pharmacy Board shall by regulation determine the classification of permit(s) that shall be required.

(3) The board shall establish by rule or regulation the criteria which each business shall meet to qualify for a permit in each classification. The board shall issue a permit to any applicant who meets the criteria as established. The board may issue various types of permits with varying restrictions to businesses where the board deems it necessary by reason of the type of activities conducted by the business requesting a permit.

(4) The board shall specify by rule or regulation the registration procedures to be followed, including, but not limited to, specification of forms for use in applying for such permits and times, places and fees for filing such applications. However, the biennial fee for an original or renewal permit shall not exceed Five Hundred Dollars ($ 500.00).

(5) Applications for permits shall include the following information about the proposed business:

(a) Ownership;

(b) Location;

(c) Identity of the responsible person or pharmacist licensed to practice in the state, who shall be the pharmacist in charge of the pharmacy, where one is required by this chapter, and such further information as the board may deem necessary.

(6) Permits issued by the board pursuant to this section shall not be transferable or assignable.

(7) The board shall specify by rule or regulation minimum standards for the responsibility in the conduct of any business/facility and/or pharmacy that has been issued a permit. The board is specifically authorized to require that the portion of the facility located in this state to which a pharmacy permit applies be operated only under the direct supervision of no less than one (1) pharmacist licensed to practice in this state, and to provide such other special requirements as deemed necessary. Nothing in this subsection shall be construed to prevent any person from owning a pharmacy.

(8) All businesses permitted by the board shall report to the board the occurrence of any of the following changes:

(a) Permanent closing;

(b) Change of ownership, management, location or pharmacist in charge;

(c) Any and all other matters and occurrences as the board may require by rule or regulation.

(9) Disasters, accidents and emergencies which may affect the strength, purity or labeling of drugs, medications, devices or other materials used in the diagnosis or the treatment of injury, illness and disease shall be immediately reported to the board.

(10) No business that is required to obtain a permit shall be operated until a permit has been issued for such business by the board. Any person, firm or corporation violating any of the provisions of this section shall be guilty of a misdemeanor and, upon conviction thereof, shall be punished by a fine of not less than One Hundred Dollars ($ 100.00) nor more than One Thousand Dollars ($ 1,000.00), or imprisonment in the county jail for not less than thirty (30) days nor more than ninety (90) days, or by both such fine and imprisonment. However, the provisions of this chapter shall not apply to physicians, dentists, veterinarians, osteopaths or other practitioners of the healing arts who are licensed under the laws of the State of Mississippi and are authorized to dispense and administer prescription drugs in the course of their professional practice.

HISTORY: SOURCES: Laws, 1983, ch. 414, § 18; Laws, 1991, ch. 527, § 18; Laws, 1993, ch. 416, § 19; Laws, 1994, ch. 513, § 8; reenacted without change, Laws, 1998, ch. 511, § 19; reenacted without change, Laws, 2002, ch. 501, § 19; reenacted without change, Laws, 2006, ch.

533, § 19; Laws, 2008, ch. 512, § 3; Laws, 2010, ch. 555, § 1; reenacted without change, Laws, 2011, ch. 546, § 17, eff from and after passage (approved Apr. 26, 2011.)

MISSISSIPPI PHARMACY PRACTICE REGULATIONS

Mississippi Board of Pharmacy
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Effective January 31, 2011

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ARTICLE XXX INSTITUTIONAL/LONG TERM CARE FACILITIES (LTCF)

A. CONSULTING PHARMACISTS TO INSTITUTIONAL (LTC) FACILITIES

1. Unless specifically authorized by the Board to do so, no person shall serve as a consultant pharmacist or act or purport to act in this capacity to any institutional facility unless he/she possesses the following qualifications:
   A. Have and maintain a license to practice pharmacy within the State of Mississippi;
   B. Have attended within the last two years a training course of not less than eight (8) hours in institutional pharmacy services that has been approved by the Board of Pharmacy;
   C. In order to be approved by the Board of Pharmacy, the training course for a consultant pharmacist to an institutional facility shall provide instruction in the areas of clinical pharmacy services, drug distribution systems and state and federal pharmacy regulations governing the practice of institutional pharmacy.

2. For purposes of this ARTICLE, a Consultant Pharmacist shall mean a Mississippi licensed pharmacist who is responsible for developing, coordinating and supervising pharmaceutical services on a regularly scheduled basis in an institutional facility, as well as the following responsibilities.

   A. Reviewing policies and procedures regarding the distribution and storage of medications within the facility and as necessary making recommendations to the facility and provider pharmacist;
   B. Monitoring utilization and therapeutic response of medications prescribed for and administered to residents of the facility as well as providing consultation on matters related to medications;
   C. Serving as a resource for pharmacy related educational services within the facility;
   D. Communication and discussion with the provider pharmacist regarding areas of concern and resolution thereof;
   E. Serving on appropriate committees;
   F. Supervising and assisting in the disposal of all discontinued, expired, or otherwise un-needed controlled substance medications;
   G. Reviewing records of the destruction of all medications and verification of the reasons for destruction;
   H. Ensuring that complete and accurate records of the acquisition and disposition of controlled substance medications which have been dispensed for residents of the institutional facility are maintained;
   I. Attending, within the last two (2) years, a consultant pharmacist seminar which has been approved by the Board;
   J. Maintain consultant pharmacist eligibility as described in Section 1.

3. A Long Term Care Facility which is permitted by the Board and where the services of a consultant pharmacist are required shall have the following responsibilities:
   A. Policy Manual. The institution shall develop policies and procedures regarding

pharmacy services which includes, but is not limited to, proper labeling of patient medications and emergency drugs, security of patient medications and emergency drugs, administration and controlled substances record-keeping and accountability. This procedural manual shall be the responsibility of the institution and is to be promulgated with the concurrence of the consultant pharmacist, nursing home administrator and the directors of medical and nursing services.

B. Reference. Reference materials shall be located in the nursing stations(s) and contain current editions of appropriate reference materials as may be deemed necessary by the consultant pharmacist and the medical and nursing directors.

C. Reporting. The institution shall establish policies and procedures which assures that all medication errors and adverse drug reactions are reported immediately to the patient's physician and the consultant pharmacist and an entry made in the patient's record. These procedures should assure that corrective measures are implemented. The consultant pharmacist should be notified within twenty-four (24) hours of discovery of any discrepancy in counts or of a loss of any controlled substances. The consultant pharmacist should notify the Board immediately upon his/her notification with a plan to investigate the loss.

D. Emergency Medication Kits. The institution shall establish policies and procedures which assure that the institution is in compliance with ARTICLE XXXV INSTITUTIONAL EMERGENCY MEDICATION KIT PERMITS of these Pharmacy Practice Regulations.

E. Disposal of Patient Medication. The Long Term Care Facility, with the assistance of the consultant pharmacist shall establish policies and procedures which assures the proper disposal of any discontinued, expired, or otherwise unwanted patient medications. Policies and procedures should ensure that any medication removed subject to destruction, does not have a current valid order for the medication on the patient's medication profile. Policies and Procedures for disposal of these medications should include as follows:

(1) All unwanted patient medications should remain in a secured location at the institution until proper disposal is made;

(2) Documentation of any disposal of patient medications should include a paper trail from the time the medication was logged into the discontinued drug storage area until destruction is made. This paper trail shall include a log containing the patient name, medication and strength, and quantity to be destroyed as well as the initials of the person logging in the medication for destruction. This documentation should be stored at the institution and be readily retrievable for inspection by Board Agents for a period of two (2) years;

(3) Discontinued and unwanted patient medications should be destroyed on a timely basis not to exceed ninety (90) days from the date that the medication was discontinued. Any such destruction should be performed by two licensed personnel and documented by their signatures.

4. A consultant pharmacist shall document communication of the findings of his/her reviews to the attending physician and director of nursing along with their response and maintain these records for a period of two (2) years. A copy of these reviews must be maintained at the facility and available for inspection.

B. UNIT DOSE DISPENSING SYSTEMS FOR (LTCF)

Definitions:

For the purpose of this ARTICLE XXX, the following definitions apply:

(1) "Provider pharmacist, means a pharmacist licensed to practice pharmacy by the Board who is responsible for supervising the accurate dispensing and proper delivery of medications to a (LTCF) located within this state. These services shall include, at a minimum, proper medication labeling, storage, transport, record keeping, and prospective drug utilization review in compliance with all federal, state and local laws and regulations.
(2) "Provider Pharmacy" means any pharmacy permitted by the Board where medications are dispensed to residents of a long term care facility located in this state.
(3) "Single unit dose package" is a package, which contains one discrete pharmaceutical medication dosage form.
(4) "Unit dose dispensing systems" are those drug medication distribution systems determined by the Board, which involve single unit, unit dose or unit of issue packaging in a manner which helps reduce or remove traditional drug stocks from patient care areas and enables the selection and distribution of medications to be provider pharmacy based and controlled. A unit dose dispensing system shall preserve the identity and the integrity of the medication until the time of administration.
(5) "Unit dose package" is a package, which contains that particular dose of a medication ordered for the patient for one administration time. A unit dose package is not always a single unit dose package.
(6) "Unit of issue package" is a medication package issued by a provider pharmacy, which provides multiple units/dosages of medications attached to each other but separated in a card or a specifically designed container.

1. Packaging for all non-sterile medications stored and dispensed in single unit dose, unit dose or unit of issue packages for use in (LTCF) other than hospitals shall:
   A. Preserve and protect the identity and integrity of the drug medication from the point of packaging to the point of patient administration;
   B. When packaged by the manufacturer or distributor, be in compliance with Federal Food and Drug Administration guidelines;
   C. Shall be in containers clean and free of extraneous matter when the dosage unit(s) are placed into the package;
   D. Utilize containers, which are classified according to USP Standard 671 as being Class A or Class B for oral solid dosage forms or is a tight container for liquid dosage forms.

2. Labeling for single unit dose or unit dose packaging shall comply with the following;
   A. Single unit doses or unit doses packaged by the manufacturer or distributor shall be

properly labeled according to Federal Food and Drug Administration requirements;

B. Single unit doses or unit doses packaged by the provider pharmacy shall be properly labeled according to ARTICLE XXIX paragraph 7.

C. Labeling for unit of issue packages shall contain the following information: Name and room or bed number of patient, name of prescribing practitioner, name and strength of drug, directions for use, and the name and address of the provider pharmacy when a unit of issue package is utilized for patients in an (LTCF) setting.

3. If a pharmacist selects a generically equivalent drug product for a brand name drug product prescribed by a practitioner, labeling must comply with ARTICLE X of the Pharmacy Practice Regulations of the Board.

4. Expiration dating for non-sterile medications dispensed and packaged into single unit doses, unit doses, and unit of issue packages shall meet the following conditions:
   A. Not exceed the manufacturer's original expiration date;
   B. Have an expiration date assigned based on the unit dose container manufacturer's recommendations;
   C. May exceed Ninety (90) days from date of repackaging provided that the container is classified according to USP Standard 671 as being Class A or Class B for oral solid dose forms or is a tight container for liquid dosage forms, the container is light resistant when the manufacturer has labeled the drug product "sensitive to light", and the expiration date is not greater than twelve (12) months;
   D. Drugs or dosage forms having known stability problems are assigned an expiration date of less than ninety (90) days or are not repackaged as determined by policies developed by the provider pharmacy.

   The shortest time span of any of the listed conditions shall be the expiration date assigned to the medication.

C. RETURN OF MEDICATIONS FROM AN INSTITUTIONAL FACILITY TO THE PROVIDER PHARMACY

1. Medication that has been dispensed for a patient residing in an institutional facility may be returned to the provider pharmacy provided that the medication has an approved reason for return as follows:
   A. Medication was discontinued prior to delivery;
   B. Patient expired prior to medication being delivered;
   C. Patient in the hospital (discharge status) at time of delivery;
   D. Medication dosage changed prior to delivery;
   E. Patient has excessive medications remaining from previous cycle (requires written explanation by the Director of Nurses);
   F. Medication is considered to be dispensed when it leaves the dispensing pharmacy and is delivered to the institutional facility.

   Any such medication subject to return must be intact with no doses removed from blister package (unit dose). Medications, which have been dispensed and placed in

bulk packages and accepted by a responsible person at the LTCF, shall not be returned to the dispensing pharmacy for any reason. All medication subject to return, must be returned to the provider pharmacy by pharmacy personnel within five (5) days. No controlled substances may be returned.

The provider pharmacy must implement approved procedures, which ensure that any returned medication has been properly stored, has not been tampered with, and the integrity of the medication remains intact. Paper trails tracking these procedures must be maintained by the provider pharmacy for a period of two (2) years and be readily retrievable for inspection by agents of the Board.

Montana Code Annotated 2011

37-7-201. Organization -- powers and duties. (1) The board shall meet at least once a year to transact its business. The board shall annually elect from its members a president, vice president, and secretary.

(2) The board shall regulate the practice of pharmacy in this state, including but not limited to:

(a) establishing minimum standards for:

(i) equipment necessary in and for a pharmacy;

(ii) the purity and quality of drugs, devices, and other materials dispensed within the state through the practice of pharmacy, using an official compendium recognized by the board or current practical standards;

(iii) specifications for the facilities, environment, supplies, technical equipment, personnel, and procedures for the storage, compounding, or dispensing of drugs and devices;

(iv) monitoring drug therapy; and

(v) maintaining the integrity and confidentiality of prescription information and other confidential patient information;

(b) requesting the department to inspect, at reasonable times:

(i) places where drugs, medicines, chemicals, or poisons are sold, vended, given away, compounded, dispensed, or manufactured; and

(ii) the appropriate records and the license of any person engaged in the practice of pharmacy for the purpose of determining whether any laws governing the legal distribution of drugs or devices or the practice of pharmacy are being violated. The board shall cooperate with all agencies charged with the enforcement of the laws of the United States, other states, or this state relating to drugs, devices, and the practice of pharmacy. It is a misdemeanor for a person to refuse to permit or otherwise prevent the department from entering these places and making an inspection.

(c) regulating:

(i) the training, qualifications, employment, licensure, and practice of interns;

(ii) the training, qualifications, employment, and registration of pharmacy technicians; and

(iii) under therapeutic classification, the sale and labeling of drugs, devices, medicines, chemicals, and poisons;

(d) examining applicants and issuing and renewing licenses of:

(i) applicants whom the board considers qualified under this chapter to practice pharmacy;

(ii) pharmacies and certain stores under this chapter;

(iii) wholesale drug distributors; and

(iv) persons engaged in the manufacture and distribution of drugs or devices;

(e) in concurrence with the board of medical examiners, defining the additional education, experience, or certification required of a licensed pharmacist to become a certified clinical pharmacist practitioner;

(f) issuing certificates of "certified pharmacy" under this chapter;

(g) establishing and collecting license and registration fees;

(h) approving pharmacy practice initiatives that improve the quality of, or access to, pharmaceutical care but that fall outside the scope of this chapter. This subsection (2)(h) may not be construed to expand on the definition of the practice of pharmacy.

(i) establishing a medical assistance program to assist and rehabilitate licensees who are subject to the jurisdiction of the board and who are found to be physically or mentally impaired by habitual

intemperance or the excessive use of addictive drugs, alcohol, or any other drug or substance or by mental illness or chronic physical illness. The board shall ensure that a licensee who is required or volunteers to participate in the medical assistance program as a condition of continued licensure or reinstatement of licensure must be allowed to enroll in a qualified medical assistance program within this state and may not require a licensee to enroll in a qualified treatment program outside the state unless the board finds that there is no qualified treatment program in this state.

(j) making rules for the conduct of its business;

(k) performing other duties and exercising other powers as this chapter requires;

(l) adopting and authorizing the department to publish rules for carrying out and enforcing parts 1 through 7 of this chapter, including but not limited to:

(i) requirements and qualifications for the transfer of board-issued licenses;

(ii) minimum standards for pharmacy internship programs and qualifications for licensing pharmacy interns;

(iii) qualifications and procedures for registering pharmacy technicians; and

(iv) requirements and procedures necessary to allow a pharmacy licensed in another jurisdiction to be registered to practice telepharmacy across state lines.

(3) The board may:

(a) join professional organizations and associations organized exclusively to promote the improvement of standards of the practice of pharmacy for the protection of the health and welfare of the public and whose activities assist and facilitate the work of the board; and

(b) establish standards of care for patients concerning health care services that a patient may expect with regard to pharmaceutical care.

History: Ap. p. Sec. 644, Pol. C. 1895; re-en. Sec. 1626, Rev. C. 1907; re-en. Sec. 5, Ch. 134, L. 1915; re-en. Sec. 3174, R.C.M. 1921; re-en. Sec. 3174, R.C.M. 1935; amd. Sec. 4, Ch. 175, L. 1939; amd. Sec. 25, Ch. 93, L. 1969; amd. Sec. 3, Ch. 241, L. 1971; amd. Sec. 150, Ch. 350, L. 1974; Sec. 66-1504, R.C.M. 1947; Ap. p. Sec. 646, Pol. C. 1895; re-en. Sec. 1628, Rev. C. 1907; re-en. Sec. 7, Ch. 134, L. 1915; re-en. Sec. 3176, R.C.M. 1921; re-en. Sec. 3176, R.C.M. 1935; amd. Sec. 6, Ch. 175, L. 1939; amd. Sec. 1, Ch. 81, L. 1969; amd. Sec. 4, Ch. 168, L. 1971; amd. Sec. 4, Ch. 241, L. 1971; amd. Sec. 1, Ch. 71, L. 1974; amd. Sec. 152, Ch. 350, L. 1974; amd. Sec. 7, Ch. 533, L. 1977; Sec. 66-1506, R.C.M. 1947; R.C.M. 1947, 66-1504(1), (2)(a) thru (2)(f), (2)(h) thru (2)(j), (3), 66-1506(part); amd. Sec. 4, Ch. 379, L. 1981; amd. Sec. 1, Ch. 134, L. 1991; amd. Sec. 4, Ch. 388, L. 2001; amd. Sec. 3, Ch. 293, L. 2009; amd. Sec. 7, Ch. 122, L. 2011.

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Rule: 24.174.1101

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Rule Title: PERSONNEL

Department: LABOR AND INDUSTRY, DEPARTMENT OF
Chapter: BOARD OF PHARMACY
Subchapter: Institutional Pharmacies

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Latest version of the adopted rule presented in Administrative Rules of Montana (ARM):

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24.174.1101 PERSONNEL

(1) Each institutional pharmacy must be directed by a pharmacist-in-charge who is licensed to engage in the practice of pharmacy in the state of Montana and who is responsible for the storage, compounding, repackaging, dispensing and distribution of drugs within the facility. Depending upon the needs of the facility, pharmacy services may be provided on a full or part-time basis, with a mechanism for emergency service provided at all times. Contractual providers of pharmacy services shall meet the same requirements as pharmacies located within the institution.

(2) Registered pharmacy technicians or technicians-in-training may be utilized pursuant to the written policies and procedures of the institutional pharmacy. Exemptions to established ratios as defined in ARM 24.174.711 may be granted with board approval.

History: 37-7-201, MCA; IMP, 37-7-201, 37-7-307, MCA; NEW, 2002 MAR p. 3605, Eff. 12/27/02.

Effective rule versions existed in ARM on or after March 31, 2007

MAR Notices	Effective From	Effective To	History Notes
	12/27/2002	Current	History: 37-7-201, MCA; IMP, 37-7-201, 37-7-307, MCA; NEW, 2002 MAR p. 3605, Eff. 12/27/02.

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Rule: 24.174.1104

Rule Title: INSTITUTIONAL PHARMACIST AND PHARMACIST-IN-CHARGE RESPONSIBILITY

Department: LABOR AND INDUSTRY, DEPARTMENT OF
Chapter: BOARD OF PHARMACY
Subchapter: Institutional Pharmacies

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Latest version of the adopted rule presented in Administrative Rules of Montana (ARM):

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24.174.1104 INSTITUTIONAL PHARMACIST AND PHARMACIST-IN-CHARGE RESPONSIBILITY

(1) The pharmacy director/pharmacist-in-charge shall provide forapplicable policies and procedures to ensure:

(a) mechanisms for receiving and verifying drug orders from prescribers and evaluating them for safety and therapeutic appropriateness based on patient parameters and dosing guidelines;

(b) appropriate filling and proper labeling of all containers from which drugs are to be dispensed or administered on an inpatient or outpatient basis;

(c) a system for the admixture of parenteral products accomplished within the pharmacy, and verification that the facility's department of nursing willprovideeducation and training of nursing personnel regarding sterile technique, stability and compatibility of parenteral products not mixed within the pharmacy;

(d) appropriate clinical services and monitoring of outcomes, and the development of new areas of pharmaceutical care appropriate for that institution;

(e) a policy by which an offer is made to convey the discharge medication regimen to a patient's pharmacies;

(f) maintaining and distributing a list of emergency drugs, antidotes, and their doses throughout the institution;

(g) pharmacy participation in formulary development;

(h) participation in drug utilization review and monitoring of adverse drug reactionsand development of procedures to avoid problems identified;

(i) evaluation of reported medication errors and development of procedures to prevent those errors;

(j) proper acquisition and secure, temperature-controlledstorage of all prescription drugs;

(k) quality control of sterile and nonsterile pharmaceutical products, including procedures for identifying, removing and destroying outdated products;

(l) pharmacy safety and security;

(m) utilization of registered technicians or technicians in training;

(n) accurate distribution systems and secure,temperature-controlled storage of pharmaceutical products throughout the institution;

(o) unit-dosing of bulk pharmaceuticals, compounding and sterilization of drug products if applicable;

(p) the appropriate use, security and accountability of controlled substances;

(q) staff development and competency evaluation;

(r) maintenance of all required records; and

(s) compliance with all other requirements of the Montana Board of Pharmacy.

History: 37-7-201, MCA; IMP, 37-7-201, 37-7-307, 37-7-308, MCA; NEW, 2002 MAR p. 3605, Eff. 12/27/02.

Effective rule versions existed in ARM on or after March 31, 2007

MAR Notices	Effective From	Effective To	History Notes
	12/27/2002	Current	History: 37-7-201, MCA; IMP, 37-7-201, 37-7-307, 37-7-308, MCA; NEW,

2002 MAR p. 3605, Eff. 12/27/02.

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Rule: 24.174.1107

Rule Title: ABSENCE OF PHARMACIST IN INSTITUTIONAL SETTINGS

Department: LABOR AND INDUSTRY, DEPARTMENT OF
Chapter: BOARD OF PHARMACY
Subchapter: Institutional Pharmacies

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Latest version of the adopted rule presented in Administrative Rules of Montana (ARM):

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24.174.1107 ABSENCE OF PHARMACIST IN INSTITUTIONAL SETTINGS

(1) During times that an institutional pharmacy does not have a pharmacist in attendance, arrangements must be made in advance by the pharmacist-in-charge for provision of drugs to the medical staff and other authorized personnel by use of night cabinets, floor stock and, in emergency circumstances, by access to the pharmacy. A mechanism for providers and nursing to obtain pharmacy consultation must be available at all times in accordance with ARM 24.174.1101.

(2) If night cabinets are used to store drugs in the absence of a pharmacist, they must be locked and sufficiently secure to deny access to unauthorized persons, and must be located outside of the pharmacy area. Contents of night cabinets must be prepackaged. Only specifically authorized personnel may obtain access by key or combination, pursuant to a valid prescription order. The pharmacist-in-charge shall, in conjunction with the appropriate committee of the facility, develop inventory listings of drugs included in these cabinets and determine who may have access.

(3) A complete verification audit of all inpatient orders and activity concerning the night cabinet or after-hours pharmacy entry must be conducted by a pharmacist, pharmacy technician, or other licensed designee of that pharmacist within 72 hours of the drugs having been removed from the night cabinet or pharmacy.

(4) Whenever any drug is not available from floor stock or night cabinets, and that drug is required to treat the immediate needs of a patient whose health would otherwise be jeopardized, the drug may be obtained from the pharmacy by an authorized registered nurse or licensed practical nurse in accordance with established policies and procedures. The responsible nurse shall be designated by the appropriate committee of the institutional facility.

(a) Removal of any drug from the pharmacy, floor stock, or night cabinet by an authorized nurse must be recorded on a suitable form showing the following information:

(i) patient name;
(ii) the patient's room number if applicable;
(iii) the name, strength, and quantity of drug removed;
(iv) the date and time the drug was removed;
(v) the signature of the nurse removing the drug; and
(vi) documentation of pharmacy review.

(b) in cases of medication not unit-dosed, the NDC number of the drug removed must also be recorded.

(5) The pharmacist-in-charge shall ensure that:

(a) written policies and procedures are established to implement the requirements of this rule;

(b) all drugs are properly labeled; and

(c) only prepackaged drugs are available, in amounts sufficient for immediate therapeutic requirements.

(6) A copy of the original drug order with the NDC number or other identifying code of the drug (s) provided may be faxed to the pharmacist. If the patient is an inpatient, a patient profile containing the patient's name, location, allergies, current medication regimen, and relevant laboratory values must be reviewed by a pharmacist within 72 hours.

History: 37-7-201, MCA; IMP, 37-7-201, MCA; NEW, 2002 MAR p. 3605, Eff. 12/27/02; AMD, 2006 MAR p. 1615, Eff. 6/23/06.

Effective rule versions existed in ARM on or after March 31, 2007

MAR Notices	Effective From	Effective To	History Notes
	6/23/2006	Current	History: 37-7-201, MCA; IMP, 37-7-201, MCA; NEW, 2002 MAR p. 3605, Eff. 12/27/02; AMD, 2006 MAR p. 1615, Eff. 6/23/06.

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Rule: 24.174.1111

Rule Title: DRUG DISTRIBUTION AND CONTROL IN AN INSTITUTIONAL FACILITY

Department: LABOR AND INDUSTRY, DEPARTMENT OF
Chapter: BOARD OF PHARMACY
Subchapter: Institutional Pharmacies

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24.174.1111 DRUG DISTRIBUTION AND CONTROL IN AN INSTITUTIONAL FACILITY

(1) The pharmacist-in-charge shall establish written policies and procedures for the safe and efficient distribution of drugs and provision of pharmaceutical care, including the mechanism by which drug review will be accomplished and documented. A currentcopy of such procedures must be on hand for inspection by the Board of Pharmacy.

(2) Automated dispensing devices must be stocked with drugs only by or under the supervision of a registered pharmacist. At the time of removal of any drug, the device must automatically make an electronic record indicating the date of removal, the name, strength, and quantity of drug removed, name of the patient for whom the drug was ordered, and the name or other identification of the person removing the drug. These records must be maintained for a period of two years.

(3) Drugs or herbal/alternative food supplement products brought into an institutional facility by a patient must not be administered unless they can be identified and their quality assured by a pharmacist, and their use has beenauthorized by the attending physician. If such drugs are not to be administered, the pharmacist-in-charge shall develop policies and procedures for storing them for return to the patient upon discharge or transferring them to an adult member of the patient's immediate family.

(4) Investigational drugs must be stored in and dispensed from the pharmacy only pursuant to written policies and procedures. Complete information regarding these drugs and their disposition must be maintained in the facility. The drug monographand a signed patient consent form must be obtained and made available in accordance with state and federal guidelines.

(5) A sample drug policy must be established if samples are used.

(6) The safe handling, storage, and administration of medications within jails, correctional facilities, and detention facilities without onsite pharmacies shall be regulated as follows:

(a) Jails, correctional facilities, and detention facilities must have written policies and procedures in place, written by the responsible practitioner or authority, for the safe handling, storage, and administration of medications. Such policies shall address security of medications, procurement, proper storage and disposal of medications, training for those administering medication, methods for documenting that medications were given or refused, procedures for confirming that the inmate has ingested each medication, and the disposition of medications at discharge. Medications brought by or with an inmate upon admission to the jail, correctional facility, or detention facility must not be used unless specifically authorized by a physician at the jail, correctional facility, or detention facility or that physician's designee, and medication identity has been confirmed by a licensed health care professional. Prescription medications brought by an inmate from outside must be recorded on the inmate property record. If they are not used while the patient is incarcerated, they must be stored in a secure area until the inmate's release.

(b) Patient medications may be transferred from one jail, correctional facility, or detention facility to another if there is a secure method for ensuring that individual inmate prescriptions are not tampered with between locations and that containers are properly labeled. During transfer, medications requiring storage at room temperature should be subjected to external temperatures no greater than 86 degrees Fahrenheit. A method of transferring refrigerated medications from one jail, correctional facility, or detention facility to another must be addressed in policy and procedure. Medications transferred pursuant to the above regulations, in control of the transferring official at all time, may continue to be used for that patient.

(c) Emergency kits supplied and maintained by a registered pharmacist may be utilized if

policies and procedures regulating their use are in place. Such emergency kits will comply with the requirements of ARM 24.174.1114.

(d) Jails, correctional facilities, and detention facilities without an on-site pharmacy that procures, stores, and administers prescription medications may request technical assistance from the board.

History: 37-7-201, MCA; IMP, 37-7-201, 37-7-307, 37-7-308, 37-7-406, MCA; NEW, 2002 MAR p. 3605, Eff. 12/27/02; AMD, 2006 MAR p. 1615, Eff. 6/23/06.

Effective rule versions existed in ARM on or after March 31, 2007

MAR Notices	Effective From	Effective To	History Notes
	6/23/2006	Current	History: 37-7-201, MCA; IMP, 37-7-201, 37-7-307, 37-7-308, 37-7-406, MCA; NEW, 2002 MAR p. 3605, Eff. 12/27/02; AMD, 2006 MAR p. 1615, Eff. 6/23/06.

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Rule: 24.174.1114

Rule Title: USE OF EMERGENCY DRUG KITS IN CERTAIN INSTITUTIONAL FACILITIES

Department: LABOR AND INDUSTRY
Chapter: BOARD OF PHARMACY
Subchapter: Institutional Pharmacies

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Latest version of the adopted rule presented in Administrative Rules of Montana (ARM):

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24.174.1114 USE OF EMERGENCY DRUG KITS IN CERTAIN INSTITUTIONAL FACILITIES

(1) In an institutional facility that does not have an in-house pharmacy, drugs may be provided for use by authorized personnel through emergency kits prepared by the registered pharmacist providing pharmaceutical services to the facility. Such emergency drug kits must meet all of the following requirements:

(a) a registered pharmacist shall prepare and seal the kit;

(b) the supplying pharmacist and the designated practitioner or appropriate committee of the institutional facility shall jointly determine the identity and quantity of drugs to be included in the kit. Such drugs shall then be approved in advance of placement in the emergency kit by the board; unless such drugs are included on a general list of drugs previously approved by the board for use in emergency kits;

(c) the kit must be locked and stored in a secure area to prevent unauthorized access and to ensure a proper storage environment for the drugs contained therein. The kit shall be secured with a seal to be of such a nature that it can be easily identified if it has been broken;

(d) all drugs in the kit must be properly labeled, including lot number and expiration date, and shall possess any additional information that may be required to prevent risk of harm to the patient;

(e) the exterior of the kit must be clearly labeled to indicate:

(i) its use and expiration date of its contents;

(ii) the name, address and telephone number of the supplying pharmacist; and

(iii) a statement indicating that the kit is to be used in emergency situations only pursuant to a valid drug order.

(2) Drugs shall be removed from emergency kits only by the supplying pharmacist or by authorized personnel pursuant to a valid drug order.

(3) Upon notice of any entry into the kit, the supplying pharmacist or another pharmacist designated by the supplying pharmacist shall restock and refill the kit, reseal the kit, and update the drug listing on the exterior of the kit within 72 hours.

(4) The expiration date of a kit must be the earliest date of expiration of any drug supplied in the kit. On or before the expiration date, the supplying pharmacist shall replace the expired drug.

(5) The supplying pharmacist shall, in conjunction with the appropriate institutional committee, be responsible for development of policies and procedures for safe and appropriate use and maintenance of emergency drug kits.

History: 37-7-201, MCA; IMP, 37-7-201, MCA; NEW, 2002 MAR p. 3605, Eff. 12/27/02; AMD, 2010 MAR p. 74, Eff. 1/15/10.

Effective rule versions existed in ARM on or after March 31, 2007

MAR Notices	Effective From	Effective To	History Notes
24-174-59	1/15/2010	Current	History: 37-7-201, MCA; IMP, 37-7-201, MCA; NEW, 2002 MAR p. 3605, Eff. 12/27/02; AMD, 2010 MAR p. 74, Eff. 1/15/10.
	12/27/2002	1/15/2010	History: 37-7-201, MCA; IMP, 37-7-201, MCA; NEW, 2002 MAR p. 3605, Eff. 12/27/02.

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Rule: 24.174.1121

Rule Title: STERILE PRODUCTS

Department: LABOR AND INDUSTRY, DEPARTMENT OF
Chapter: BOARD OF PHARMACY
Subchapter: Institutional Pharmacies

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Latest version of the adopted rule presented in Administrative Rules of Montana (ARM):

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24.174.1121 STERILE PRODUCTS

(1) Policies and procedures must be prepared for the compounding, dispensing, delivery, administration, storage and use of sterile pharmaceutical products. The policies must include a quality assurance program for monitoring personnel qualifications and training in sterile technique, product storage, stability standards, and infection control. Policies andprocedures mustbe current and available for inspection by a designee of the Board of Pharmacy.

(2) An institutional pharmacy compounding sterile products must have an isolated area designed to avoid unnecessary traffic and airflow disturbances.

(3) An institutional pharmacy compounding sterile products must utilize an appropriate aseptic environmental control device such as a laminar flow biological safety cabinet capable of maintaining Class 100 conditions during normal activity, or have policies and procedures in place limiting the pharmacy's scope of sterile product preparation.

(4) An institution preparing cytotoxic drugs must have a vertical flow Class II biological safety cabinet. Cytotoxic drugs must be prepared in a vertical flow Class II biological safety cabinet.

(a) Protective apparel including nonvinyl gloves, gowns and masks must be available, and gloves must be worn at all times.

(b) Appropriate containment techniques must be used in addition to aseptic techniques required for sterile product preparation.

(c) Prepared doses of cytotoxic drugs must be clearly identified, labeled with proper precautions and dispensed in a manner to minimize risk of cytotoxic spills.

(d) Disposal of cytotoxic waste must comply with all applicable local, state and federal laws.

(e) Written procedures for handling cytotoxic spills must be included in the policies and procedures manual.

(5) All parenteral admixtures must be labeled with date of preparation and expiration date clearly indicated, patient name and room number, name and strength and/or amount of drug and base solution, and any special handling or storage instructions.

(6) All aseptic environmental control devices must be certified by an independent contractor for operational efficiency at least every 12 months or when relocated, according to Federal Standard 209E. Prefilters must be inspected periodically and replaced if needed.

(7) Inspection and replacement dates must be documented and maintained for a period of at least two years.

(8) Documented records of ongoing quality assurance programs, justification of expirationdates chosen, and employee training records and technique audits must be available for inspection by the Board of Pharmacy.

History: 37-7-201, MCA; IMP, 37-7-201, 37-7-307, 37-7-308, MCA; NEW, 2002 MAR p. 3605, Eff. 12/27/02.

Effective rule versions existed in ARM on or after March 31, 2007

MAR Notices	Effective From	Effective To	History Notes
	12/27/2002	Current	History: 37-7-201, MCA; IMP, 37-7-201, 37-7-307, 37-7-308, MCA; NEW, 2002 MAR p. 3605, Eff. 12/27/02.

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Rule: 24.174.1122

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Rule Title: OUTPATIENT CENTERS FOR SURGICAL SERVICES

Department: LABOR AND INDUSTRY
Chapter: BOARD OF PHARMACY
Subchapter: Institutional Pharmacies

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24.174.1122 OUTPATIENT CENTERS FOR SURGICAL SERVICES

(1) The board shall annually register and inspect all outpatient centers for surgical services in Montana, regardless of pharmacy status.

(2) In an outpatient center for surgical services without an on-site pharmacy, drug distribution must be directed by a physician or consulting pharmacist licensed to practice in Montana and who is responsible for the security, storage, and distribution of drugs within the facility.

(3) The physician director or consulting pharmacist shall provide for applicable policies and procedures to ensure:

(a) proper acquisition and secure, temperature-controlled storage of all pharmaceuticals;

(b) security and accountability of controlled substances;

(c) quality control of sterile and nonsterile pharmaceutical products including procedures for identifying, removing, and destroying outdated products;

(d) evaluation of reported medication errors and development of procedures to prevent those errors;

(e) maintenance of all required records; and

(f) compliance with all requirements of the board.

(4) Ambulatory surgical centers that store and/or administer controlled substances shall register with the board and with the DEA, and shall comply with all applicable state, local, and DEA regulations.

History: 50-32-314, MCA; IMP, 50-32-314, MCA; NEW, 2006 MAR p. 1615, Eff. 6/23/06; AMD, 2007 MAR p. 1936, Eff. 11/22/07; AMD, 2008 MAR p. 1151, Eff. 6/13/08.

Effective rule versions existed in ARM on or after March 31, 2007

MAR Notices	Effective From	Effective To	History Notes
24-174-58	6/13/2008	Current	History: 50-32-314, MCA; IMP, 50-32-314, MCA; NEW, 2006 MAR p. 1615, Eff. 6/23/06; AMD, 2007 MAR p. 1936, Eff. 11/22/07; AMD, 2008 MAR p. 1151, Eff. 6/13/08.
24-174-56	11/22/2007	6/13/2008	History: 50-32-314, MCA; IMP, 50-32-314, MCA; NEW, 2006 MAR p. 1615, Eff. 6/23/06; AMD, 2007 MAR p. 1936, Eff. 11/22/07.
	6/23/2006	11/22/2007	History: 50-32-314, MCA; IMP, 50-32-314, MCA; NEW, 2006 MAR p. 1615, Eff. 6/23/06.

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Rule: 24.174.1141

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Rule Title: RETURN OF MEDICATION FROM LONG TERM CARE FACILITIES -- DONATED DRUG PROGRAM

Department: LABOR AND INDUSTRY, DEPARTMENT OF
Chapter: BOARD OF PHARMACY
Subchapter: Institutional Pharmacies

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Latest version of the adopted rule presented in Administrative Rules of Montana (ARM):

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24.174.1141 RETURN OF MEDICATION FROM LONG TERM CARE FACILITIES -- DONATED DRUG PROGRAM

(1) In facilities licensed by the Montana Department of Public Health and Human Services where United States pharmacopeia storage requirements are assured, unit-dosed legend drugs, with the exception of controlled substances, no longer needed by the patient for whom they were prescribed, may be transferred to a provisional permitted pharmacy for relabeling and dispensing free of charge to patients who are uninsured, indigent or have insufficient funds to obtain needed prescription drugs. Prescription medications may be dispensed pursuant to a valid prescription order. A usual and customary dispensing fee may be charged at the pharmacist's discretion.

(2) The pharmacist-in-charge of the provisional permitted pharmacy shall be responsible for determining the suitability of the legend drug for use. Medications must be unopened in sealed, unaltered unit dose containers that meet USP standards for light, moisture and air permeation. No product in which drug integrity cannot be assured shall be accepted for redispensing by the pharmacist.

(3) A redispensed prescription medication must be assigned the expiration date stated on the unit dose packaging. Medications packaged in unit dose form within a pharmacy must be given an expiration date of one year or actual date of expiration of the medication, whichever comes first, and must not be repackaged.

(4) No medication can be redistributed more than once.

(5) Only authorized personnel shall carry out the physical transfer of medication in either facility, pursuant to established policies and procedures.

(6) The patient's name and other identifying marks must be obliterated from packaging prior to transfer. The drug name, strength, lot number and expiration date must remain clearly visible on the packaging.

(7) An inventory list of drugs transferred, including expiration dates, must accompany the drugs, and must be maintained in the provisional permitted pharmacy for a period of two years.

(8) Policies and procedures to document safe storage and transfer of unneeded medications must be written and adhered to by the facilities involved, and must be available for inspection by an authorized representative of the Montana Board of Pharmacy or Department of Public Health and Human Services.

History: 37-7-201, 37-7-1401, MCA; IMP, 37-7-201, 37-7-1401, 37-7-1402, MCA; NEW, 2002 MAR p. 3605, Eff. 12/27/02.

Effective rule versions existed in ARM on or after March 31, 2007

MAR Notices	Effective From	Effective To	History Notes
	12/27/2002	Current	History: 37-7-201, 37-7-1401, MCA; IMP, 37-7-201, 37-7-1401, 37-7-1402, MCA; NEW, 2002 MAR p. 3605, Eff. 12/27/02.

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2011

STATE OF NEBRASKA

STATUTES RELATING TO PHARMACY PRACTICE ACT

Department of Health and Human Services
Division of Public Health
Licensure Unit

301 Centennial Mall South, Third Floor
PO Box 94986
Lincoln, NE 68509-4986

71-425. Pharmacy, defined. Pharmacy means a facility advertised as a pharmacy, drug store, hospital pharmacy, dispensary, or any combination of such titles where drugs or devices are dispensed as defined in the Pharmacy Practice Act.
Source: Laws 2000, LB 819, § 25; Laws 2001, LB 398, § 66; Laws 2007, LB463, § 1180. Operative date December 1, 2008.

NRS 639.0085 "Institutional pharmacy" defined. "Institutional pharmacy" means a pharmacy or other storage place as defined by regulations adopted by the Board which is a part of or is operated in conjunction with a medical facility as that term is defined in NRS 449.0151. The term includes:

1. A pharmacy on the premises of the medical facility which provides a system of distributing and supplying medication to the facility, whether or not operated by the facility; and

2. A pharmacy off the premises of the medical facility which provides services only to the patients of the facility and provides a system of distributing medication based upon chart orders from the medical facility.

(Added to NRS by 1983, 1504; A 1987, 1649; 1993, 1989)

NRS 639.012 "Pharmacy" defined.

1. "Pharmacy" means every store or shop licensed by the Board where drugs, controlled substances, poisons, medicines or chemicals are stored or possessed, or dispensed or sold at retail, or displayed for sale at retail, or where prescriptions are compounded or dispensed.

2. "Pharmacy" includes:

(a) Pharmacies owned or operated by the State of Nevada and political subdivisions and municipal corporations therein.

(b) Institutional pharmacies.

(c) Pharmacies in correctional institutions.

(d) Nuclear pharmacies.

(e) Internet pharmacies.

(Added to NRS by 1967, 1652; A 1973, 774; 1979, 1683; 1983, 1505; 1987, 1649; 1989, 1751; 2001, 1067)

NRS 639.070 General powers.

1. The Board may:

(a) Adopt such regulations, not inconsistent with the laws of this State, as are necessary for the protection of the public, appertaining to the practice of pharmacy and the lawful performance of its duties.

(b) Adopt regulations requiring that prices charged by retail pharmacies for drugs and medicines which are obtained by prescription be posted in the pharmacies and be given on the telephone to persons requesting such information.

(c) Adopt regulations, not inconsistent with the laws of this State, authorizing the Executive Secretary of the Board to issue certificates, licenses and permits required by this chapter and chapters 453 and 454 of NRS.

(d) Adopt regulations governing the dispensing of poisons, drugs, chemicals and medicines.

(e) Regulate the practice of pharmacy.

(f) Regulate the sale and dispensing of poisons, drugs, chemicals and medicines.

(g) Regulate the means of recordkeeping and storage, handling, sanitation and security of drugs, poisons, medicines, chemicals and devices, including, but not limited to, requirements relating to:

(1) Pharmacies, institutional pharmacies and pharmacies in correctional institutions;

(2) Drugs stored in hospitals; and

(3) Drugs stored for the purpose of wholesale distribution.

(h) Examine and register, upon application, pharmacists and other persons who dispense or distribute medications whom it deems qualified.

(i) Charge and collect necessary and reasonable fees for the expedited processing of a request or for any other incidental service the Board provides, other than those specifically set forth in this chapter.

(j) Maintain offices in as many localities in the State as it finds necessary to carry out the provisions of this chapter.

(k) Employ an attorney, inspectors, investigators and other professional consultants and clerical personnel necessary to the discharge of its duties.

(l) Enforce the provisions of NRS 453.011 to 453.552, inclusive, and enforce the provisions of this chapter and chapter 454 of NRS.

(m) Adopt regulations concerning the information required to be submitted in connection with an application for any license, certificate or permit required by this chapter or chapter 453 or 454 of NRS.

(n) Adopt regulations concerning the education, experience and background of a person who is employed by the holder of a license or permit issued pursuant to this chapter and who has access to drugs and devices.

(o) Adopt regulations concerning the use of computerized mechanical equipment for the filling of prescriptions.

(p) Participate in and expend money for programs that enhance the practice of pharmacy.

2. This section does not authorize the Board to prohibit open-market competition in the advertising and sale of prescription drugs and pharmaceutical services.

[Part 7:286:1913; A 1951, 290; 1953, 588]—(NRS A 1961, 755; 1963, 156, 474; 1967, 1643; 1971, 2039; 1973, 259; 1975, 202, 1307, 1315; 1979, 1684; 1983, 1506; 1987, 804, 1650; 1991, 1157; 1993, 630; 1995, 290; 2001, 1067; 2003, 563, 2280; 2007, 2952)

NRS 639.071 Regulations: Institutional pharmacies. The Board may adopt such regulations as are necessary for the safe and efficient operation of institutional pharmacies.

(Added to NRS by 1987, 1649)

Nevada State BOARD OF PHARMACY

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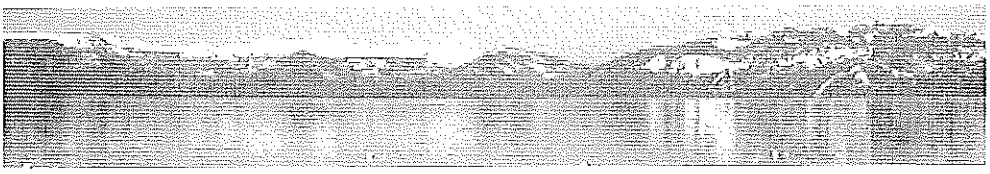

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- NAC 639 - Pharmacists and Pharmacy

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MEDICAL FACILITIES AND CORRECTIONAL INSTITUTIONS

General Provisions

NAC 639.440 Definitions. (NRS 639.070) As used in NAC 639.440 to 639.490, inclusive, unless the context otherwise requires, the words and terms defined in NAC 639.441 to 639.460, inclusive, have the meanings ascribed to them in those sections.
(Added to NAC by Bd. of Pharmacy, eff. 3-27-90; A 9-12-91)

NAC 639.441 "Administer" defined. (NRS 639.070) "Administer" means the direct application of a drug or medicine, whether by injection, inhalation, ingestion, or any other means, to the body of a patient or the subject of research.
(Added to NAC by Bd. of Pharmacy, eff. 3-27-90)

NAC 639.442 "Chart order" defined. (NRS 639.070) "Chart order" means an order entered on the chart of an inpatient in a medical facility licensed by the Health Division of the Department of Health and Human Services or on the chart of a patient under emergency treatment in a hospital by a practitioner or on the written or oral order of a practitioner authorizing the administration of a drug to the patient.
(Added to NAC by Bd. of Pharmacy, eff. 3-27-90)

NAC 639.445 "Compound" and "compounding" defined. (NRS 639.070) "Compound" or "compounding" means to form or create a composite product by combining two or more different ingredients.
(Added to NAC by Bd. of Pharmacy, eff. 3-27-90)

NAC 639.446 "Consultant pharmacist" defined. (NRS 639.070) "Consultant pharmacist" means a pharmacist retained by a medical facility or correctional institution under contract to consult with the facility or institution in areas that relate to the practice of pharmacy.
(Added to NAC by Bd. of Pharmacy, eff. 3-27-90; A 9-12-91)

NAC 639.4465 "Correctional institution" defined. (NRS 639.070) "Correctional institution" means any penal facility used for confinement of persons or any facility used for detention of juveniles, which is operated by or under the supervision of a subdivision of the State. The term includes a jail.
(Added to NAC by Bd. of Pharmacy, eff. 9-12-91)

NAC 639.447 "Deliver" and "delivery" defined. (NRS 639.070) "Deliver" or "delivery" means the actual, constructive, or attempted transfer of a controlled substance or dangerous drug from one person to another, whether or not there is an agency relationship.
(Added to NAC by Bd. of Pharmacy, eff. 3-27-90; A 9-12-91)

NAC 639.448 "Device" defined. (NRS 639.070) "Device" means any instrument, apparatus or contrivance, including its components, parts and accessories, intended:

1. For use in the diagnosis, cure, mitigation, treatment or prevention of disease in persons or animals; or
2. To affect the structure of any function of the body of a person or an animal.

(Added to NAC by Bd. of Pharmacy, eff. 3-27-90)

NAC 639.449 "Direct copy" defined. (NRS 639.070) "Direct copy" includes an electronic or carbonized copy.
(Added to NAC by Bd. of Pharmacy, eff. 3-27-90)

NAC 639.450 "Dispense" defined. (NRS 639.070) "Dispense" means the furnishing of a controlled substance or dangerous drug in any amount greater than that necessary for the present and immediate needs of the ultimate user. The term does not include the furnishing of a controlled substance or dangerous drug by a pharmacy in a medical facility to an inpatient of the medical facility in which the pharmacy is located.
(Added to NAC by Bd. of Pharmacy, eff. 3-27-90; A 9-12-91)

NAC 639.451 "Distribute" defined. (NRS 639.070) "Distribute" means to deliver other than by administering or dispensing a controlled substance, dangerous drug or other drug.
(Added to NAC by Bd. of Pharmacy, eff. 3-27-90; A 9-12-91)

NAC 639.452 "Floor stock" defined. (NRS 639.070) "Floor stock" means drugs or devices not labeled for a specific patient and maintained at a nursing station or other department of a medical facility or correctional institution, excluding the pharmacy, for the purpose of administering to a patient of the facility or institution.
(Added to NAC by Bd. of Pharmacy, eff. 3-27-90; A 9-12-91)

NAC 639.453 "Formulary" defined. (NRS 639.070) "Formulary" means a list of drugs approved by an appropriate committee that evaluates, appraises and selects from among the various available drugs and drug products those drugs considered most useful in caring for patients.
(Added to NAC by Bd. of Pharmacy, eff. 3-27-90)

NAC 639.455 "Investigational drug" defined. (NRS 639.070) "Investigational drug" means a new drug intended for investigational use by experts qualified to evaluate the safety and effectiveness of the drug as authorized by the Food and Drug Administration.
(Added to NAC by Bd. of Pharmacy, eff. 3-27-90)

NAC 639.456 "IV admixture" defined. (NRS 639.070) "IV admixture" means the compounding of parenteral solutions by aseptic procedures.
(Added to NAC by Bd. of Pharmacy, eff. 3-27-90)

NAC 639.457 "Medical facility" defined. (NRS 639.070) "Medical facility" includes:
1. A surgical center for ambulatory patients;
2. An obstetric center;
3. An independent center for emergency medical care;
4. An agency to provide nursing in the home;
5. A facility for intermediate care;
6. A facility for skilled nursing;
7. A hospice;
8. A hospital;
9. A psychiatric hospital;
10. A facility for the treatment of irreversible renal disease; and
11. A rural clinic.

(Added to NAC by Bd. of Pharmacy, eff. 3-27-90)

NAC 639.4575 "Pharmacy" defined. (NRS 639.070) "Pharmacy" means an area in a medical facility or correctional institution where drugs are stored, compounded, delivered, dispensed and distributed to other areas or departments of the facility or institution or dispensed to an ultimate user.
(Added to NAC by Bd. of Pharmacy, eff. 9-12-91)

NAC 639.458 "Prescription" defined. (NRS 639.070)
1. "Prescription" means:
(a) An order given individually for the person for whom a drug is prescribed, directly from a practitioner, or his or her agent, to a pharmacist or indirectly by means of an order signed by the practitioner.
(b) A chart order written for an inpatient specifying drugs that the inpatient is to take home upon his or her discharge.
2. The term does not include a chart order written for an inpatient for use while he or she is an inpatient.
(Added to NAC by Bd. of Pharmacy, eff. 3-27-90)

NAC 639.459 "Unit dose" defined. (NRS 639.070) "Unit dose" means medication packaged in packages containing only a single unit of medication.
(Added to NAC by Bd. of Pharmacy, eff. 3-27-90)

NAC 639.460 "Unit of use" defined. (NRS 639.070) "Unit of use" means:
1. Medication intended to provide a specific dosage as a single dose; or
2. More than one dose of medication packaged as a single unit to provide a specific dosage.
(Added to NAC by Bd. of Pharmacy, eff. 3-27-90)

NAC 639.461 Licensing. (NRS 639.070, 639.071)
1. A separate license to conduct a pharmacy in a hospital must be obtained for each location of a hospital which is required to obtain a license from the Bureau of Regulatory Health Services of the Health Division of the Department of Health and Human Services. A hospital may apply for more than one license to conduct an institutional pharmacy at a location.
2. Retail, nuclear and other pharmaceutical functions may be performed within a hospital under the license to conduct a pharmacy. If a hospital is required to obtain only one license from the Bureau of Regulatory Health Services of the Health Division of the Department of Health and Human Services for a pharmacy, the pharmacy may serve inpatients in an institutional satellite operation without obtaining a separate license to conduct such a pharmacy. A pharmacy which serves outpatients in an institutional satellite operation is required to obtain a separate license to conduct such a pharmacy.
(Added to NAC by Bd. of Pharmacy, eff. 3-27-90; A 9-11-91; 9-12-91)

NAC 639.462 Biennial registration. (NRS 639.070, 639.071, 639.072)
1. A pharmacy shall register biennially with the Board on a form provided by the Board. A list of each type of pharmaceutical service provided by the pharmacy that would otherwise be required to be licensed must be included.
2. For a pharmacy in a medical facility, the registration form must be signed by:
(a) The managing pharmacist of the pharmacy; and
(b) The chief executive officer of the hospital in which the pharmacy is located.
3. The chief executive officer must agree to comply with the regulations adopted by the Board governing pharmacies.
4. The registration form must state whether the pharmacy is a sole ownership and, if so, include the name of the owner. If the pharmacy is owned by a partnership, the registration form must include the names of the partners. If the pharmacy is owned by a corporation, the registration form must include the names of the corporate officers.
5. If the pharmacy is owned or operated by a management or consulting firm:
(a) The registration form must include the name of the firm or the operator; and
(b) The firm must be registered by the Drug Enforcement Administration, unless the firm:
(1) Enters into a contract with the hospital in which the pharmacy is located that assigns the responsibility for the controlled substances to the hospital; and
(2) The firm maintains dual responsibility for the controlled substances.
(Added to NAC by Bd. of Pharmacy, eff. 3-27-90; A 9-12-91)

NAC 639.463 Change of ownership. (NRS 639.070, 639.170)
1. If a pharmacy changes ownership, it must obtain a new and separate registration from the Board.
2. The fee established in NRS 639.170 will be charged for the issuance of a new certificate of registration.
(Added to NAC by Bd. of Pharmacy, eff. 3-27-90; A 9-12-91)

Standards of Operation

NAC 639.464 Scope of services in hospital or correctional institution. (NRS 639.070, 639.071, 639.072) In a hospital or correctional institution:
1. The scope of services provided by a pharmacy must be consistent with the needs of the patients for medication as determined by the medical staff, managing pharmacist and other health care professionals involved in delivering or administering drugs in the hospital or correctional institution in which the pharmacy is located.
2. Pharmaceutical services may include, but are not limited to:
(a) Interpreting orders for prescriptions and medication.
(b) Compounding, dispensing, distributing, labeling and administering drugs and devices.
(c) Monitoring drug therapy.

(d) Therapeutic interchange.
(e) Participating in evaluations of the uses of drugs and the selection of drug products.
(f) Ensuring the proper and safe storage and distribution of drugs and devices, and the maintenance of proper records related thereto.
(g) Providing information related to drugs, including, but not limited to, the proper dosages, hazards and the optimal use of drugs and devices.
(h) Supervising pharmaceutical technicians and pharmaceutical technicians in training.
(i) Conducting research.
3. As used in this section, "therapeutic interchange" means the dispensing of one drug in place of another pursuant to guidelines approved by an appropriate committee of the medical staff.
(Added to NAC by Bd. of Pharmacy, eff. 3-27-90; A 9-12-91; 11-15-93)

NAC 639.4645 Maintenance of registration certificates required. (NRS 639.070, 639.071) If the primary function of a pharmacy in a hospital is the provision of inpatient services, the pharmacy shall maintain registration certificates and current renewal receipts thereof for all pharmacists, intern pharmacists and pharmaceutical technicians together in one location within the pharmacy. The certificates must be readily available for review upon the request of the Board.
(Added to NAC by Bd. of Pharmacy, eff. 10-17-91)

NAC 639.465 Managing pharmacist. (NRS 639.070, 639.071, 639.072)
1. A pharmacy located in a:
(a) Hospital with 100 beds or more; or
(b) Correctional institution housing 1,500 inmates or more,
➥ must have one full-time managing pharmacist. That pharmacist may be a managing pharmacist for only one such pharmacy.
2. Each pharmacy located in a:
(a) Hospital with less than 100 beds; or
(b) Correctional facility housing less than 1,500 inmates,
➥ must have one managing pharmacist who is retained as a consultant, or who is employed part-time or full-time.
(Added to NAC by Bd. of Pharmacy, eff. 3-27-90; A 9-12-91; R015-05, 10-31-2005; R098-07, 12-4-2007)

NAC 639.466 Consultant pharmacist. (NRS 639.070, 639.071, 639.072)
1. A consultant pharmacist may be the managing pharmacist of a pharmacy.
2. A consultant pharmacist and the medical facility or correctional institution that employs the consultant pharmacist must enter into a written employment contract. The contract must be made available to the Board upon request.
(Added to NAC by Bd. of Pharmacy, eff. 3-27-90; A 9-12-91)

NAC 639.467 Staff pharmacists. (NRS 639.070, 639.071, 639.072)
1. The managing pharmacist of a pharmacy must be assisted by a sufficient number of additional registered pharmacists as are required to operate the pharmacy competently and safely, and to meet adequately the needs of the hospital or correctional institution in which the pharmacy is located.
2. Staff pharmacists shall assist the managing pharmacist in carrying out the duties enumerated in NAC 639.468.
3. A staff pharmacist is responsible for any delegated act performed by pharmaceutical technicians under his or her supervision.
(Added to NAC by Bd. of Pharmacy, eff. 3-27-90; A 9-12-91)

NAC 639.468 Establishment of policies, procedures and systems. (NRS 639.070, 639.071, 639.072) The managing pharmacist of a pharmacy shall establish policies, procedures and systems related to the following matters, without limitation:
1. Preparation of parenteral medications compounded within the pharmacy.
2. Supervision of the admixture of parenteral products and training of personnel in incompatible admixtures if they are not performed within the pharmacy.
3. Supervision of the bulk compounding of drugs.

4. Procurement and storage of all materials in the pharmacy, including drugs, chemicals and biologicals.

5. Participation in the development of a formulary for the medical facility or correctional institution in which the pharmacy is located, subject to the approval of the appropriate committee at the facility or institution.

6. Distribution of drugs to be administered to patients, pursuant to an original or a direct copy of a practitioner's order for medication.

7. Filling and labeling of all containers from which drugs are to be distributed or dispensed.

8. Maintenance and availability in the pharmacy, and in areas where care is provided to inpatients, of:

(a) A sufficient inventory of emergency drugs;

(b) The telephone numbers of poison control centers and other organizations for emergency assistance; and

(c) Such other materials and information as are considered necessary by the appropriate committee.

9. Recording of all transactions of the pharmacy required by applicable state and federal laws.

10. Participation in those aspects of the medical facility's program to evaluate care provided to patients that relate to the use and effectiveness of pharmaceutical materials.

11. Participation in teaching and research programs at the medical facility.

12. Carrying out the policies and decisions of the appropriate committee relating to pharmaceutical services of the medical facility.

13. Labeling, storage and distribution of investigational drugs, and maintenance of information in the pharmacy and nursing stations where such drugs are being administered concerning the dosage form, route of administration, strength, uses, side effects, interactions and symptoms of toxicity of those drugs.

(Added to NAC by Bd. of Pharmacy, eff. 3-27-90; A 9-12-91)

NAC 639.4685 Handling of medications in correctional institutions without pharmacies. (NRS 639.070, 639.072) A correctional institution that does not have a pharmacy may store medications to be dispensed to an ultimate user pursuant to the following requirements:

1. The responsible practitioner or authority shall develop written plans, establish procedures and provide space and accessories for the secure storage, control, administration and disposal of all such drugs in consultation with a pharmacist and the manager of the facility. Such plans, procedures, space or accessories must include:

(a) Cabinets, closets and refrigeration units that are lockable.

(b) Procedures for administration or delivery of medicines to inmates as prescribed.

(c) Procedures for confirming the fact that the inmate has ingested the medication.

(d) A procedure for recording the fact that prescribed medications have or have not been administered, by whom the medication was administered and, if the medication was not administered, the reason it was not administered.

(e) A policy prohibiting the administration, distribution, delivery or dispensing of drugs by inmates.

(f) A policy limiting the length of time medications may be administered without further medical evaluation.

(g) A requirement that the pharmacist prepare, at least annually, a written report on the status of services by the pharmacy in the institution which must be delivered to the responsible practitioner or authority and the manager of the facility.

(h) Procedures describing the circumstances and methods for contacting the pharmacist.

2. Procedures related to the handling of medication and the classifications of personnel who are authorized to handle medication must include provisions for the:

(a) Procurement of medication;

(b) Storage of medication;

(c) Administration of medication;

(d) Disposal of medication; and

(e) Providing of medication to inmates upon their release.

(Added to NAC by Bd. of Pharmacy, eff. 9-12-91)

NAC 639.469 Standards for premises. (NRS 639.070, 639.071, 639.072)

1. A pharmacy shall have adequate space necessary for the storage, compounding, labeling, dispensing, distribution and sterile preparation of drugs prepared in the pharmacy.

2. The pharmacy must be kept clean and arranged in an orderly manner. All required equipment must

be clean and in good operating condition.

3. A sink with hot and cold running water must be available to all personnel of the pharmacy and must be maintained in a sanitary condition at all times.

4. The pharmacy must be well lighted and ventilated.

5. The temperature of the pharmacy must be maintained within a range compatible with the proper storage of drugs. The temperature of the refrigerator must be maintained within the range set forth in subsection 1 of NAC 639.527.

6. The pharmacy must have a locked storage area for controlled substances listed in schedule II and other controlled substances requiring additional security.

7. Flammable materials must be stored in a designated area. The area must meet the requirements of local and state fire laws.

(Added to NAC by Bd. of Pharmacy, eff. 3-27-90; A 9-12-91; R128-10, 12-16-2010)

NAC 639.470 Security of premises. (NRS 639.070, 639.071, 639.072)

1. All areas occupied by a pharmacy must be able to be locked to prevent access by unauthorized personnel.

2. All personnel of the pharmacy, while on duty, are responsible for the security of the pharmacy and shall provide adequate safeguards against the theft or diversion of controlled substances and dangerous drugs and the records of those drugs.

(Added to NAC by Bd. of Pharmacy, eff. 3-27-90; A 9-12-91)

NAC 639.472 Maintenance of reference library. (NRS 639.070, 639.071, 639.072) A pharmacy must maintain a reference library that includes the following:

1. A current copy of:

(a) All state statutes and regulations relating to the practice of pharmacy and to the sale of drugs and controlled substances; and

(b) The Federal Controlled Substances Act (Title II of Pub. L. 91-513, Oct. 27, 1970, 84 Stat. 1242) and the regulations adopted pursuant thereto or an official publication describing the requirements of that act and the regulations adopted pursuant thereto.

2. The American Hospital Formulary Service, with current supplements, or Facts and Comparisons, with current supplements.

3. At least one current text in one of the following subjects:

(a) Theoretical and practical pharmacy.

(b) Pharmacology.

(c) Therapeutics.

4. A current text relating to each of the following:

(a) Compatibility information, if parenteral admixture is performed by the pharmacy;

(b) Information concerning the interaction of drugs; and

(c) Information concerning antidotes.

5. Current copies of one of the following:

(a) *United States Pharmacopeia - National Formulary*, as adopted by reference in paragraph (c) of subsection 1 of NAC 639.670;

(b) *United States Pharmacopeia - Drug Information*; or

(c) *Remington's Pharmaceutical Sciences.*

6. A current copy of the Food and Drug Administration Approved Drug Products.

(Added to NAC by Bd. of Pharmacy, eff. 3-27-90; A 9-12-91; R035-06, 9-18-2008)

NAC 639.473 Procurement and storage of drugs. (NRS 639.070, 639.071, 639.072)

1. The managing pharmacist of a pharmacy is responsible for the procurement and storage of drugs in that pharmacy. The managing pharmacist shall determine the specifications of all drugs procured by the medical facility or correctional institution in which the pharmacy is located.

2. A drug may not be dispensed or distributed after the expiration date of the drug.

3. Outdated drugs must be removed from stock and identified and maintained separately from other stock until disposal.

(Added to NAC by Bd. of Pharmacy, eff. 3-27-90; A 9-12-91)

NAC 639.474 Development and use of formulary. (NRS 639.070, 639.071, 639.072) A formulary

must be developed and available for use by the managing or consultant pharmacist of a pharmacy.
(Added to NAC by Bd. of Pharmacy, eff. 3-27-90; A 9-12-91)

NAC 639.475 Preparation and labeling of admixtures. (NRS 639.070, 639.071, 639.072)
1. The managing pharmacist shall provide written guidelines for preparing parenteral admixture products to ensure that all pharmaceutical requirements are met.
2. A label must be affixed to the container of any admixture. The label must include, but is not limited to:
(a) The name of the patient for whom the admixture was prepared and the facility's or institution's identification of that patient;
(b) The name and amount of the drugs added;
(c) The name of the basic solution;
(d) The name, initials or identifying code of the pharmacist who prepared or verified the admixture; and
(e) The expiration date of the solution.
(Added to NAC by Bd. of Pharmacy, eff. 3-27-90; A 9-12-91)

NAC 639.476 Prepackaging of drugs. (NRS 639.070, 639.071, 639.072)
1. A pharmacy may prepackage drugs in quantities suitable for distribution within the facility or institution. The prepackaging may be performed only by a pharmacist or a pharmaceutical technician.
2. The label of a prepackaged unit must include:
(a) The generic or trade name of the drug, its strength and the dosage form;
(b) The lot number;
(c) The expiration date of the drug; and
(d) The quantity of the drug if the unit dose does not equal the unit of use.
3. A record of a prepackaged drug must be maintained that includes:
(a) The generic or trade name of the drug, its strength and the dosage form;
(b) The pharmacy's lot number;
(c) The name of the manufacturer;
(d) The manufacturer's lot number;
(e) The manufacturer's expiration date for the drug;
(f) The quantity per package, if more than one tablet or capsule is in a unit dose package;
(g) The number of packages;
(h) The date it was packaged and the assigned expiration date; and
(i) The initials of the responsible pharmacist.
4. Stock packages, prepackaged units and control records must be inspected by the pharmacist before the drugs may be included in regular stock.
(Added to NAC by Bd. of Pharmacy, eff. 3-27-90; A 9-12-91; 11-15-93)

NAC 639.477 Policies and procedures for distribution of drugs. (NRS 639.070, 639.071, 639.072)
1. All medical facilities and correctional institutions shall develop and carry out written policies and procedures for the distribution of drugs in that facility or institution. The standards for accreditation of the American Correctional Association and the National Commission of Correctional Health Care must be used as a guideline for these policies and procedures by a correctional institution. The standards for accreditation of the American Correctional Association may be obtained by writing to the American Correctional Association, Publishing and Periodicals Division, 206 North Washington Street, Suite 200, Alexandria, Virginia 22314, or by calling (800) 222-5646 ext. 0129. The standards of accreditation of the National Commission of Correctional Health Care may be obtained by writing to the National Commission of Correctional Health Care, 1145 West Diversey Parkway, Chicago, Illinois 60614.
2. The written policies and procedures must include procedures regarding:
(a) Controlled substances.
(b) Investigational drugs.
(c) Prepackaging and manufacturing.
(d) Stop orders.
(e) Orders for medication.
(f) Physicians' orders.
(g) Floor stocks.

(h) Reports of adverse reactions.
(i) Drugs brought into the facility by patients.
(j) Medications for furloughs.
(k) The self-administration of drugs.
(l) Emergency supplies of drugs.
(m) A formulary.
(n) Monthly inspections of nursing stations and storage areas for drugs.
(o) Samples of drugs.
(p) Reports of defects in drug products.
(q) The recall of drugs.
(r) Outdated drugs.
(s) The routine distribution of medication for inpatients.
(t) The preparation and distribution of IV admixtures.
(u) The handling of orders for medication if a pharmacist is not on duty.
(v) Requests for drugs that are not listed on the formulary.
(w) Administering medication.
(Added to NAC by Bd. of Pharmacy, eff. 3-27-90; A 9-12-91)

NAC 639.478 Limitations on distribution of drugs. (NRS 639.070, 639.071, 639.072)
1. A drug may be given to a patient in a medical facility or correctional institution only on the order of a practitioner or an agent of the practitioner.
2. A drug may be distributed in a medical facility or correctional institution only from the original or a direct copy of the practitioner's order for medication.
3. A controlled substance listed in schedule II may be distributed to outpatients only pursuant to a written prescription.
(Added to NAC by Bd. of Pharmacy, eff. 3-27-90; A 9-12-91)

NAC 639.479 Withdrawal of drugs when full-time pharmacist is absent. (NRS 639.070, 639.071, 639.072) If a medical facility or correctional institution encompasses a pharmacy with a full-time pharmacist, and a practitioner orders a drug for administration to a patient of the facility or institution while the pharmacy is closed:
1. Prescription drugs and devices may be removed from the pharmacy only in sufficient quantities for immediate therapeutic needs.
2. Only a designated licensed nurse or practitioner may remove those drugs and devices.
3. The person authorized to make the withdrawal shall make a record at the time of the withdrawal containing:
(a) The name of the patient;
(b) The name of the device or drug withdrawn;
(c) If a drug is withdrawn, its strength and the dosage form;
(d) The dose prescribed;
(e) The quantity taken;
(f) The time and date of the withdrawal; and
(g) The signature of the person making the withdrawal.
4. The original or a direct copy of the order for the medication must be forwarded to the pharmacy.
5. The pharmacist shall verify the withdrawal as soon as practicable, but not later than:
(a) Seventy-two hours after the time of the withdrawal for a pharmacist in a medical facility; or
(b) Ninety-six hours after the time of the withdrawal for a pharmacist in a correctional institution.
(Added to NAC by Bd. of Pharmacy, eff. 3-27-90; A 9-12-91)

NAC 639.480 Withdrawal of drugs when part-time or consultant pharmacist is absent. (NRS 639.070, 639.071, 639.072) If a medical facility or correctional institution has a pharmacy with a part-time or consultant pharmacist, and a practitioner orders a drug for administration to a patient of the facility or institution while the pharmacist is not on duty or the pharmacy is closed:
1. Controlled substances, dangerous drugs and devices may be removed from the pharmacy only in sufficient quantities for therapeutic needs.
2. Only a designated licensed nurse or practitioner may remove those drugs and devices.
3. The person authorized to remove the drugs and devices shall make a record at the time of the

withdrawal containing:
(a) The name of the patient;
(b) The name of the device or drug withdrawn;
(c) If a drug is withdrawn, its strength and the dosage form;
(d) The dose prescribed;
(e) The quantity taken;
(f) The time and date of the withdrawal; and
(g) The signature of the person making the withdrawal.
4. The original or a direct copy of the order for the medication must be forwarded to the pharmacy.
5. The pharmacist shall verify the withdrawal:
(a) Personally at least every 90 days; and
(b) By reviewing the records made pursuant to subsection 3 at least every 30 days during the intervals between the pharmacist's personal verifications.
(Added to NAC by Bd. of Pharmacy, eff. 3-27-90; A 9-11-91; 9-12-91; R077-08, 8-26-2008)

NAC 639.481 Withdrawal of drugs when facility uses floor stock and pharmacy is closed. (NRS 639.070, 639.071, 639.072) If a medical facility or correctional institution uses a full or partial floor stock to distribute drugs and its pharmacy is closed:
1. Controlled substances, dangerous drugs and devices may be removed from the pharmacy only in the original manufacturer's container or prepackaged container.
2. Only a designated licensed nurse or practitioner may remove those drugs and devices.
3. The person authorized to make the withdrawal shall make a record at the time of the withdrawal containing:
(a) The name of the device or drug withdrawn;
(b) If a drug is withdrawn, its strength and the dosage form;
(c) The quantity removed;
(d) The location of the floor stock;
(e) The date and the time of the withdrawal; and
(f) The signature of the person making the withdrawal.
4. A pharmacist shall verify the withdrawal pursuant to the following schedule:
(a) In a facility or institution with a full-time pharmacist, the withdrawal must be verified as soon as practicable, but not later than:
(1) Seventy-two hours after the time of the withdrawal for a pharmacist in a medical facility; or
(2) Ninety-six hours after the time of the withdrawal for a pharmacist in a correctional institution.
(b) In a facility or institution with a part-time or consultant pharmacist, the withdrawal must be verified after a reasonable interval, but not later than 30 days after the withdrawal.
(Added to NAC by Bd. of Pharmacy, eff. 3-27-90; A 9-11-91; 9-12-91)

Records

NAC 639.482 Maintenance and availability of records. (NRS 639.070, 639.071, 639.072)
1. Each record required to be kept pursuant to NAC 639.483 to 639.489, inclusive, must be kept by a pharmacy for at least 2 years after the date of the record.
2. Records maintained by a pharmacy must be made available for inspection and copying upon the request of the Board, its representatives, or another authorized local, state or federal law enforcement agency.
(Added to NAC by Bd. of Pharmacy, eff. 3-27-90; A 9-12-91)

NAC 639.483 Statutes applicable to maintenance of records. (NRS 639.070, 639.071, 639.072) A pharmacy must maintain records for outpatients pursuant to the provisions of chapters 453, 454 and 639 of NRS governing retail pharmacies.
(Added to NAC by Bd. of Pharmacy, eff. 3-27-90; A 9-12-91)

NAC 639.484 Contents and maintenance of chart orders. (NRS 639.070, 639.071, 639.072)
1. Each original chart order must contain:
(a) The patient's name and the medical facility's or correctional institution's identification of that patient;

(b) The name of the drug, its strength and the route of administration;
(c) Directions for the use of the drug;
(d) The date; and
(e) The practitioner's signature. Any verbal order signed by a practitioner's agent must be cosigned by the practitioner.
2. An original chart order must be maintained in the medical records of the patient along with the record of the administration of the medication.
(Added to NAC by Bd. of Pharmacy, eff. 3-27-90; A 9-12-91; R190-01, 3-4-2002)

NAC 639.485 Maintenance of records for controlled substances. (NRS 639.070, 639.071, 639.072)
1. A pharmacy shall maintain records for controlled substances:
(a) In a readily retrievable manner.
(b) In a manner that establishes the receipt, distribution and destruction of all controlled substances handled by the pharmacy.
2. A pharmacy shall maintain a perpetual inventory of any controlled substance listed in schedule II.
3. Records of the distribution of controlled substances listed in schedule II, schedule III or schedule IV must include:
(a) The name of the drug, dosage form and strength.
(b) The name of the pharmacist distributing or authorizing the distribution of the controlled substance.
(c) The name of the authorized person receiving the controlled substance. This information may be included on the record of administration.
(d) The location to which the controlled substance is being distributed.
(e) Controlled substances returned to the pharmacy.
(f) A record of any waste of any prepared or partially administered dose of a controlled substance, which must be witnessed and cosigned by another person who is licensed to provide medical care.
(Added to NAC by Bd. of Pharmacy, eff. 3-27-90; A 9-12-91; R156-99, 3-1-2000)

NAC 639.486 Maintenance of records of controlled substances administered from floor stock. (NRS 639.070, 639.071, 639.072)
1. A pharmacy shall maintain records of controlled substances administered from floor stock. The records must include:
(a) The name of the patient to whom the controlled substance was administered.
(b) The name of the controlled substance, its dosage form and strength.
(c) The time and date on which the controlled substance was administered to the patient.
(d) The quantity of the controlled substance administered.
(e) The signature of the person removing the controlled substance.
(f) Controlled substances returned to the pharmacy.
(g) A record of any waste of a controlled substance which, except as otherwise provided in subsection 2, must be witnessed and cosigned by another person who is licensed to provide medical care.
2. A record of any waste of a controlled substance kept pursuant to subsection 1 is not required to be witnessed and cosigned as required by subsection 1 if:
(a) The record of waste is for a controlled substance which was administered by a practitioner authorized to administer anesthesia; and
(b) Other current, complete and accurate records for the controlled substance administered and wasted are created and maintained.
3. Records maintained pursuant to this section must be maintained separately from records of patients.
(Added to NAC by Bd. of Pharmacy, eff. 3-27-90; A 9-12-91; 5-22-96; R157-99, 3-1-2000; R042-04, 5-25-2004)

NAC 639.487 Maintenance of additional records. (NRS 639.070, 639.071, 639.072) In addition to any other requirements for keeping records, a pharmacy shall maintain the following records:
1. Copy 3 of the order form of the Drug Enforcement Administration (DEA 222C), properly dated, initialed and filed, copies of each unaccepted or defective order form, and any attached statements or other documents.
2. Suppliers' invoices of controlled substances and dangerous drugs. The pharmacist or other

personnel of the pharmacy shall clearly record on each invoice the actual date on which the controlled substance or dangerous drug was received.

3. Suppliers' credit memos for controlled substances and dangerous drugs.

4. The biennial inventory of controlled substances required by the Drug Enforcement Administration.

5. Any reports of theft or significant loss of controlled substances submitted to the Drug Enforcement Administration.

6. Reports of the surrender or destruction of controlled substances or dangerous drugs, or both, to an appropriate state or federal agency.

7. A register book for nonprescription drugs listed in schedule V.

(Added to NAC by Bd. of Pharmacy, eff. 3-27-90; A 9-12-91)

NAC 639.488 Maintenance of records for distribution of controlled substances to another pharmacy or practitioner. (NRS 639.070, 639.071, 639.072)

1. If a pharmacy distributes controlled substances listed in schedule III, IV or V to another pharmacy or a practitioner, it shall maintain invoices showing:

(a) The actual date of distribution;

(b) The name, strength and quantity of controlled substances distributed;

(c) The distributing pharmacy's name, address and registration number given to it by the Drug Enforcement Administration; and

(d) The name, address and registration number of the pharmacy or practitioner to whom the controlled substances were distributed.

2. If a pharmacy distributes controlled substances listed in schedule I or II to another pharmacy or a practitioner, it shall maintain Copy 1 of the order form of the Drug Enforcement Administration (DEA 222C) furnished by the pharmacy or practitioner to whom the controlled substances were distributed. The form must show the quantity of controlled substances distributed and the actual date of distribution.

(Added to NAC by Bd. of Pharmacy, eff. 3-27-90; A 9-12-91)

NAC 639.489 Separation of certain records. (NRS 639.070, 639.071, 639.072)

1. Except for records of distributions from floor stock, records of controlled substances listed in schedules I and II must be maintained separately from other records maintained by a pharmacy.

2. Records of controlled substances listed in schedules III, IV and V may be maintained either separately from all other records maintained by the pharmacy or in such form that the records are readily retrievable.

(Added to NAC by Bd. of Pharmacy, eff. 3-27-90; A 9-12-91)

NAC 639.490 Permission to use centralized system for keeping records. (NRS 639.070, 639.071, 639.072) A pharmacy wishing to use a centralized system for keeping records must submit written notification to the Regional Director of the Drug Enforcement Administration by registered or certified mail. A copy of the notification must be submitted to the Board. Unless the pharmacy is informed by the Regional Director that permission to keep central records is denied, the pharmacy may begin to maintain such records 14 days after receipt of the notification by the Regional Director. A copy of the notification must be maintained by the pharmacy.

(Added to NAC by Bd. of Pharmacy, eff. 3-27-90; A 9-12-91)

Chart Order Processing Services

NAC 639.491 Definitions. (NRS 639.070) As used in NAC 639.491 to 639.4917, inclusive, unless the context otherwise requires, the words and terms defined in NAC 639.4911 to 639.4914, inclusive, have the meanings ascribed to them in those sections.

(Added to NAC by Bd. of Pharmacy by R015-05, eff. 10-31-2005; A by R098-07, 12-4-2007)

NAC 639.4911 "Chart order" defined. (NRS 639.070) "Chart order" has the meaning ascribed to it in NAC 639.442.

(Added to NAC by Bd. of Pharmacy by R015-05, eff. 10-31-2005)

NAC 639.49115 "Chart order processing services" defined. (NRS 639.070) "Chart order processing services" means nondispensary pharmaceutical services that are provided by a pharmacy to a

hospital or correctional institution, including, without limitation:

1. Receiving, interpreting and clarifying a chart order received from a hospital or correctional institution;
2. Entering information regarding a chart order into the computerized data system of a hospital or correctional institution;
3. Interpreting clinical data regarding a patient of a hospital or correctional institution;
4. Performing therapeutic interventions regarding a patient of a hospital or correctional institution;
5. Providing information to the appropriate staff of a hospital or correctional institution regarding a chart order submitted by the hospital or correctional institution; and
6. Providing information regarding the treatment of a patient of a hospital or correctional institution.

(Added to NAC by Bd. of Pharmacy by R098-07, eff. 12-4-2007)

NAC 639.4912 "Correctional institution" defined. (NRS 639.070) "Correctional institution" has the meaning ascribed to it in NAC 639.4465.

(Added to NAC by Bd. of Pharmacy by R015-05, eff. 10-31-2005)

NAC 639.4913 "Off-site pharmaceutical service provider" defined. (NRS 639.070) "Off-site pharmaceutical service provider" means a pharmacy that provides remote chart order processing services to a hospital or correctional institution that is owned by the same entity as the pharmacy or with which the pharmacy has contracted to provide remote chart order processing services.

(Added to NAC by Bd. of Pharmacy by R015-05, eff. 10-31-2005)

NAC 639.4914 "Remote chart order processing services" defined. (NRS 639.070) "Remote chart order processing services" means chart order processing services provided by an off-site pharmaceutical service provider to a hospital or correctional institution, including, without limitation, transferring information regarding a chart order from the off-site pharmaceutical service provider to members of the staff of the hospital or correctional institution that submitted the chart order.

(Added to NAC by Bd. of Pharmacy by R015-05, eff. 10-31-2005; A by R098-07, 12-4-2007)

NAC 639.4915 Provision of services by pharmacies within certain hospitals and correctional institutions. (NRS 639.070, 639.071, 639.072) A pharmacy located within a hospital or correctional institution that is required to have a full-time managing pharmacist pursuant to NAC 639.465 shall provide chart order processing services to the hospital or correctional institution. The pharmacy shall provide the chart order processing services by:

1. Operating at all times; or
2. Employing a pharmacist who is on duty at all times that the pharmacy is operating and either:

(a) Employing a pharmacist who is available at all times that the pharmacy is not operating; or

(b) Contracting with an off-site pharmaceutical service provider that is available at all times that the pharmacy is not operating.

(Added to NAC by Bd. of Pharmacy by R015-05, eff. 10-31-2005; A by R098-07, 12-4-2007)

NAC 639.4916 Provision of remote services by pharmacist employed by off-site pharmaceutical service provider. (NRS 639.070)

1. A pharmacist who is employed by an off-site pharmaceutical service provider to provide remote chart order processing services to a hospital or correctional institution pursuant to NAC 639.4915 must:

(a) Be licensed to practice in Nevada;

(b) Be trained in the policies and procedures of the hospital or correctional institution regarding all policies and procedures of the hospital or correctional institution with which the pharmacist must comply, including, without limitation, the provision of pharmaceutical services, security and confidentiality of patient records;

(c) Except as otherwise provided in subsection 3, be provided with the same computerized system and access to data regarding a patient for whom a chart order has been submitted that would be available to a pharmacist employed by the pharmacy located within the hospital or correctional institution, including, without limitation:

(1) The height, weight and age of the patient and any allergies that the patient may have;

(2) The medical records regarding any medications prescribed to the patient;

(3) The results of any relevant laboratory tests, to the extent that those results are available in the

computerized system of the hospital or correctional institution;

(4) The health history and notes regarding physical examinations, to the extent that the information is available in the computerized system of the hospital or correctional institution;

(5) Any notes provided by a physician, nurse or other medical staff of the institution, to the extent that those notes are available in the computerized system of the hospital or correctional institution;

(6) A legible copy of the chart order that is available through a scanned image in the computerized system of the hospital or correctional institution or by facsimile machine; and

(7) Any other information that is available in the computerized system of the hospital or correctional institution that is relevant or necessary for the pharmacist to provide pharmaceutical services; and

(d) Demonstrate to the off-site pharmaceutical service provider that the pharmacist is competent and knowledgeable in the use of the computerized system of the hospital or correctional institution and in providing pharmaceutical services in a hospital or correctional institution.

2. Before a pharmacist who is employed by an off-site pharmaceutical service provider provides remote chart order processing services to a hospital or correctional institution, the pharmacist must review any relevant information regarding the patient for whom a chart order has been submitted. The pharmacist must, before approving a chart order to be filled, evaluate:

(a) The overutilization or underutilization of a medication;

(b) Therapeutic duplication;

(c) The appropriateness of the prescribed dosage and route of administration;

(d) The appropriateness of the directions for use of the medication;

(e) The appropriateness of the duration of the treatment with the prescribed medication;

(f) Any contraindications of the medication and a particular disease, ailment or allergy of the patient;

(g) Any contraindications or interactions between multiple medications prescribed for the patient; and

(h) The potential abuse or misuse of a medication.

3. In an emergency, a pharmacist may render remote chart order processing services without being provided with all of the information required by paragraph (c) of subsection 1 if the pharmacist believes, in his or her professional judgment, that he or she has received sufficient information from the staff of the hospital or correctional institution to render the services.

4. A pharmacist who is employed by an off-site pharmaceutical service provider may refuse to approve the filling of a chart order if, in the judgment of the pharmacist, the chart order is not safe or reasonable for the patient. A pharmacist who refuses to approve the filling of a chart order pursuant to this subsection must notify the hospital or correctional institution as soon as practicable that he or she has refused to approve the filling of the chart order.

5. Each time that a pharmacist who is employed by an off-site pharmaceutical service provider provides remote chart order processing services pursuant to this section, the pharmacist shall make a notation in the computerized system of the hospital or correctional institution that indicates:

(a) The name or other identifier of the pharmacist;

(b) The date and time that the pharmacist provided the services and, if applicable, approved the filling of a chart order; and

(c) The specific services provided by the pharmacist.

6. The managing pharmacist of a pharmacy that has a contract with or is owned by the same entity as an off-site pharmaceutical service provider may limit the remote chart order processing services provided by a pharmacist employed by the off-site pharmaceutical service provider.

(Added to NAC by Bd. of Pharmacy by R015-05, eff. 10-31-2005)

NAC 639.4917 Policies and procedures of off-site pharmaceutical service providers. (NRS 639.070) Each off-site pharmaceutical service provider shall establish and follow policies and procedures for:

1. Protecting the confidentiality and integrity of patient information;

2. Assuring that pharmacists employed by the off-site pharmaceutical service provider comply with the provisions of NAC 639.4916;

3. Complying with all applicable state and federal statutes, regulations and rules, including, without limitation, maintaining records;

4. Ensuring that its records are made readily accessible to members of the Board and employees, agents and designees of the Board;

5. Conducting an ongoing program for the improvement of the provision of pharmaceutical services

that is designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, improve patient care and resolve problems identified by the program;

6. Performing an annual review of the program conducted pursuant to subsection 5;

7. Assuring that the pharmacists employed by the off-site pharmaceutical service provider are able to communicate with identified employees of the hospital or correctional institution as necessary to provide pharmaceutical services, including, without limitation, communicating with pharmacists employed by the hospital or correctional institution; and

8. The provision of pharmaceutical services at times when the off-site pharmaceutical service provider temporarily or permanently cannot provide such services.

(Added to NAC by Bd. of Pharmacy by R015-05, eff. 10-31-2005)

Laws and Rules

- State Pharmacy Laws
- State Pharmacy Administrative Rules
- Important Legal Time Limits

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TITLE XXX
OCCUPATIONS AND PROFESSIONS

CHAPTER 318
PHARMACISTS AND PHARMACIES

Pharmacy Board

Section 318:8

318:8 Enforcement of Law. – It shall be the duty of the board, through officials and employees appointed by it or under its supervision for that purpose, and of all peace officers within the state, and of all county attorneys, to enforce all the provisions of this chapter. When so requested, the department of health and human services and its officials and employees shall cooperate with the board in collecting and analyzing samples of drugs and medicines sold, or suspected of being sold, in violation of this chapter. The members of the board, its inspectors and investigators shall have free access during business hours to all places where drugs, medicines, poisons or hypodermic devices are held, stored, or offered for sale and to all records of sale and disposition of drugs.

Source. 1921, 122:5. PL 210:8. 1931, 123:1. RL 256:8. RSA 318:8. 1965, 275:2. 1981, 484:18. 1985, 324:4. 1995, 310:181, eff. Nov. 1, 1995.

Licensure of Pharmacies

Section 318:38

318:38 Permit; Fees. –

I. The board shall, upon application and hearing, issue a permit to maintain and operate a pharmacy to such persons, firms, or corporations as they deem qualified to conduct a pharmacy. The permit shall be issued to the pharmacy in the name of the corporation or the owner of the pharmacy. This permit, to be known as a pharmacy permit, shall certify that the designated pharmacist-in-charge has accepted the responsibility for the safe, effective operation of a pharmacy and compliance with all pharmacy and drug laws or regulations; that the premises named in the permit are a fit place to practice pharmacy including, but not limited to, the compounding and dispensing of medicines upon prescriptions and for the manufacture, sale, and distribution of drugs, medicines, and poisons; and that such premises and acts shall be under the direct supervision of a licensed pharmacist. The holder of a pharmacy permit may keep this pharmacy open at all hours for the compounding, dispensing, and sale of drugs and medicines provided that a pharmacist is present and on duty; except that in an institutional setting, in the

absence of a pharmacist, a registered nurse, designated by the institution for this purpose, may enter and obtain from an institutional pharmacy such drugs as are needed in an emergency situation or as may otherwise be provided for in this chapter. The applicant for a pharmacy permit or a renewal thereof shall provide the board with all information it deems necessary for determining the applicant's qualifications to own and operate a pharmacy in the public interest.

II. All pharmacy permits shall expire when there is a change of ownership of the pharmacy or at midnight on December 31 of each year. Every pharmacy that wishes to continue to operate as such shall renew its permit annually as of January 1 or immediately when the permit expires for any other reason. It shall be deemed a violation of the provisions of this chapter for any pharmacy to be open or operated beyond the expiration date of its permit.

III. All applicants for a pharmacy permit shall pay a reasonable fee as established by the board for each original pharmacy permit and for each renewal thereof.

Source. 1921, 122:25, 26. PL 210:39. 1931, 123:2. RL 256:39. RSA 318:38. 1955, 241:4. 1963, 83:6. 1967, 191:1. 1971, 458:6. 1973, 453:7. 1977, 563:44. 1979, 155:28. 1981, 484:18, 19, 21. 2001, 282:7, eff. July 1, 2001.

PART Ph 709 INSTITUTIONAL PRACTICES

Ph 709.01 Definitions.

(a) "Automated medication supply system" means an electronically controlled system that performs operations or activities relative to the storage and distribution of medications for administration and which collects, controls, and maintains all transaction information.

(b) "Electronic signature", for purposes of paragraph (a) above, means a unique security code or other identifier which specifically identifies the person entering information into a data processing system. An institution which utilizes electronic signatures shall maintain a permanent list of the unique security codes and the persons to whom they have been assigned.

(c) "Satellite pharmacy" means a pharmacy in an institutional setting under the direction of a licensed pharmacist, that is remote from the centrally licensed pharmacy, but within the same facility/location and dependent upon the centrally licensed pharmacy for administrative control, staffing and drug procurement.

Source. #2260, eff 01-05-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED, 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05; ss by #8572, eff 2-23-06

Ph 709.02 Licensing and Practice Standards.

(a) A pharmacy permit shall be required for each institution with an on-premise pharmacy. Such permit shall be issued to a pharmacist-in-charge, who shall be licensed in the state of New Hampshire. When an institution procures prescription drugs for its patients only on individual prescriptions for specific patients from an off-premise licensed pharmacy, the institution shall not be required to obtain a pharmacy permit.

(b) If an institution does not have a pharmacy on its premises, it may enter into an agreement with a pharmacy licensed to provide such services. Such agreement shall be in writing and shall state the policy and procedures as required by Ph 709. A copy of the agreement shall be made available by the consultant pharmacist to the board upon request. The consultant pharmacist shall be responsible for the maintenance of all records and the compliance with state and federal laws and rules governing the practice of pharmacy.

(c) An institutional license shall permit the pharmacy to dispense medications to in-patients of the institution, staff or employees of the institution, interim supplies of medication to outpatients in emergency situations and home infusion therapy to contractual patients not requiring hospitalization. If a pharmacist is on the premises, outpatient prescription services may be provided by the pharmacy, on a one-time, no-refill basis, to an ambulatory care patient and any patient who is being discharged with medications related to the patient's hospitalization. Labeling for all outpatient prescriptions shall be according to RSA 318:47-a and RSA 318-B:13, II.

(d) Satellite pharmacies located in an institution shall:

(1) Function under the central pharmacy license; and

(2) Be mobile or stationary and lockable so as to prevent access by unauthorized personnel.

(e) Members of the board and/or their agents shall inspect the pharmacy, drug room/medication room and all areas or departments of the facility where drugs are stored, manufactured, compounded, dispensed or distributed to ensure:

(1) That adequate drug security and storage requirements are met;

(2) That proper records are maintained; and

(3) That the facility is in compliance with all local, state and federal drug and pharmacy laws and rules.

(f) Those facilities obtaining prescription drugs only on individual prescriptions for specific patients from an off-premise licensed pharmacy shall not be exempt from inspection.

(g) Each institution shall have a pharmacy and therapeutics committee or a comparable committee of its medical staff. This committee shall be composed of representatives of the medical staff and the pharmacist-in-charge, or a licensed staff pharmacist designated by the pharmacist-in-charge, and representatives of the administrative and nursing departments. The committee shall meet at least twice a year. The major functions of this committee shall be to establish the written policies and procedures governing the practice of pharmacy, use of drugs, drug specifications and drug distribution.

(h) When a drug has been prescribed by brand name, an institutional pharmacy may dispense a generic or therapeutic equivalent that has been approved by the pharmacy and therapeutics committee or its equivalent only to in-patients of the institution, staff or employees of the institution, or interim supplies of medication to outpatients in emergency situations.

Source. #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED: 1-19-96

New. #6181-B, eff 2-5-96; amd by #6933, eff 2-1-99; paragraphs (a), (b), (d), (e), and (f) EXPIRED: 2-5-04; amd by #8316, eff 3-26-05; ss by #8572, eff 2-23-06

Ph 709.03 Environment.

(a) The institutional pharmacy shall be enclosed, lockable and alarmed;

(b) The institutional pharmacy shall have adequate space necessary for the storage, compounding, labelling, dispensing and sterile preparation of drugs prepared in the pharmacy.

(c) The institutional pharmacy shall be arranged in an orderly fashion and shall be kept clean.

(d) A sink with hot and cold running water shall be available to all pharmacy personnel.

(e) The institutional pharmacy shall have locked storage for schedule II controlled substances and other controlled drugs requiring additional security.

(f) The institutional pharmacy shall have designated areas for the storage of flammable and caustic materials. Such areas shall meet the requirements set by local and state fire laws.

(g) The institutional pharmacy shall have a designated area for the laminar air flow hood for the preparation of sterile products.

Source. #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED, 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05

Ph 709.04 Drug Security.

(a) Drugs stored in any area or department of the facility shall be plainly labelled and kept in a specifically designated, well-illuminated cabinet, closet or storage area and shall be accessible only to authorized personnel.

(b) When controlled drugs are stored in authorized areas other than in the pharmacy, special locked storage for all controlled substances requiring additional security shall be used.

(c) When using an automated medication supply system, the pharmacist-in-charge shall have the responsibility for assigning, discontinuing, or changing personnel access codes.

(d) A pharmacist or registered pharmacy technician under the direction of a pharmacist shall visit and create a written record, at least monthly, all areas or departments of the institution where drugs, biologicals, pharmaceutical chemicals or other pharmaceutical preparations are stored to ensure that they are properly labelled, have not reached their expiration date and show no signs of deterioration. Any substance not conforming to these standards shall be removed from stock.

(e) A written record of each monthly inspection specified in (d) above shall be maintained in the pharmacy and shall be available to the board upon request.

(f) The pharmacist shall ensure that the areas specified in (d) above are in compliance with federal and state drug laws relative to security, drug distribution and product tampering.

(g) The pharmacist-in-charge shall develop a distribution system which shall prevent the illicit diversion of drugs. When applicable, the inventory of all schedule II controlled

substances and other controlled drugs as required by local, state and federal law stored in any area or department of the facility except the pharmacy shall be checked and recorded by 2 persons at least every 24 hours or at each shift change when using a manual dispensing system when the department is open or every 7 days when using an automated dispensing system and accountability records shall be maintained in the department of the facility or the pharmacy.

(h) When an emergency drug kit other than regulated by Ph 705.03, containing controlled substances is opened, shift counts shall be done by the nursing staff on all controlled substances until resealed by a pharmacist.

Source. #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED, 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05; amd by #8572, eff 2-23-06

Ph 709.05 Dispensing Practices.

(a) Drugs shall be dispensed only by or in the presence of and under the supervision of a pharmacist, physician, dentist, optometrist, advanced registered nurse practitioner, physician assistant or podiatrist in compliance with local, state and federal pharmacy-related laws and rules. Upon the written order of a physician, dentist, optometrist, advanced registered nurse practitioner, physician assistant or podiatrist, a nurse may leave a properly labelled container of any non-controlled drug at the patient's bedside. A licensed nurse shall not dispense or compound drugs except as permitted by RSA 318:42.

(b) Whenever feasible, the pharmacy shall dispense medications from the original or direct copy of the prescriber's written order. Drugs shall be provided to patients in institutions only on the order of a practitioner legally authorized to write prescriptions. No change in the order for drugs shall be made without the approval of a practitioner qualified to write prescriptions.

(c) Each order pursuant to (b) above shall include at least the:

(1) Patient's name and location;

(2) Date of the order;

(3) Name and dosage of the drug;

(4) Directions; and

(5) Signature of the prescriber or licensed health care professional receiving the order.

(d) Written policies and procedures shall be adopted which establish the method utilized in the procurement, storage and distribution of drugs in all areas or departments of the facility, and which are consistent with state and federal pharmacy laws and rules.

Source. #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED, 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05; amd by#8572, eff 2-23-06

Ph 709.06 Access to the Pharmacy.

(a) Only a pharmacist shall have access to the pharmacy and its drug supplies. However, this shall not preclude the use of supportive personnel, approved by the pharmacist-in-charge, from being present in the pharmacy provided that the pharmacist is in the institution. The pharmacist-in-charge of each institutional pharmacy shall establish written policies identifying specific situations when pharmacy supportive personnel may be present in the pharmacy in the absence of a licensed pharmacist.

(b) In the absence of a pharmacist and in accordance with RSA 318:38,I licensed nurses, designated for this purpose by the pharmacist-in-charge, may obtain from the pharmacy or night cabinet such drugs as needed in an emergency when these drugs are not available in floor stock supplies.

(c) The authorized nurse may enter the pharmacy area and remove the following:

(1) A drug in its original container or a drug prepackaged for use within the facility subject to these rules; or

(2) An emergency supply of a drug from the original container to be administered to a specific patient.

(d) The authorized nurse shall leave a direct copy of the physician's order in the pharmacy or night cabinet and on a suitable form record the following:

(1) Name and strength of the drug taken;

(2) Dosage form taken;

(3) Quantity taken;

(4) Time and date of withdrawal;

(5) Patient name and/or location, where applicable;

(6) Nurse's signature.

(e) The nurse shall leave with the record the bulk container from which the medication was taken or a representative sample of the unit-dose medication.

Source. #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED, 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05

Ph 709.07 Drug Control in Ambulatory Patient Treatment Areas.

(a) In the ambulatory patient treatment areas, a medical practitioner may dispense drugs for the immediate needs of the patient, not in excess of a 72-hour supply, except that for Schedule II controlled substances a maximum of 48-hour supply shall be allowed, if permitted by the institution. However, the drug container shall be properly labeled.

(b) If a licensed pharmacist is on the premises, that pharmacist may fill one time, full amount, non-refillable prescriptions for patients for medications related to the ambulatory patient treatment visit.

(c) A readily retrievable record shall be made of all administrations and dispensing of controlled drugs in the ambulatory patient area.

(d) This record shall be separate from the patient's chart and include:

(1) Name and address of the patient;

(2) Name of the medical practitioner;

(3) Name, strength and quantity of the drug(s);

(4) Date of administration or dispensing; and

(5) Signature or electronic designation, as defined in Ph 709.01(b), of the agent removing the drug(s) from the inventory.

Source. #2260, eff 01-05-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED: 1-19-96

New. #6181-B, eff 2-5-96; amd by #6933, eff 2-1-99; paragraph (b) EXPIRED: 2-5-04; amd by #8316, eff 3-26-05; amd by #8572, eff 2-23-06; paras. (a) & (c) EXPIRED: 2-1-07

Ph 709.08 Investigational Drugs. Investigational drugs for research shall be used only under the supervision of the principal investigator and shall be approved by an appropriate medical staff committee. Such drugs shall be controlled by the pharmacy and shall be properly labelled. A central unit, which may be the pharmacy, shall be established where essential information on investigational drugs is maintained. Nurses shall be given basic pharmacologic information about the drug before administering.

Source. #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED, 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05; ss by #8572, eff 2-23-06

Ph 709.09 Purchase of Drugs.

(a) The pharmacist-in-charge, with the consent of the institution's pharmacy and therapeutics committee or comparable committee of its medical staff shall be responsible for the quality of all drugs, biologicals and pharmaceutical chemicals.

(b) Purchasing of drugs, pharmaceuticals, biologicals, intravenous and irrigation fluids shall be subject to approval of the pharmacist-in-charge with the consent of the institution's pharmacy and therapeutic committee or comparable committee of its medical staff.

(c) Radiopharmaceuticals, blood and blood products, radiopaque media and medical devices may be exempted from the approval and/or control of the pharmacist-in-charge by the institution's pharmacy and therapeutics committee.

Source. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05

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(1) The family and the first name of the person for whom the medication is intended (the patient);

(2) The street address and telephone number of the patient;

(3) Indication of the patient's age, birth date or age group (infant, child, adult) and gender;

(4) The height, weight and other patient specific criteria for those medications that are height or weight dose dependent;

(5) The original or refill date the medication is dispensed and the initials of the dispensing pharmacist, if those initials and date are not recorded on the original prescription or in any other record approved by the board;

(6) The number or designation identifying the prescription;

(7) The practitioner's name;

(8) The name, strength and quantity of the drug dispensed;

(9) The individual history, if significant, including known allergies and drug reactions, known diagnosed disease states and a comprehensive list of medications and relevant devices; and

(10) Any additional comments relevant to the patient's drug use, which may include any failure to accept the pharmacist's offer to counsel.

c. The information obtained shall be recorded in the patient's manual or electronic profile, or in the prescription signature log, or in any other system of records, and may be considered by the pharmacist in the exercise of his professional judgment concerning both the offer to counsel and content of counseling. The absence of any record of a failure to accept the pharmacist's offer to counsel shall be presumed to signify that the offer was accepted and that the counseling was provided.

L.2003,c.280,s.29.

45:14-69 Issuance of permit for pharmacy practice sites.

30. a. All pharmacy practice sites in this State, which engage in the practice of pharmacy in the State of New Jersey, shall be issued a permit by the board, and shall annually renew their permit with the board. If operations are conducted at more than one location, each location shall be issued a permit by the board for the dispensing of medicine.

b. The board may determine by rule or regulation the permit classifications of all pharmacy practice sites issued a permit under this act, and establish minimum standards for

pharmacy practice sites.

c. The board shall establish by rule or regulation the criteria which each site shall meet to qualify for a permit in each classification. The board may issue permits with varying restrictions to pharmacy practice sites if the board deems it necessary.

d. Each holder of a pharmacy practice site permit shall ensure that a licensed pharmacist be immediately available on the premises to provide pharmacy services at all times the pharmacy practice site is open.

e. Each pharmacy practice site shall have a pharmacist-in-charge. The pharmacist-in-charge and the owner of a pharmacy practice site shall be responsible for any violation of any laws or regulations pertaining to the practice of pharmacy.

f. The board may enter into agreements with other states or with third parties for the purpose of exchanging information concerning the granting of permits and the inspection of pharmacy practice sites located in this State and those located outside this State.

g. The board may deny, suspend, revoke, restrict or refuse to renew a permit for a pharmacy practice site that does not comply with the provisions of this act or any rule or regulation promulgated pursuant to this act.

L.2003,c.280,s.30.

45:14-70 Permit application procedures.

31. a. The board shall specify by rule or regulation the permit application procedures to be followed, including, but not limited to, the specification of forms to be used, the time and place the application is to be made and the fees to be charged.

b. Applicants for a permit to operate a pharmacy practice site within this State shall file with the board a verified application containing the information that the board requires of the applicant relative to the qualifications for the specific permit.

c. The board shall specify, by rule or regulation, minimum standards for any pharmacy practice site within this State. Pharmacy practice sites located in New Jersey shall be operated at all times under the immediate supervision of a pharmacist licensed to practice in this State.

d. Permits issued by the board pursuant to this act shall not be transferable or assignable without the approval of the board.

L.2003,c.280,s.31.

45:14-71 Licensure required for use of certain terms.

7. Prescription refill information; and

8. Action to be taken in the event of a missed dose.

(b) The offer to counsel may be made by pharmacy personnel. However, counseling shall be performed only by a pharmacist, or by a pharmacy intern or pharmacy extern under the immediate personal supervision of a pharmacist consistent with the requirements of N.J.A.C. 13:39-6.2(f)5.

(c) A pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses such counseling. The absence of any record of a failure to accept the pharmacist's offer to counsel shall be presumed to signify that the offer was accepted and that the counseling was provided.

(d) If the patient or caregiver is not physically present, the offer to counsel shall be made by telephone or in writing on a separate document accompanying the prescription. A written offer to counsel shall be in bold print, easily read, and shall include the hours a pharmacist is available and a telephone number where a pharmacist may be reached. The telephone service must be available at no cost to the pharmacy's primary patient population.

(e) The requirements of this section shall not apply to a pharmacist who dispenses any drug to an inpatient at a hospital or a long term care facility in which the resident is provided with 24-hour nursing care.

New Rule, R.2010 d.090, effective June 21, 2010.
See: 42 N.J.R. 132(a), 42 N.J.R. 1221(a).

SUBCHAPTER 8. (RESERVED)

SUBCHAPTER 9. PHARMACEUTICAL SERVICES FOR HEALTH CARE FACILITIES

13:39-9.1 Purpose and scope

(a) The rules in this subchapter shall apply to all retail pharmacies which contract to provide pharmaceutical services for healthcare facilities and to all institutional pharmacies which provide pharmaceutical services for their own health care system.

(b) An institutional pharmacy filling prescriptions for outpatient use shall comply with all retail pharmacy requirements of this chapter.

New Rule, R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
Former N.J.A.C. 13:39-9.1, Definitions, recodified to N.J.A.C. 13:39-9.2.

Case Notes

Out-of-state applicant could not be deemed an institutional pharmacy because: (1) the applicant's Wisconsin license stated only that it was a "pharmacy" and did not further describe the licensee as either retail or institutional; (2) the Justice Department registration recognized petitioner as a retail pharmacy; (3) an "institutional pharmacy" under New Jersey regulations must be within a healthcare facility or system licensed as such by the Board; and (4) the New Jersey regulations also state that the term "pharmacy" standing alone indicates a retail pharmacy. Because the applicant was not deemed an institutional pharmacy, its authorization as a Medicaid provider was not proscribed under N.J.A.C. 10:51-2.2(b)1. Phoenix Pharmacy, Inc. v. DMAHS, OAL Dkt. No. HMA 03266-07, 2007 N.J. AGEN LEXIS 489, Initial Decision (July 6, 2007).

13:39-9.2 Definitions

The following words and terms, as used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise.

"Drug administration" means a procedure in which a prescribed drug is given to a patient by an authorized person in accordance with all laws and rules governing such procedures.

"Formulary" means a continually revised compilation of pharmaceuticals available in the pharmacy for use in the facility developed by the Pharmacy and Therapeutics Committee.

"Health care facility" means a facility or institution licensed by the Department of Health and Senior Services pursuant to N.J.S.A. 26:2H-1 et seq.

"Health care system" means one or more health care facilities which are owned or controlled by the same legal entity.

"Institutional pharmacy" means the area in a health care facility or a health care system licensed by the Board as a pharmacy that maintains an institutional permit. "Institutional pharmacy" includes any areas of the health care facility or the health care system where pharmaceuticals are stored, compounded or dispensed.

"Medication order" means a written request for medication originated by a practitioner and intended for patient use in the health care facility, and not for use of the institution's employees or their dependents or outpatients of the facility's clinics. A valid medication order contains the date ordered, the patient's name and location within the facility, the name, dose, route, and frequency of administration of the medication, and any additional instructions. Computer-generated medication orders within an institutional setting, utilizing the practitioner's electronic signature or password will meet legal requirements for a practitioner's original handwritten signature on medication orders. Computerized signatures or passwords will be accepted provided that the facility has adequate safeguards which assure the confidentiality of each electronic signature or password and which prohibit their improper or unauthorized use.

"Pharmacy and Therapeutics Committee" means the active standing committee of the institution or health care facility which is the organizational line of communication and liaison between the medical service and pharmacists and which acts to review and promote rational drug therapy and utilization in the facility.

"Unit dose packaging" means a single unit use non-parenteral medication provided in packaging which contains the following information for each unit in the package:

1. Product name;

2. Strength and/or quantity and/or volume, where appropriate;

3. Lot number;

4. The phrase "use by" followed by the product's use by date.

i. For purposes of this paragraph, "use by date" means the earlier of one year from the date of packaging or the expiration date on the manufacturer's container;

5. Manufacturer or repackager; and

6. If there is more than one product in the single unit, a physical description of each medication in the single unit.

Amended by R.1994 d.351, effective July 18, 1994.
See: 26 N.J.R. 1596(a), 26 N.J.R. 2905(b).
Amended by R.1998 d.167, effective April 6, 1998.
See: 29 N.J.R. 4740(b), 30 N.J.R. 1298(a).
Amended N.J.A.C. reference in "Pharmacy and Therapeutics Committee" definition.
Amended by R.1999 d.214, effective July 19, 1999.
See: 31 N.J.R. 1151(a), 31 N.J.R. 1932(a).
Deleted "Authorized prescriber" and "Direct supervision"; in "Health care facility", substituted a reference to patients and residents for a reference to the sick and injured; in "Unit dose drug distribution system", deleted a reference to biologicals; and added "Unit use packaging".
Amended by R.2000 d.457, effective November 20, 2000.
See: 31 N.J.R. 3044(a), 32 N.J.R. 4123(a).
Inserted "Health care system"; in "Institutional pharmacy", inserted references to health care systems throughout, substituted "any" for "other" following "includes", and deleted "manufactured," following "stored,".
Recodified from N.J.A.C. 13:39-9.1 and amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
Rewrote "Health care facility"; in "Pharmacy and Therapeutics Committee", substituted "medical service and pharmacists" for "medical and pharmacy staff" and deleted the last sentence; rewrote "Unit use packaging". Former N.J.A.C. 13:39-9.2, Licensure of institutional pharmacies, recodified to N.J.A.C. 13:39-9.3.
Amended by R.2010 d.090, effective June 21, 2010.
See: 42 N.J.R. 132(a), 42 N.J.R. 1221(a).
In definition "Medication order", substituted "a practitioner" for "an authorized prescriber" and "practitioner's" for "prescriber's" twice; deleted definition "Unit dose drug distribution system"; substituted definition "Unit dose packaging" for definition "Unit use packaging"; and rewrote definition "Unit dose packaging".

13:39-9.3 Licensure of institutional pharmacies

(a) Any institutional pharmacy as defined under N.J.A.C. 13:39-9.2 shall be registered with and possess an institutional permit issued by the Board. The permit shall be conspicuously displayed in the facility's pharmacy. The institutional pharmacy is subject to and shall be conducted in accordance with all existing State and Federal rules and regulations.

(b) An institutional pharmacy that is part of a health care system may fill medication orders for health care facilities that are part of the health care system and that provide pharmaceutical services directly to the patients of the health care system.

Amended by R.2000 d.457, effective November 20, 2000.
See: 31 N.J.R. 3044(a), 32 N.J.R. 4123(a).
Designated existing section as (a); and added (b).
Recodified from N.J.A.C. 13:39-9.2 and amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
In (a), amended the N.J.A.C. reference. Former N.J.A.C. 13:39-9.3, Control of institutional pharmaceutical, recodified to N.J.A.C. 13:39-9.8

13:39-9.4 Contract pharmaceutical services; institutional permit required

An institutional permit is required for any area within an institution serviced by an outside vendor that performs on-site pharmaceutical services as defined in N.J.A.C. 13:39-1.2.

Amended by R.1994 d.351, effective July 18, 1994.
See: 26 N.J.R. 1596(a), 26 N.J.R. 2905(b).
Recodified from N.J.A.C. 13:39-4.14 and amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
Deleted "where drugs are stored, manufactured or compounded and which is" following "within an institution" and inserted "on-site" preceding "pharmaceutical services". Former N.J.A.C. 13:39-9.4, Pharmaceutical services, recodified to N.J.A.C. 13:39-9.9.

13:39-9.5 Advisory committees

The pharmacist-in-charge, or designee, shall be an actively participating member on any committees of the facility that may be concerned with drugs and their utilization.

Recodified from 13:39-9.10 by R.1994 d.351, effective July 18, 1994.
See: 26 N.J.R. 1596(a), 26 N.J.R. 2905(b).
Amended by R.1999 d.214, effective July 19, 1999.
See: 31 N.J.R. 1151(a), 31 N.J.R. 1932(a).
Substituted a reference to registered pharmacist-in-charge for a reference to pharmacist-in-charge.
Recodified from N.J.A.C. 13:39-9.19 by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
Former N.J.A.C. 13:39-9.5, Pharmaceuticals, recodified to N.J.A.C. 13:39-9.10.
Amended by R.2010 d.090, effective June 21, 2010.
See: 42 N.J.R. 132(a), 42 N.J.R. 1221(a).
Deleted "registered" preceding "pharmacist-in-charge".

13:39-9.6 Pharmacy and Therapeutics Committee; applicability; polices and procedures

(a) In all health care facilities providing pharmaceutical services to patients, an active standing committee of the institution entitled the Pharmacy and Therapeutics Committee or other appropriate name shall be established if required pursuant to Department of Health and Senior Services rules. Pharmacy and Therapeutics Committee shall be multidisciplinary and include a pharmacist.

(b) In all health care facilities providing pharmaceutical services to patients that are not required to maintain a Pharmacy and Therapeutics Committee pursuant to Department of Health and Senior Services rules, the pharmacist-in-charge of the provider pharmacy, in cooperation with the health care facility, shall create policies and procedures as needed to provide pharmaceutical services to the health care facility. Copies of the policies and procedures shall be made available to the Board upon request.

Recodified from 13:39-9.11 by R.1994 d.351, effective July 18, 1994.
See: 26 N.J.R. 1596(a), 26 N.J.R. 2905(b).
Recodified from N.J.A.C. 13:39-9.20 and amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
Rewrote the section. Former N.J.A.C. 13:39-9.6, Drug disbursement; written orders; outpatient prescriptions, recodified to N.J.A.C. 13:39-9.11.
Amended by R.2010 d.090, effective June 21, 2010.
See: 42 N.J.R. 132(a), 42 N.J.R. 1221(a).
In (b), substituted "Copies of the" for "The written" and inserted "made" and "upon request".

13:39-9.7 (Reserved)

Recodified from 13:39-9.12 by R.1994 d.351, effective July 18, 1994.
See: 26 N.J.R. 1596(a), 26 N.J.R. 2905(b).
Recodified from N.J.A.C. 13:39-9.21 and amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
Inserted "consistent with the requirements of N.J.A.C. 13:39-6.2(f)1" at the end of the paragraph. Former N.J.A.C. 13:39-9.7, Drug disbursement; oral orders, recodified to N.J.A.C. 13:39-9.12.
Repealed by R.2010 d.090, effective June 21, 2010.
See: 42 N.J.R. 132(a), 42 N.J.R. 1221(a).
Section was "Institutional pharmacy staff".

13:39-9.8 Control of health care pharmaceutical services; responsibilities of the pharmacist-in-charge of the provider pharmacy

(a) The pharmaceutical services of the health care facility shall be the responsibility of and under the control, supervision, and direction of the pharmacist-in-charge of the provider pharmacy.

(b) If a health care facility does not have an institutional pharmacy on its premises or chooses to utilize the services of a pharmacy outside the health care system, it may enter into an agreement with a retail pharmacy licensed by the Board. The pharmacist-in-charge of the retail pharmacy shall direct, control, supervise and be responsible for the pharmaceutical services provided to the facility.

(c) The pharmacist-in-charge of the provider pharmacy, with the cooperation of the Pharmacy and Therapeutics Committee, shall develop written policies and procedures as needed to provide pharmaceutical services to the facility. The written policies and procedures shall be available to the Board.

Amended by R.1994 d.351, effective July 18, 1994.
See: 26 N.J.R. 1596(a), 26 N.J.R. 2905(b).
Amended by R.1999 d.214, effective July 19, 1999.
See: 31 N.J.R. 1151(a), 31 N.J.R. 1932(a).
Substituted references to registered pharmacists-in-charge for references to pharmacists-in-charge throughout.
Recodified from 13:39-9.6 and amended by R.1994 d.351, effective July 18, 1994.
See: 26 N.J.R. 1596(a), 26 N.J.R. 2905(b).
Amended by R.1999 d.214, effective July 19, 1999.
See: 31 N.J.R. 1151(a), 31 N.J.R. 1932(a).
Recodified from N.J.A.C. 13:39-9.3 and amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
Rewrote the section. Former N.J.A.C. 13:39-9.8, Compounding, repealed.
Amended by R.2010 d.090, effective June 21, 2010.
See: 42 N.J.R. 132(a), 42 N.J.R. 1221(a).
Section was "Control of health care pharmaceutical services; responsibilities of the registered pharmacist-in-charge of the provider pharmacy". Deleted "registered" preceding "pharmacist-in-charge" throughout.

13:39-9.9 (Reserved)

Amended by R.1994 d.351, effective July 18, 1994.
See: 26 N.J.R. 1596(a), 26 N.J.R. 2905(b).
Recodified from N.J.A.C. 13:39-9.4 by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
Former N.J.A.C. 13:39-9.9, Monitoring of patient drug therapy, recodified to N.J.A.C. 13:39-9.13.
Repealed by R.2010 d.090, effective June 21, 2010.
See: 42 N.J.R. 132(a), 42 N.J.R. 1221(a).
Section was "Pharmaceutical services".

13:39-9.10 Pharmaceuticals; drug supply; investigational drugs; controlled dangerous substances

(a) The pharmacist-in-charge shall be responsible for determining the specifications for drugs and pharmaceutical preparations used in the treatment of patients of the facility as to quality, quantity and source of supply. An authorized purchasing agent and/or materials manager and/or pharmacy buyer of the facility may perform the actual procurement. All purchases shall be reviewed by the pharmacist-in-charge or his or her designee, who shall be a pharmacist.

(b) Written policies and procedures for the maintenance, content, control and accountability of drugs supplied and located throughout the facility shall be developed by the pharmacist-in-charge and approved by the Pharmacy and Therapeutics Committee.

(c) Written policies and procedures for the control, use and accountability of Investigational New Drugs shall be developed by the pharmacist-in-charge and the Pharmacy and Therapeutics Committee. The storage, labeling and dispensing of all Investigational New Drugs shall be a pharmaceutical service provided in cooperation with, and in support of the principal investigator. Under these parameters, the dispensing of these drugs shall not be construed to be a violation of N.J.A.C. 13:39-7.5(a). A facility participating in experimental research involving residents shall comply with Federal Department of Health and Human Services regulations, set forth at 45 CFR Part 46, Protection of Human Subjects of Research, which is incorporated by reference herein, as amended and supplemented and with the New

Jersey Department of Health and Senior Services' Policy on the Protection of Human Research Subjects, which is incorporated by reference herein, as amended and supplemented, and which is available at http://www.state.nj.us/health/irb/policies.shtml.

(d) Written policies and procedures for the control, use and accountability of controlled dangerous substances shall be developed by the pharmacist-in-charge and the Pharmacy and Therapeutics Committee. Controlled dangerous substances shall be purchased, received, stored, dispensed, administered, recorded and controlled in accordance with State and Federal laws and regulations.

Amended by R.1994 d.351, effective July 18, 1994.
See: 26 N.J.R. 1596(a), 26 N.J.R. 2905(b).
Amended by R.1999 d.196 effective June 21, 1999.
See: 30 N.J.R. 4113(a), 31 N.J.R. 253(a), 31 N.J.R. 1618(a).
In (e), deleted "by a pharmacist" following "conducted" in the second sentence, added "or by supportive personnel and co-signed by the supervising pharmacist" at the end of the fourth sentence, and inserted a new fifth sentence.
Recodified from N.J.A.C. 13:39-9.5 and amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
In (a), substituted "supervised" for "approved" following "the purchase shall be"; rewrote (c); in (d)' amended N.J.A.C. reference and inserted ", which is incorporated by reference herein, as amended and supplemented"; deleted existing (e); added a new (e) and (f). Former N.J.A.C. 13:39-9.10, Medication not dispensed in finished form, recodified to N.J.A.C. 13:39-9.14.
Amended by R.2010 d.090, effective June 21, 2010.
See: 42 N.J.R. 132(a), 42 N.J.R. 1221(a).
In (a), substituted "All purchases" for "In such a case, the" and "reviewed" for "supervised"; deleted former (b); recodified former (c) and (d) as (b) and (c); in (b), deleted the first and second sentences and deleted "registered" preceding "pharmacist-in-charge"; rewrote (c); deleted (e); recodified former (f) as (d); and in (d), inserted the first sentence and deleted the last sentence.

13:39-9.11 Drug disbursement; written orders

(a) The pharmacist shall review the practitioner's original order or a copy of the original order generated by any media that facilitates the reproduction of the original order before any initial dose of medication is dispensed, except as provided for in N.J.A.C. 13:39-9.13.

(b) Drugs not specifically limited as to time or number of doses when ordered shall be controlled by the automatic stop order procedure or other methods in accordance with written policies of the facility.

(c) The Pharmacy and Therapeutics Committee shall develop a list of unapproved or unacceptable abbreviations and symbols which shall not be used in the facility. Orders involving symbols or abbreviations shall only be dispensed consistent with this list.

(d) When appropriate, the pharmacist shall make necessary entries into the patient medical record relative to drug use in accordance with health care facility policies and, where applicable, pursuant to regulations of the Department of Health and Senior Services and/or Centers for Medicare and Medicaid Services.

Amended by R.1994 d.351, effective July 18, 1994.
See: 26 N.J.R. 1596(a), 26 N.J.R. 2905(b).
Recodified from N.J.A.C. 13:39-9.6 and amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
In (a), substituted "a" for "an electro-mechanical" preceding "facsimile" and amended N.J.A.C. reference; rewrote (c) and (d); deleted (e). Former N.J.A.C. 13:39-9.11, Drug labeling, recodified to N.J.A.C. 13:39-9.15.
Amended by R.2009 d.293, effective October 5, 2009.
See: 41 N.J.R. 1637(a), 41 N.J.R. 3840(a).
Section was "Drug disbursement; written orders; outpatient prescriptions".
Amended by R.2010 d.090, effective June 21, 2010.
See: 42 N.J.R. 132(a), 42 N.J.R. 1221(a).
Rewrote (a).

Case Notes

Violation not found due to failure of Board to prove pharmacist's knowledge or receipt of equipment and test requirements. New Jersey State Bd. of Pharmacy v. Yanuzzi, 4 N.J.A.R. 489 (1981).

13:39-9.12 Drug disbursement; oral orders

(a) The provisions of this section shall be implemented in accordance with the policies and procedures of, and protocols of the Pharmacy and Therapeutics Committee.

(b) A pharmacist shall receive oral orders only from an authorized practitioner. Such orders shall be immediately recorded and signed by the person receiving the order on the medication order sheet or into the electronic data processing system.

(c) Oral orders for Schedule II controlled substances sl be permitted only in the case of a bona fide emergen situation.

(d) Oral orders received consistent with the requirements of (b) and (c) above shall be countersigned by the practitioner.

(e) The pharmacist may release to the patient at discharge any remaining medication in a multiple dose container (for example, inhalers, multiple dose injectable medications, such as insulin, topical preparation, drops, ointments and topical irrigation solutions), and a limited supply of other medications, provided that the pharmacist:

1. Labels the medications for out-patient use pursuant to labeling requirements set forth in N.J.A.C. 13:39-7.12;

2. Counsels the patient prior to discharge from the hospital or medical facility pursuant to N.J.A.C. 13:39-7.21; and

3. Ensures that discharge orders contain the attending physician's authorizations to dispense the remaining doses of the prescription or the limited supply of other medications to the patient or guardian.

Recodified from 13:39-9.6 and amended by R.1994 d.351, effective July 18, 1994.
See: 26 N.J.R. 1596(a), 26 N.J.R. 2905(b).
Amended by R.1997 d.502, effective December 1, 1997.
See: 28 N.J.R. 5048(a), 29 N.J.R. 5072(a).

Inserted new (a); recodified existing (a) through (c) as (b) through (d); and added (e).
Amended by R.1999 d.214, effective July 19, 1999.
e: 31 N.J.R. 1151(a), 31 N.J.R. 1932(a).
In (d), deleted "as required by 42 CFR 463" at the end.
Recodified from N.J.A.C. 13:39-9.7 and amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
In (a), substituted "provisions" for "mandatory requirements" following "The"; in (b), substituted "medication" for "prescriber's " preceding "order sheet"; in (e), amended the N.J.A.C. reference in 2. Former N.J.A.C. 13:39-9.12, Use of patient's own medication, recodified to N.J.A.C. 13:39-9.16.
Amended by R.2010 d.090, effective June 21, 2010.
See: 42 N.J.R. 132(a), 42 N.J.R. 1221(a).
In (a), substituted "policies and procedures of," for "policy"; in (b) and (d), substituted "practitioner" for "prescriber"; in (d), inserted "received consistent with the requirements of (b) and (c) above"; in the introductory paragraph of (e), inserted a comma following the first occurrence of "medications", deleted a comma following "ointments", and inserted "and a limited supply of other medications,"; in (e)1, substituted "N.J.A.C. 13:39-7.12" for "N.J.S.A. 45:14-24"; in (e)2, updated the N.J.A.C. reference; and in (e)3, substituted "dispense" for "release" and inserted "or the limited supply of other medications".

13:39-9.13 Monitoring of patient drug therapy

(a) The pharmacist shall be responsible for monitoring drug therapy of patients in the facility. This shall include, but is not limited to, maintaining and reviewing the patient medication profile prior to the dispensing of medications.

(b) In instances involving the issuance and administration of STAT orders (orders requiring immediate attention) these drugs shall be documented on the patient's medication profile immediately after dispensing.

(c) When the pharmacy is closed, these drugs shall be documented on the patient's medication profile immediately after the pharmacy is reopened.

Recodified from 13:39-9.6 and amended by R.1994 d.351, effective July 18, 1994.
See: 26 N.J.R. 1596(a), 26 N.J.R. 2905(b).
Recodified from N.J.A.C. 13:39-9.9 by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
Former N.J.A.C.13:39-9.13, Investigational drugs; removal of outdated and recalled drugs; emergency drug supply; controlled dangerous substances, repealed.

13:39-9.14 Medication not dispensed in finished form

The pharmacist shall be responsible for providing medication in a form that requires little or no further alterations, preparation, reconstitution, dilution or labeling by other licensed personnel. The pharmacist shall provide adequate instructions for those products that are not dispensed in finished form.

Recodified from 13:39-9.6 and amended by R.1994 d.351, effective July 18, 1994.
See: 26 N.J.R. 1596(a), 26 N.J.R. 2905(b).
Recodified from N.J.A.C. 13:39-9.10 by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
Former N.J.A.C. 13:39-9.14, Drug-dispensing devices, recodified to N.J.A.C. 13:39-9.17.

13:39-9.15 Drug labeling

Labeling of medications, other than intravenous solutions, shall be in conformance with written policies and procedures controlling the drug distribution system in use within the facility and in accord with current acceptable standards of pharmaceutical practice. Labeling of intravenous solutions shall be consistent with the labeling requirements set forth in N.J.A.C. 13:39-11.

Recodified from 13:39-9.6 and amended by R.1994 d.351, effective July 18, 1994.
See: 26 N.J.R. 1596(a), 26 N.J.R. 2905(b).
Amended by R.1999 d.214, effective July 19, 1999.
See: 31 N.J.R. 1151(a), 31 N.J.R. 1932(a).
Deleted a former (a); and deleted a former (b) designation.
Recodified from N.J.A.C. 13:39-9.11 and amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
Deleted the last sentence. Former N.J.A.C. 13:39-9.15, Disposal of unused medications, recodified to N.J.A.C. 13:39-9.18.
Amended by R.2010 d.090, effective June 21, 2010.
See: 42 N.J.R. 132(a), 42 N.J.R. 1221(a).
Inserted the last sentence.

13:39-9.16 Use of patient's own medication

(a) No drugs shall be administered to a patient except those provided through the pharmacy or as provided by written policies and procedures developed by the pharmacist-in-charge or, where applicable, the director of pharmaceutical services and approved by the Pharmacy and Therapeutics Committee.

(b) Although the use of patient's own medications may be warranted in certain situations, it should be discouraged as a general or routine practice. If a patient's previously acquired medication is to be used, a written order to this effect shall be signed and dated by the patient's physician. Such medications shall be identified by the pharmacist as to contents and dispensing origin. Also, these medications shall be documented as part of the pharmacy's patient profile record system.

Recodified from 13:39-9.6 and amended by R.1994 d.351, effective July 18, 1994.
See: 26 N.J.R. 1596(a), 26 N.J.R. 2905(b).
Amended by R.1999 d.214, effective July 19, 1999.
See: 31 N.J.R. 1151(a), 31 N.J.R. 1932(a).
In (a), substituted "and except as provided" for ". Any exception to this rule must be governed" following "pharmacy", and substituted a reference to registered pharmacists-in-charge for a reference to pharmacists-in-charge.
Recodified from N.J.A.C. 13:39-9.12 and amended by R.2005 d. 25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
In (a), substituted "or" for "and except" preceding "as provided" and inserted "or, where applicable, the director of pharmaceutical services" following "pharmacist-in-charge". Former N.J.A.C. 13:39-9.16, Records and reports, recodified to N.J.A.C. 13:39-9.19.
Amended by R.2010 d.090, effective June 21, 2010.
See: 42 N.J.R. 132(a), 42 N.J.R. 1221(a).
In (a), deleted "registered" preceding "pharmacist-in-charge".

Case Notes

Violation found due to having outdated medication and "Not to be Sold" sample medications in prescription area; penalties (also cited as N.J.A.C. 13:39-9.2). New Jersey State Bd. of Pharmacy v. Yanuzzi, 4 N.J.A.R. 489 (1981).

13:39-9.17 Drug-dispensing devices

(a) Where the use of a drug-dispensing device is approved as an integral part of the drug distribution system by the facility, the pharmacist-in-charge and the Pharmacy and Therapeutics Committee, the device may be used when the pharmacist is not on duty (absent during either the day or night), provided that any absence of the pharmacist does not exceed 24 hours, or when the pharmacist is on duty, provided that proper review of the use of the drug-dispensing device can be ascertained. The supervision of any drug dispensing device so utilized shall be the responsibility of the pharmacist-in-charge servicing the health care facility. The drug-dispensing device data shall be checked for accuracy every 24 hours by a pharmacist and so documented.

(b) Packaging and labeling of medication for drug-dispensing devices, when done by the pharmacy, shall be performed under the immediate personal supervision of a pharmacist in the employ of or under contract to the facility.

(c) Stocking of the drug-dispensing devices with prepackaged medications shall be performed by or under the supervision of a pharmacist.

(d) The cleanliness of the drug dispensing devices shall be maintained by a pharmacist or by a person under the supervision of a pharmacist.

(e) Controlled substances and other medications to which, in the professional judgment of the pharmacist-in-charge, access should be limited, shall be secured within the drug dispensing device to limit access to single medications only and shall be checked and documented by the pharmacist or his or her designee who shall be a licensed health care professional, every 24 hours. Other than a pharmacist, only authorized registered nurses, licensed practical nurses, practitioners, pharmacy technicians, interns and externs shall have access to the medication in each drug-dispensing device. The activity regarding all medication, including the identity of the person accessing the medication, shall be recorded and available to the pharmacist.

(f) All medications withdrawn from a drug dispensing device require a medication order by an authorized practitioner. All such medication orders shall be checked by the pharmacist within 24 hours from the time of the original order and so noted on the pharmacy's patient medication profile.

(g) When there is no pharmacy on the premises and when the drug-dispensing devices are an integral part of the approved drug distribution system of the facility, the devices shall be controlled by the pharmacist-in-charge who is responsible for the pharmaceutical services of the institution. Under these circumstances, the time between medication order checks shall not exceed 24 hours.

Recodified from 13:39-9.6 and amended by R.1994 d.351, effective July 18, 1994.
See: 26 N.J.R. 1596(a), 26 N.J.R. 2905(b).
Amended by R.1999 d.214, effective July 19, 1999.
See: 31 N.J.R. 1151(a), 31 N.J.R. 1932(a).
Rewrote the section.
Recodified from N.J.A.C. 13:39-9.14 and amended by R.2005 d. effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
In (b), substituted "immediate personal" for "direct" preceding "supervisor of a pharmacist"; in (c) and (d), deleted "direct" preceding "supervision of a pharmacist"; in (e), substituted "technicians, interns and externs" for "supportive personnel" following "authorized prescribers or designated pharmacy"; deleted (h). Former N.J.A.C. 13:39-9.17, Drug information and education, recodified to N.J.A.C. 13:39-9.20.
Amended by R.2010 d.090, effective June 21, 2010.
See: 42 N.J.R. 132(a), 42 N.J.R. 1221(a).
In (a), (e) and (g), deleted "registered" preceding "pharmacist-in-charge" throughout; in (b), substituted "by the pharmacy" for "in the facility"; in (e), inserted "health care" and substituted "practitioners," for "physicians, authorized prescribers or designated"; in (f), substituted "practitioner" for "prescriber"; and in (g), deleted "licensed" preceding "pharmacy".

13:39-9.18 Disposal of unused medications

(a) Written policies and procedures governing unused medications shall be established and implemented by the pharmacist-in-charge and shall comply with the following requirements:

1. All medications where the drug source, lot or control number, or expiration or use by date are missing, shall be sent to the pharmacy for final disposition, or shall be disposed of by the health care facility according to its written protocol.

2. If a unit dose packaged medication has been sto in a medication room or secure area in the institution and the medication seal and control number are intact, the medication may be recycled and redispensed.

3. Any and all medication returned by out-patients of the facility shall not be redispensed.

4. The record of disposal of unused or nonadministered dispensed controlled dangerous substances expended or wasted either by accident or intent shall be signed and co-signed and witnessed by a licensed nurse, physician or pharmacist, or where allowed by Department of Health and Senior Services rules an administrator of the health care facility, and disposed of by the health care facility according to its written protocol and consistent with all local, State and Federal laws and regulations.

Recodified from 13:39-9.6 and amended by R.1994 d.351, effective July 18, 1994.
See: 26 N.J.R. 1596(a), 26 N.J.R. 2905(b).
Amended by R.1999 d.214, effective July 19, 1999.
See: 31 N.J.R. 1151(a), 31 N.J.R. 1932(a).
In (a), substituted a reference to registered pharmacists-in-charge for a reference to pharmacists-in-charge in the introductory paragraph, and rewrote 1 and 4.
Recodified from N.J.A.C. 13:39-9.15 and amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
In (a), inserted "lot or" following "drug source" and inserted "or use by" following "expiration" in 1 and rewrote 4. Former N.J.A.C. 13:39-9.18, After hours access to the institutional pharmacy, recodified N.J.A.C. 13:39-9.21.

Amended by R.2010 d.090, effective June 21, 2010.
See: 42 N.J.R. 132(a), 42 N.J.R. 1221(a).
In the introductory paragraph of (a), deleted "registered" preceding harmacist-in-charge".

13:39-9.19 Records and reports

(a) Records of the pharmaceutical services of the provider pharmacy for the facility shall be the responsibility of the pharmacist-in-charge. On or after April 5, 2011, a pharmacy shall maintain an audit trail that records and documents the unique and secure user identifier(s) of the pharmacist(s), pharmacy technician(s), intern(s) or extern(s) performing the component functions of prescription handling, as defined in N.J.A.C. 13:39-4.18, which are required to be performed by a pharmacist, pharmacy technician, intern or extern pursuant to the requirements of this chapter. All steps performed by a pharmacy technician, intern or extern shall be documented in the audit trail. All entries to the audit trail made by a pharmacy technician, intern or extern shall be reviewed and approved by the pharmacist. When more than one pharmacist is involved in the component functions of prescription handling, the unique and secure user identifier(s) of the pharmacist(s) responsible for the accuracy and appropriateness of each component function(s) shall be recorded in an audit trail. Audit trail documentation shall be generated at the time the component function(s) is performed. All audit trail and medication order information shall be maintained or stored in original hard copy form or in any other media that facilitates the reproduction of the original hard copy and shall be aintained for a period of not less than five years. The oldest four years of information shall be maintained in such a manner so as to be retrievable and readable within two weeks. The most recent one year of information shall be retrievable and readable within one business day. Records not currently in use need not be stored in the pharmacy, but off-site facilities used to store such records shall be secure. Patient records shall be kept confidential, but shall be made available to persons authorized to inspect them under State and Federal statutes and regulations.

(b) The pharmacy shall maintain a patient profile record for each patient receiving drug therapy in accordance with N.J.A.C. 13:39-7.19 and as follows:

1. The profile records for inpatients shall contain: the date of each entry; the name; sex; age or birthdate; location of the patient; the drug name, dose, route of administration and quantity dispensed; the reported diagnosis, allergies and chronic condition(s) of the patient.

2. All notations made on the inpatients' profile records by pharmacy technicians, interns and externs shall be verified and countersigned, either manually or electronically, by the supervising pharmacist.

3. The inpatient profile record shall be filed and stored for five years following patient discharge. The oldest four years of information shall be maintained in such a manner so as to be retrievable and readable within two weeks. The most recent one year of information shall be retrievable and readable within one business day.

(c) All outpatient prescriptions dispensed and outpatient profile records in the institutional pharmacy shall conform to the requirements set forth in N.J.A.C. 13:39-7.6.

(d) Records for receipt, use and final disposition of controlled dangerous substances shall be maintained by the institutional pharmacy in compliance with the requirements of Federal and State controlled dangerous substances laws and regulations. Nursing administration and audit records for controlled dangerous substances shall be available for review by the pharmacy.

(e) Records of the receipt, dispensing and disposal of investigational drugs shall be maintained by the institutional pharmacy in compliance with Federal and State laws and regulations.

(f) The pharmacist-in-charge shall be responsible for maintaining a system by which all reported adverse drug reactions are recorded and reviewed by the Pharmacy and Therapeutics Committee, where applicable, and are submitted to all appropriate State and local agencies consistent with State and local laws and regulations.

Recodified from 13:39-9.7 and amended by R.1994 d.351, effective July 18, 1994.
See: 26 N.J.R. 1596(a), 26 N.J.R. 2905(b).
Amended by R.1999 d.214, effective July 19, 1999.
See: 31 N.J.R. 1151(a), 31 N.J.R. 1932(a).
In (a) and (f), substituted references to registered pharmacists-in-charge for references to pharmacists-in-charge; in (a), substituted a reference to statutes and regulations for a reference to laws; and in (f), deleted a former second sentence.
Recodified from N.J.A.C. 13:39-9.16 and amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
Rewrote (a), (b), (f). Former N.J.A.C. 13:39-9.19, Advisory committees, recodified to N.J.A.C. 13:39-9.5.
Amended by R.2009 d.305, effective October 5, 2009.
See: 40 N.J.R. 5170(a), 41 N.J.R. 3840(a).
Rewrote (a) and (c); in (b)1, deleted "the initials of the pharmacist performing the dispensing or supervising;" preceding "the reported", and inserted a comma following "diagnosis"; and in (b)3, deleted "immediately" preceding the last occurrence of "retrievable", and inserted "within one business day".
Amended by R.2010 d.090, effective June 21, 2010.
See: 42 N.J.R. 132(a), 42 N.J.R. 1221(a).
In (a) and (f), deleted "registered" preceding "pharmacist-in-charge".

13:39-9.20 Drug information and education

(a) The pharmacist-in-charge shall be responsible for maintaining drug standards, references and sources of drug information current and adequate to meet the needs of the pharmacists, physicians, nurses, other health care personnel, and patients of the facility. Reference texts shall include, but not be limited to, those required by the Board under N.J.A.C. 13:39-5.8.

(b) On each patient care unit, the pharmacist shall maintain the following:

1. A copy of the current institutional formulary;

2. A reference drug compendium which will give basic information concerning drugs approved by the Pharmacy and Therapeutics Committee; and

3. The telephone number of either the local or regional poison control center.

(c) The pharmacist shall participate in the drug education programs of the facility.

Recodified from 13:39-9.8 by R.1994 d.351, effective July 18, 1994.
See: 26 N.J.R. 1596(a), 26 N.J.R. 2905(b).
Amended by R.1999 d.214, effective July 19, 1999.
See: 31 N.J.R. 1151(a), 31 N.J.R. 1932(a).
In (a), substituted a reference to registered pharmacists-in-charge for a reference to pharmacists-in-charge; and in (b), deleted a former 1, a recodified former 2 through 4 as 1 through 3.
Recodified from N.J.A.C. 13:39-9.17 and amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
In (a), amended the N.J.A.C. reference. Former N.J.A.C. 13:39-9.20, Pharmacy and Therapeutics Committee, recodified to N.J.A.C. 13:39-9.6.
Amended by R.2010 d.090, effective June 21, 2010.
See: 42 N.J.R. 132(a), 42 N.J.R. 1221(a).
In (a), deleted "registered" preceding "pharmacist-in-charge".

13:39-9.21 After hours access to the institutional pharmacy

(a) Only a pharmacist shall have access to the pharmacy stock of controlled dangerous substances in Schedules II through V.

(b) Only a pharmacist shall have access to the institutional pharmacy except that in a pharmacist's absence from an institution, a registered nurse designated by the registered pharmacist-in-charge may obtain medication from the hospital pharmacy as needed in an emergency and not available as floor stock.

(c) A designated registered nurse shall remove only those medication doses which shall be administered prior to the opening of the pharmacy. The designated registered nurse may remove the following from the pharmacy stock of drugs or automated dispensing device:

1. A drug in its original container or a drug prepackaged by the pharmacy for use in the institution;

2. The required dose(s) of a drug from the original container for a specific patient.

(d) The pharmacist-in-charge shall obtain from the registered nurse on a suitable form a record of any drugs removed showing the following:

1. The name of the drug;

2. The dosage size;

3. The amount taken;

4. The date;

5. The patient's name and location; and

6. The signature of the nurse.

(e) The pharmacist-in-charge shall obtain with the record in (d) above the container from which the required dose was taken for drug administration purposes in order that it may be properly checked by a pharmacist.

(f) All records in (d) above shall be maintained or stored in original hard copy form or in any other media that facilitates the reproduction of the original hard copy, and shall be kept by the pharmacy for five years. The oldest four years of information shall be maintained in such a manner so as to be retrievable and readable within two weeks. The most recent one year of information shall be retrievable and readable within one business day. Records not currently in use need not be stored in the pharmacy, but off-site facilities used to store such records shall be secure. Patient records shall be kept confidential, but shall be made available to persons authorized to inspect them under State and Federal statutes and regulations.

Recodified from 13:39-9.9 and amended by R.1994 d.351, effective July 18, 1994.
See: 26 N.J.R. 1596(a), 26 N.J.R. 2905(b).
Amended by R.1999 d.214, effective July 19, 1999.
See: 31 N.J.R. 1151(a), 31 N.J.R. 1932(a).
Rewrote (b) and (c); in (d) and (e), substituted references to registered pharmacists-in-charge for references to pharmacists-in-charge; and in (e), substituted a reference to required doses for a reference to single doses.
Recodified from N.J.A.C. 13:39-9.18 and amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
Rewrote (f). Former N.J.A.C. 13:39-9.21, Institutional pharmacist staff, recodified to N.J.A.C. 13:39-9.7.
Amended by R.2009 d.305, effective October 5, 2009.
See: 40 N.J.R. 5170(a), 41 N.J.R. 3840(a).
Rewrote (f).
Amended by R.2010 d.090, effective June 21, 2010.
See: 42 N.J.R. 132(a), 42 N.J.R. 1221(a).
In the introductory paragraph of (d) and in (e), substituted "pharmacist-in-charge" for "registered pharmacist in charge".

13:39-9.22 Pharmacy facilities; space

(a) Adequate facilities (space, lighting, equipment, temperature control and supplies) shall be provided for the control of the professional, technical and administrative functions of the institutional pharmacy as needed for the effective and efficient assurance of patient safety through proper purchasing, receipt, storage, dispensing, administration and control of drugs.

(b) The facilities shall include, but are not limited to, those requirements provided in N.J.A.C. 13:39-5.4 through 5.8.

Recodified from 13:39-9.15 by R.1994 d.351, effective July 18, 1994.
See: 26 N.J.R. 1596(a), 26 N.J.R. 2905(b).
In (a), substituted references to registered pharmacists-in-charge for references to pharmacists-in-charge in 1 and 2, substituted a reference to certified preceptors for a reference to qualified preceptors and inserted a reference to faculty preceptors in 3, and added 4.
Recodified from N.J.A.C. 13:39-9.24 and amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
In (b), amended N.J.A.C. reference. Former N.J.A.C. 13:39-9.25 Pharmacist staff, repealed.

Amended by R.2010 d.090, effective June 21, 2010.
See: 42 N.J.R. 132(a), 42 N.J.R. 1221(a).
Deleted (c).

13:39-9.23 Storage and security

(a) Provisions shall be made for adequate safe storage of drugs wherever they are stored in the health care facility.

1. All drugs shall be secured for safe use and protected against illicit diversion. Controlled dangerous substances in the institutional pharmacy and throughout the facility shall be stored and protected in conformance with State and Federal laws and regulations.

2. Supplies of external preparations stored in patient care areas shall be kept separate from internal medications.

3. The pharmacist-in-charge or, where provided for in Department of Health and Senior Services rules, the director of pharmaceutical services shall be responsible for all the medications in the facility.

4. The drugs throughout the facility shall be maintained under adequate storage conditions including proper lighting, ventilation and temperature control as required by the drug manufacturer.

(b) The pharmacist-in-charge or, where provided for in Department of Health and Senior Services rules, the director of pharmaceutical services shall establish a system of control for all drugs dispensed for use in the drug therapy of patients the facility. Inspections shall be conducted of all medication areas located in the facility or any other service area of the facility at least once every two months to check for expiration or use by dates, proper storage, misbranding, physical integrity, security and accountability of all drugs. These inspections shall be fully documented. Written inspection reports shall be prepared and signed by the inspecting pharmacist or by the pharmacy technician, intern or extern and co-signed by his or her supervising pharmacist. The pharmacist-in-charge shall be responsible for ensuring that, prior to performing any inspections pursuant to this subsection, pharmacy technicians, interns and externs are trained and can successfully demonstrate competency. Procedures for the review of these reports shall be developed and instituted by the pharmacist-in-charge and can be incorporated into the overall quality assurance program of the health care facility.

(c) Procedures shall be established to assure the immediate and efficient removal of all outdated and recalled drugs from patient care areas and from the active stock of the pharmacy. The pharmacist-in-charge shall develop written policies and procedures governing the removal from the facility of outdated or recalled drugs.

Recodified from 13:39-9.16 by R.1994 d.351, effective July 18, 1994.
See: 26 N.J.R. 1596(a), 26 N.J.R. 2905(b).
Amended by R.1999 d.214, effective July 19, 1999.
See: 31 N.J.R. 1151(a), 31 N.J.R. 1932(a).
In (a)3, substituted a reference to registered pharmacists-in-charge for reference to pharmacists-in-charge.
Recodified from N.J.A.C. 13:39-9.25 and amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
In (a), rewrote 3, substituted "drug manufacturer" for "United States Pharmacopoeial/National Formulary" in 4, and deleted 5; added (b) and (c). Former N.J.A.C. 13:39-9.23, "Supportive personnel staffing was reserved.
Amended by R.2010 d.090, effective June 21, 2010.
See: 42 N.J.R. 132(a), 42 N.J.R. 1221(a).
In (a)3 and (c), deleted "registered" preceding "pharmacist-in-charge"; in (a)3, deleted ", that is, the drugs in the pharmacy area, drugs in transit, and the drugs in the patient care areas" following "facility"; and in (b), inserted "proper storage,", deleted "dispensed for use" following the second occurrence of "drugs" and substituted "or" for ", except for hospitals, where they can also be prepared and signed" following "inspecting pharmacist".

13:39-9.24 Equipment

Adequate equipment shall be provided for the compounding, packaging, labeling, refrigeration, sterilization, testing and safe distribution of drugs and other functions.

Recodified from 13:39-9.17 by R.1994 d.351, effective July 18, 1994.
See: 26 N.J.R. 1596(a), 26 N.J.R. 2905(b).
Amended by R.1999 d.214, effective July 19, 1999.
See: 31 N.J.R. 1151(a), 31 N.J.R. 1932(a).
Deleted a reference to biologicals.
Recodified from N.J.A.C. 13:39-9.26 by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
Former N.J.A.C. 13:39-9.24, Pharmacy facilities; space, recodified to N.J.A.C. 13:39-9.22.
Amended by R.2010 d.090, effective June 21, 2010.
See: 42 N.J.R. 132(a), 42 N.J.R. 1221(a).
Deleted the last sentence.

13:39-9.25 Institutional decentralized pharmacies

(a) An institutional decentralized pharmacy or a "satellite pharmacy", means an area within a health care system that has been issued an institutional permit and is in a location other than the original permitted location, where the preparation or dispensing or compounding of medications is performed.

(b) Medication shall not be dispensed from a decentralized pharmacy without a pharmacist present, except that, when the decentralized pharmacy is closed, a licensed nurse may dispense medication in accordance with the written policies and procedures of the institution.

(c) Institutions operating decentralized pharmacies shall notify the Board, in writing, of the existence of, and the discontinuation of, each decentralized pharmacy location.

(d) Institutional decentralized pharmacies shall be subject to normal Board inspections.

(e) Inspections of all medications in a decentralized institutional pharmacy shall be performed consistent with the requirements of N.J.A.C. 13:39-9.23.

(f) Institutional decentralized pharmacies shall comply with all requirements in this subchapter applicable to the

pharmaceutical services provided by the decentralized pharmacy, as determined by the pharmacist-in-charge.

Recodified from 13:39-9.18 by R.1994 d.351, effective July 18, 1994.
See: 26 N.J.R. 1596(a), 26 N.J.R. 2905(b).
Amended by R.1999 d.214, effective July 19, 1999.
See: 31 N.J.R. 1151(a), 31 N.J.R. 1932(a).
Rewrote (d)1.
Recodified from N.J.A.C. 13:39-9.27 and amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
Rewrote the section. Former N.J.A.C. 13:39-9.25, Storage and security, recodified to N.J.A.C. 13:39-9.23.
Amended by R.2010 d.090, effective June 21, 2010.
See: 42 N.J.R. 132(a), 42 N.J.R. 1221(a).
In (f), deleted "registered" preceding "pharmacist-in-charge".

13:39-9.26 Valid medication orders; out-of-State medication orders

(a) Only medication orders issued by a practitioner licensed to write medication orders in the United States or any territory of the United States shall be considered valid medication orders and such medication orders shall be filled pursuant to New Jersey law.

(b) Medication orders, other than those listed in (a) above, shall not be filled by a pharmacy in New Jersey.

New Rule, R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
Former N.J.A.C. 13:39-9.26, Equipment, recodified to N.J.A.C. 13:39-9.24.
Amended by R.2010 d.090, effective June 21, 2010.
See: 42 N.J.R. 132(a), 42 N.J.R. 1221(a).
In (a), substituted "a practitioner" for "an authorized prescriber".

13:39-9.27 Prescriptions and medication orders transmitted by technological devices in an institution

(a) A pharmacist may, subject to the conditions set forth in this section, accept for dispensing a prescription or a medication order transmitted by a facsimile (FAX) machine or other technological device as approved by the Board.

(b) A pharmacist filling prescriptions under an institutional permit for employees of the institution and their dependents and for eligible outpatients may accept for dispensing prescriptions for all substances consistent with the requirements of N.J.A.C. 13:39-7.10 and 7.11.

(c) A pharmacist who is authorized to fill inpatient medication orders, as defined in N.J.A.C. 13:39-9.2, in an institutional pharmacy may accept all inpatient medication orders, including orders for Schedule II substances, which have been transmitted by technological device.

(d) Whenever a pharmacist has reason to question the accuracy or authenticity of a prescription or medication order transmitted by technological device, the pharmacist shall verify the transmission directly with the prescribing practitioner.

(e) It shall be deemed professional misconduct for a pharmacist to use a technological device in order to circumvent his or her responsibilities with regard to documenting, authenticating and verifying medication orders and prescriptions or in order to circumvent other standards of pharmacy practice.

(f) No licensee or permit holder registered under N.J.S.A. 45:14-40 et seq. shall under any circumstances provide a technological device to, or accept a technological device from, any practitioner licensed to write prescriptions.

(g) No licensee or permit holder shall enter into any agreement with an authorized practitioner which denies the patient the right to have his or her prescription transmitted by technological device to a pharmacy of the patient's choice.

New Rule, R.1992 d.166, effective April 6, 1992.
See: 23 N.J.R. 2469(a), 24 N.J.R. 1371(a).
Amended by R.1999 d.214, effective July 19, 1999.
See: 31 N.J.R. 1151(a), 31 N.J.R. 1932(a).
In (c), added the last sentence.
Amended by R.2003 d.373, effective September 15, 2003.
See: 34 N.J.R. 3064(a), 35 N.J.R. 4290(a).
In (b), deleted "at a retail pharmacy and a registered pharmacist" preceding "filling prescriptions".
Recodified from N.J.A.C. 13:39-5.8 and amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
In (b), substituted "eligible outpatients" for "out-patients who are treated by staff members of the institution in their respective clinics, as permitted pursuant to N.J.S.A.45:14-32" following "institution and their dependents and for" in the introductory paragraph and amended the N.J.A.C. reference in 1; in (c), amended the N.J.A.C. reference and inserted "or for direct administration to patients by parental, intravenous, intramuscular, subcutaneous or intraspinal infusion" following "hospital patients". Former N.J.A.C. 13:39-9.27, Institutional decentralized pharmacies, recodified to N.J.A.C. 13:39-9.25.
Amended by R.2010 d.090, effective June 21, 2010.
See: 42 N.J.R. 132(a), 42 N.J.R. 1221(a).
Rewrote (b); in (c), deleted "registered" preceding "pharmacist", and deleted the last sentence; and in (f), updated the N.J.S.A. reference.

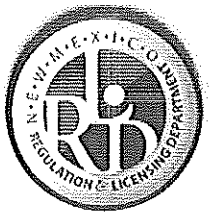
SUBCHAPTER 10. AUTOMATED MEDICATION SYSTEMS

13:39-10.1 Purpose and scope

The rules in this subchapter establish standards applicable to all pharmacies and/or facilities that utilize automated medication systems to store, package, dispense and distribute prescriptions or medication orders.

13:39-10.2 "Automated medication system" definition

As used in this subchapter, "automated medication system" means any process that performs operations or activities, other than compounding or administration, relative to the storage, packaging, dispensing and distribution of medications, and which collects, controls and maintains all transaction information. "Automated medication system" does not mean an automatic counting device operated pursuant



BOARDS AND COMMISSIONS

Overview
- Individual Boards and Commissions
- Accountancy
- Acupuncture and Oriental Medicine
- Animal Sheltering Board
- Athletic Commission
- Athletic Trainers
- Barbers and Cosmetologists
- Chiropractic Examiners
- Counseling and Therapy Practice
- Dental Health Care
- Interior Design
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Pharmacy: Rules and Laws

The text of our rules is available at the official site of the New Mexico Administrative Code.

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Chapter 19 - Pharmacists

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TITLE 16 OCCUPATIONAL AND PROFESSIONAL LICENSING
CHAPTER 19 PHARMACISTS
PART 7 HOSPITAL PHARMACIES

16.19.7.1 ISSUING AGENCY: Regulation and Licensing Department Board of Pharmacy, 1650 University Blvd, NE - Ste. 400B, Albuquerque, NM 87102, (505) 841-9102.
[08-16-99; 16.19.7.1 NMAC - Rn, 16 NMAC 19.7.1, 03-30-02]

16.19.7.2 SCOPE: All pharmacies, hospital-based skilled nursing facilities and all drug rooms maintained in hospitals.
[08-16-99; 16.19.7.2 NMAC - Rn, 16 NMAC 19.7.2, 03-30-02]

16.19.7.3 STATUTORY AUTHORITY: Section 61-11-6A.(6) NMSA 1978 requires that the Board of Pharmacy provide for the licensing of hospital pharmacies and the drug rooms of hospitals and the inspection of their facilities and activities.
[08-16-99; 16.19.7.3 NMAC - Rn, 16 NMAC 19.7.3, 03-30-02]

16.19.7.4 DURATION: Permanent.
[08-16-99; 16.19.7.4 NMAC - Rn, 16 NMAC 19.7.4, 03-30-02]

16.19.7.5 EFFECTIVE DATE: August 16, 1999, unless a later date is cited at the end of a Section or Paragraph.
[08-16-99; 16.19.7.5 NMAC - Rn, 16 NMAC 19.7.5, 03-30-02]

16.19.7.6 OBJECTIVE: The objective of Part 7 of Chapter 19 is to establish standards for the safe and competent delivery of quality pharmaceutical care.
[08-16-99; 16.19.7.6 NMAC - Rn, 16 NMAC 19.7.6, 03-30-02]

16.19.7.7 DEFINITIONS:

A. "Automated Medication Management System" means automated devices that compound, measure, count, , or package and deliver a specified quantity of dosage units for a designated drug product and which collects, controls and maintains all transaction information.

B. "Bar-Code" means a graphic composed of parallel bars and spaces of various widths intended for use in the detection and automatic processing of item identities or other intelligence by electro-optical means.

C. "Dispensing" as defined in the NMSA, Section 61-11-2(I), and pursuant to 61-11-21(C) dispensing is limited to a registered pharmacist.

D. "Electronic Signature" means a unique security code or other identifier which specifically identifies the person entering information to a data processing system.

E. "Facility" means a hospital or other inpatient institution which has a pharmacy within the premises.

F. "Formulary" means a list of drugs approved for use in a facility by its medical staff through the Pharmacy and Therapeutics Committee or its equivalent.

G. "Hard Copy" means a paper-based record keeping system that is readable without the use of a special device , i.e., computer, microfiche reader, etc.

H. "Hospital" means any place offering in-patient skilled nursing, overnight care on a 24 hour basis for diagnosing, treating and providing medical or surgical care for patients.

I. "Hospital-based Skilled Nursing Facility" means a long-term care facility or unit thereof that is an integral and subordinate part of the hospital, is operated with other departments of the hospital under common governance and professional supervision such that the skilled nursing facility and the hospital are subject to the bylaws and operating decisions of common governing board, is fully integrated with all other services of the hospital, is owned, operated and managed by the hospital and is physically located within said hospital.

J. "In-house Clinic" means a clinic located in a hospital which has a pharmacy within the premises. The clinic is a facility where one or more licensed practitioners diagnose and treat patients, and where drugs are stored, dispensed, distributed or administered for the diagnosis and treatment of the facility's patients; provided that this definition shall not include the privately owned practice of any licensed practitioner or group of licensed practitioners exempt under Section 61-11-22 of the Pharmacy Act.

K. "Integrated Healthcare System" means an integrated network of healthcare services provided by a single corporation or system. Systems offer comprehensive care which may include, acute, urgent care, long term or home health:

L. "Medication Profile" means a record and drug listing for each patient based on available information, containing but not limited to, patient name, patient age, sex, patient weight, current diagnosis, allergies or sensitivities, and current therapy.

M. "Medication-use Measurement Program" means a program that entails measuring, assessing, and improving the prescribing or ordering; preparation and dispensing; administration; and monitoring of medications.

N. "Parenteral Products" means any preparation administered by injection through one or more layers of skin tissue.

O. "Pharmacist-in-Charge" means a pharmacist employed by the facility on either a part-time or full-time basis as the activity of service requires and as outlined in 16.19.6.9 NMAC.

P. "Pharmacy and Therapeutics Committee" means an advisory committee of the medical staff of the facility recommending policy regarding evaluation, selection, and therapeutics of drugs.

Q. "Policy and Procedures Manual" shall outline the scope of services for safe delivery of quality pharmaceutical care for all patients.

[08-16-99; 16.19.7.7 NMAC - Rn, 16 NMAC 19.7.7, 03-30-02]

16.19.7.8 LEADERSHIP:

A. There shall be a pharmacist-in-charge of the hospital pharmacy. The pharmacist in charge may be employed part-time or full-time as the activity of service requires. When services are provided on a part-time basis, the pharmacist-in-charge or designated pharmacist shall visit the facility at least every 72 hours. Visitation schedules exceeding 72 hours must request Board approval.

B. The pharmacist-in-charge shall be assisted by an adequate number of competent and qualified personnel.

C. Written job descriptions for all categories of pharmacy personnel shall be prepared and revised as necessary.

D. A pharmacy policy and procedure manual shall be prepared by the pharmacist-in-charge and readily available. The manual shall be reviewed annually for the purpose of establishing its consistency with current hospital practices and the process documented. A copy of this manual shall be submitted to the Board or its agent for review and approval at the time of the hospital license application. Any subsequent changes shall be reviewed by the Board or its agent.

[08-16-99; 16.19.7.8 NMAC - Rn, 16 NMAC 19.7.8, 03-30-02; A, 04-30-03]

16.19.7.9 FACILITIES:

A. The hospital pharmacy shall be enclosed and locked if a pharmacist is not present in the facility. Adequate security systems shall be maintained and be consistent with the security plan of the facility.

B. The pharmacist-in-charge shall control access to the pharmacy and develop an emergency access procedure that may include the following situations or conditions:

(1) The hospital administrator or designee may possess a key to the pharmacy for emergency access.

(2) For the purposes of withdrawing limited doses of a drug for administration in emergencies when the pharmacy is closed, if the drugs are not available in floor or emergency drug supplies, the following is applicable:

(a) Only one designated licensed nurse per shift may remove drugs from the pharmacy. The quantity of drugs shall not exceed the quantity needed to last until the pharmacist is in the facility:

(b) A record shall be made at the time of withdrawal by the authorized person removing the drugs. The record shall contain the following:

(i) name of patient;
(ii) name of drug, strength, and dosage form;
(iii) dose prescribed;
(iv) quantity taken;
(v) time and date; and
(vi) signature (first initial and last name or full signature) or electronic signature of person making the withdrawal.

(c) The original or direct copy of the medication order may substitute for such record, providing the medication order meets all of the requirements of 16.19.7.9.B(2)(b) NMAC (record).

(d) The nurse withdrawing the drug shall place upon the record of withdrawal an example of the medication removed.

(e) An electronic record of the withdrawal is required when the nurse is withdrawing more than a 72 hour supply.

(f) The pharmacist shall verify the withdrawal after a reasonable interval, but in no event may such interval exceed 72 hours from time of withdrawal. Verification may be accomplished electronically from a remote site, if approved by the board.

(g) A drug regimen review, pursuant to a new medication order, will be conducted by a pharmacist either on-site or by electronic transmission within 24 hours of the new order.

(h) Another duly registered pharmacy may supply medications pursuant to a patient specific medication order provided:

(i) supplying pharmacy is licensed in this state;
(ii) supplying pharmacist is licensed in this state;
(iii) all pharmacy preparations of sterile products (including total parenteral nutrition and chemotherapy) shall be performed in accordance with board of pharmacy 16.19.6.11 NMAC.

(3) The pharmacist-in-charge or designated pharmacist, intern or technician may prepackage drugs for

emergency withdrawal.

C. A pharmacist shall be "on call" during all absences from the facility.

D. A hospital pharmacy shall have within the institutional facility it services sufficient floor space allocated to ensure that pharmaceutical services are provided in an environment which allows for the proper compounding, dispensing and storage of medications. The minimum required pharmacy floor space excluding office area is:

Average daily census including skilled beds	Specialty designation	1-25	26-50	51-100	101-200	201-500	>500
Minimum Square Feet	Adequate	Adequate	280	500	750	1000	1500
Min. Sq. Ft. for Sterile Prep Area (in addition to above)	100	100	100	100	100	100	100

A hospital may petition the board for a variance to the required minimum square footage. The license application shall include an average daily inpatient census for the last year.

E. Specialty Designation:

(1) Adequate square footage will be decided by the board at the time of licensure. The yearly license application will be accompanied by photos and a drawing of the pharmacy area. The board may ask for more detailed information to make a determination.

(2) A hospital must petition the board for a specialty designation. The board may consider, but is not limited to the following:

(a) size of facility;
(b) type of patient population; or
(c) number and types of drugs stored and dispensed from the pharmacy.

F. Hospitals having licensed outpatient pharmacies shall comply with retail pharmacy 16.19.6.10 NMAC.

G. The hospital pharmacy shall have the necessary equipment for the safe and appropriate storage, compounding, packaging, labeling, dispensing and preparation of drugs and parenteral products depending on the scope of pharmaceutical services provided.

(1) Refrigerator.
(2) Sink with hot and cold water.

H. Only one registered or certified pharmacy technician may be present in the pharmacy when the pharmacist is not in the facility, only to perform clerical tasks. A written log shall be maintained of technician activities while alone in the pharmacy

[08-16-99; 16.19.7.9 NMAC - Rn, 16 NMAC 19.7.9, 03-30-02; A, 04-30-03; A, 01-31-07]

16.19.7.10 PHARMACY SERVICE UNIT:

A. A pharmacy service unit:

(1) is a separate entity from the central hospital pharmacy, within the same physical building;
(2) provides limited and/or specialized inpatient pharmacy services with a minimum of 100 square feet;
(3) has the necessary space, references and equipment to perform the pharmacy service to be provided.

B. If controlled substances are stored in and/or dispensed from the Pharmacy Service Unit, a locked storage space must be provided and used to store all controlled substances.

C. The Pharmacy Service Unit shall be covered by the hospital pharmacy license.

D. A pharmacist shall be available to the Pharmacy Service Unit during operational hours.

E. A pharmacist shall control access to the Pharmacy Service Unit. Pharmacy technician(s) or intern(s) may be present in the Pharmacy Service Unit during operational hours when the pharmacist is present in the facility.

[08-16-99; 16.19.7.10 NMAC - Rn, 16 NMAC 19.7.10, 03-30-02]

16.19.7.11 DRUG DISTRIBUTION AND CONTROL:

A. In hospitals where there is not a pharmacy, prelabeled, prepackaged medications shall be stored in and distributed from a drug storage area or automated medication management system, which is under the supervision of a pharmacist.

B. The pharmacist-in-charge shall have the responsibility for the procurement and storage of all drugs.

C. All medications, with the exception of those for emergency use, shall be issued for inpatients use pursuant to the review of the physician's order or direct copy thereof, prior to dispensing. If the pharmacy is closed when the order is written, the pharmacist shall review the order within 24 hrs.

D. A medication profile for all inpatients and outpatients shall be maintained and used. The medication profile shall serve as the distribution record for inpatient medications. Dangerous drug distribution records, for inpatient use, must include the following information:

(1) the patient's name and room (or bed) number;

(2) the name, strength, quantity and dosage form of the drug distributed;
(3) the name of the technician filling the drug order and pharmacist responsible for checking the technician's work; or
(4) the name of the pharmacist or pharmacist intern filling the drug order;
(5) the date filled; and
(6) the date and amount of unwanted/ unused drug returned to the pharmacy stock;
(7) records for schedule II controlled substances must be kept separate; and
(8) schedule III-V must be kept separate or if stored with non-controlled records, readily retrievable.

E. Floor stock dangerous drug distribution records must include the following:
(1) name, strength, dosage form, and quantity of the drug distributed;
(2) date of filling;
(3) a name of technician filling the drug order and the supervising pharmacist; or
(4) the name of the pharmacist or pharmacist intern filling the drug order;
(5) the destination location of the drug in the hospital; and
(6) the date and quantity of unwanted/ unused drug returned to the pharmacy's stock;
(7) schedule II controlled substance records must be kept separate from all other records; and
(8) schedule IV controlled substance records must either be kept separate from other non-controlled substances records or are readily retrievable.

F. Dangerous drug distribution records, inpatient and floor stock, and medication profiles may be stored electronically if such system is capable of producing a printout of all the required information and the information is retrievable within 72 hours upon demand. The pharmacist stating that it is a true and accurate record must certify the printout. Hospitals utilizing automated drug distribution must comply with Subsection M of 16.19.7.11 NMAC in lieu of the above. Hospital pharmacies are subject to all applicable state and federal record keeping requirements when a prescription from a licensed practitioner is filled.

G. A distribution system for controlled substances shall be maintained including perpetual inventory of all schedule II controlled substances. All schedule II controlled substances that are stored in the pharmacy will be kept in a locked storage area in the pharmacy.

H. Drug storage and preparation areas within the facility shall be the responsibility of the pharmacist-in-charge. All areas shall be inspected on a monthly basis and documented by a pharmacist, intern or technician.

I. All pharmacy preparations of sterile products shall be performed in accordance with the sterile products regulations, 16.19.6 NMAC.

J. Floor stock drugs, including those issued from automated medication management systems, shall be limited to drugs for emergency use and routinely used items as listed in the pharmacy policy and procedure manual and approved by the pharmacy and therapeutics committee. Floor stock drugs shall be supplied in individual doses unless the bulk container cannot be individualized. Dangerous drug floor stock must be reviewed by the pharmacist or pharmacist intern on a routine basis to insure appropriate use.

K. Where such committees exist, the pharmacist-in-charge or designated pharmacist shall be a voting member of the pharmacy and therapeutics committee or its equivalent.

L. Medications dispensed in the emergency room will be dispensed only by a licensed pharmacist, a licensed pharmacist intern or a licensed practitioner and shall comply with the following:
(1) a record shall be kept of all medications dispensed from the emergency room of a hospital; the record shall include:
(a) the date the drug was dispensed;
(b) name and address of the patient;
(c) name of the prescribing physician;
(d) the name of the drug;
(e) the strength of the drug;
(f) the quantity of drug dispensed;
(g) initials of the person recording the information if not a physician;
(2) a separate record shall be kept for schedule II controlled substances;
(3) the following will be recorded in the patient's medical chart:
(a) the name of the drug(s) prescribed;
(b) the strength of the drug;
(c) the quantity of the drug dispensed;
(4) when medications are prescribed by the physician and dispensed to the patient in the emergency room of the hospital the dispensing label shall contain the following information:
(a) the name of the patient;
(b) the name of the prescribing physician;
(c) name of the drug;
(d) strength of the drug;
(e) quantity of the drug;

(f) name and address of the hospital;
(g) date the drug is dispensed;
(h) directions for use;
(i) expiration date of medication.

M. Automated Pharmacy Systems.

(1) General Statement: Automated devices for storage and distribution of floor stock or patient profile drugs or both, shall be limited to licensed health care facilities and shall comply with all the following provisions. Written policies and procedures, approved by the appropriate health care facility committee, shall be in place to ensure safety, accuracy, security, and patient confidentiality. Personnel allowed access to an automated dispensing device shall have a confidential access code that records the identity and electronic signature of the person accessing the device.

(2) Security/Access: The control of access to the automated device must be controlled by the pharmacist-in-charge. Proper identification and access control, including electronic passwords or other coded identification, must be limited and authorized by the pharmacist-in-charge. The pharmacist-in-charge must be able to stop or change access at any time. The pharmacist-in-charge must maintain a current and retrievable list of all persons who have access and the limits of that access. Review of user access reports shall be conducted at least quarterly as established by policy and procedures to ensure that persons who are no longer employed at the facility do not have access to the system.

(3) Records: The records kept by the automated drug delivery system must comply with all state, federal, and board requirements. Records must be maintained by the pharmacy and be readily retrievable. Records may be retained in hard copy or an alternative data retention system may be used where current technology allows.

(4) Automated Drug Distribution: An automated medication management system shall be under the control of the pharmacist-in-charge. If used for storage and dispensing of doses scheduled for administration, there shall be a procedure by which orders for a drug are reviewed and approved by the pharmacist before the drug may be withdrawn from the automated dispensing device. There shall be written procedures for downtime in the event of system malfunction or otherwise inoperable. A downtime log shall be maintained and include:

(a) date of transaction;
(b) patient;
(c) drug/dose;
(d) quantity of transaction;
(e) nurse signature;
(f) beginning count;
(g) ending count;
(h) wasted amount;
(i) witness signature, if needed; and
(j) prescriber (for controlled substances only).

(5) Quality Assurance: The pharmacist-in-charge shall be responsible for developing and implementing a quality assurance program which monitors total system performance. Quality monitors shall include:

(a) the proper loading/refilling of the device, including proof of delivery;
(b) the proper removal, return or waste of drugs;
(c) processes for recording, resolution, and reporting of discrepancies; and
(d) processes for conducting periodic audits to assure compliance with policies and procedures.

(6) Records: Transaction records: At the time of any event involving the contents of the automated device, the device shall automatically produce on demand, a written or electronic record showing:

(a) the date and time of transaction;
(b) the type of transaction;
(c) the name, strength, and quantity of medication;
(d) the name of the patient for whom the drug was ordered;
(e) the name or identification code (electronic signature) of the person making the transaction;
(f) the name of the attending, admitting or prescribing practitioner; and
(g) the identity of the device accessed.

(7) Delivery Records: A delivery record shall be generated on demand for all drugs filled into an automated dispensing device which shall include:

(a) date;
(b) drug name;
(c) dosage form
(d) strength;
(e) quantity;
(f) identity of device; and
(g) name or initials of the person filling the automated dispensing device.

(8) Filling: There shall be policies and procedures in place, utilizing either manual , bar coding or other electronic processing means of item identities as current technology allows, to ensure pharmacist verification of accuracy in the filling and refilling of the automated device. A delivery record of medications filled into an automated pharmacy system

shall be maintained and shall include identification of the person filling the device.

(9) Labeling/Packaging: Drugs filled into automated dispensing devices shall be in manufacturers' sealed, original packaging or in repackaged containers in compliance with the requirements of the board regulations relating to packaging and labeling.

N. Outsourcing of Pharmaceutical Services: A hospital pharmacy may contract or enter into an agreement with another licensed pharmacy/pharmacist to provide pharmaceuticals and/or other pharmacist services under the following conditions:

(1) the contract pharmacy is licensed by the board of pharmacy;

(2) the pharmacist providing the services by the contracted pharmacy shall be licensed as a pharmacist in this state;

(3) the contract is incorporated into the pharmacy's policy and procedure manual and complies with the requirements of 16.19.7 NMAC;

(4) the contracted pharmacy/pharmacist must have complete access to the patient's profile in order to perform a drug regimen review;

(5) the contracted pharmacy/pharmacist must have access to the licensed practitioners of the hospital;

(6) records of all pharmaceuticals transferred from the contracted pharmacy to the hospital pharmacy comply with the requirements;

(7) documentation of the services provided by the contracted pharmacy/pharmacist.

[08-16-99; 16.19.7.11 NMAC - Rn, 16 NMAC 19.7.11, 03-30-02; A, 01-31-07]

16.19.7.12 DRUG INFORMATION:

A. The pharmacist-in-charge is responsible for provision of drug information to the staff and patients of the healthcare facility. The pharmacist-in-charge shall be responsible for providing in-service education to the facility's professional staff. In-service activities shall be documented.

B. The pharmacist-in-charge is responsible for maintaining up-to-date reference materials or electronic access to reference publications commensurate with the scope of practice. At a minimum, these references will include the current editions of:

(1) a drug interactions text;

(2) an injectable drug text;

(3) a general drug information text; and

(4) New Mexico Pharmacy Law and Rules and Regulations and all available revisions.

C. The telephone number of a regional Poison and Drug Information Center shall be posted in all areas where medications are stored.

[08-16-99; 16.19.7.12 NMAC - Rn, 16 NMAC 19.7.12, 03-30-02]

16.19.7.13 ASSURING RATIONAL DRUG THERAPY:

A. The pharmacist in conjunction with practitioners, nurses and other professional staff shall develop a procedure for the review and reporting of significant adverse drug reactions and medication errors. These events shall be reported to the prescribing practitioner and the appropriate hospital quality assurance committee such as the Pharmacy and Therapeutics Committee or its equivalent..

B. Clinical information about patients must be available and accessible to the pharmacist for use in daily practice activities.

C. The pharmacist shall review each medication order for safety and appropriateness and communicate with the prescriber when adjustments may be necessary. Suggested changes made to the prescriber must be documented.

D. A documented medication-use-measurement program, developed shall be in place to evaluate the medication-use-process of prescribing, dispensing, administering and monitoring.

[08-16-99; 16.19.7.13 NMAC - Rn, 16 NMAC 19.7.13, 03-30-02]

16.19.7.14 RESEARCH:

A. The pharmacist shall conduct, participate in and support medical and pharmaceutical research appropriate to the goals, objectives and resources of the facility.

B. There shall be a pharmacist member on the facility's Institutional Review Board, or its equivalent. The pharmacist shall ensure that policies and procedures for the appropriate use of investigational drugs are established and followed.

C. A copy of the research protocol for a study involving investigational drugs and the facility's patients, shall be provided to the pharmacist. A copy of drug protocols shall be maintained in the pharmacy of all active investigational drug studies and similar research projects involving drugs in which the facility's patients are participants.

[08-16-99; 16.19.7.14 NMAC - Rn 16 NMAC 19.7.14, 03-30-02]

16.19.7.15 IN-HOUSE CLINICS: In-house clinics owned and operated by the institution must meet regulations set forth in Part 10 "Limited Drug Clinics" and Part 4 "Pharmacists". The clinic may operate under the license of the hospital

pharmacy and is not required to obtain a separate license or permit from the Board.
[08-16-99; 16.19.7.15 NMAC - Rn, 16 NMAC 19.7.15, 03-30-02]

16.19.7.16 APPLICATION OF REGULATION: Pharmacies licensed by the board prior to adoption of this regulation shall comply with the facility floor space standards defined in section 9.D by December 31, 2002. When these pharmacies change ownership, remodel the pharmacy or relocate the pharmacy after the effective date of this regulation, Section 9.D shall apply. All other portions of this regulation apply on the effective date.
[08-16-99; 16.19.7.16 NMAC - Rn, 16 NMAC 19.7.16, 03-30-02]

HISTORY of 16.19.7 NMAC:
Pre-NMAC History:
The material in this Part was derived from that previously filed with the State Records Center and Archives under: BOP 67-4, Regulation No. 19-67, Hospital Pharmacies And Drug Dispensaries, 11-17-67.
BOP 69-2, Rules And Regulations, Of The State Board Of Pharmacy, 6-13-69.
BOP 69-3, New Mexico Laws And Regulations, Pharmacy Act, Drug and Cosmetic Act, Narcotic Drug Act, Poisons Act, Board of Pharmacy Rules and Regulations, 8-15-69.
BOP72-1, New Mexico Board Of Pharmacy Rules And Regulations Promulgated Pursuant To New Mexico Drug and Cosmetic Act, Pharmacy Act, Controlled Substances Act, 7-31-72.
Regulation No. 7, Hospital Pharmacies and Drug Room Facilities, 2-7-80.
Regulation No. 7, Hospital Pharmacies and Drug Room Facilities, 10-23-85.
Regulation No. 7, Hospital Pharmacies And Drug Room Facilities, 2-2-87.
Regulation No. 7, Hospital Pharmacies And Drug Room Facilities, 7-27-90.

History of Repealed Material:
16.19.7, Hospital Pharmacies And Drug Room Facilities, filed 2-2-96 with the State Records Center & Archives, is repealed effective 8-16-99.
BOP 72-1, New Mexico Board of Pharmacy Rules and Regulations Promulgated Pursuant to New Mexico Drug and Cosmetic Act, Pharmacy Act, Controlled Substances Act - Repealed, 10-29-85.

Other History: 16 NMAC 19.7, Pharmacists - Hospital Pharmacies and Drug Room Facilities, filed 02-02-96; 16 NMAC 19.7, Pharmacists - Hospital Pharmacies, filed 08-02-99; reformatted and renumbered to 16.19.15 NMAC, Hospital Pharmacies, effective 03-30-2002.

Office of the Professions

Education Law

Article 137, Pharmacy

§6800. Introduction | §6801. Definition of practice of pharmacy | §6801-a. Collaborative drug therapy management demonstration program | §6802. Definitions | §6803. Practice of pharmacy and use of title "pharmacist" | §6804. State board of pharmacy | §6805. Requirements for a professional license | §6806. Limited permits | §6807. Exempt persons | §6808. Registering and operating establishments | §6808-a. Identification of pharmacists | §6808-b. Registration of nonresident establishments | §6810. Prescriptions | §6811. Misdemeanors | §6811-a. Certain drugs to be clearly marked or labeled | §6811-b. Door-to-door distribution of drugs prohibited | §6812. Special provisions | §6813. Seizure | §6814. Records of shipment | §6815. Adulterating, misbranding and substituting | §6816. Omitting to label drugs, or labeling them wrongly | §6816-a. When substitution is required | §6817. New drugs | §6818. Adulterated and misbranded cosmetics | §6818-a. Cosmetic samples | §6819. Regulations making exceptions | §6820. Certification of coal-tar colors for drugs and cosmetics | §6821. Poison schedules; register | §6822. Examinations and investigations | §6823. Factory inspection | §6824. Injunction proceedings | §6825. Proof required in prosecution for certain violations | §6826. Drug retail price lists | § 6826-a. Reducing certain copayments | §6827. Mandatory continuing education | * §6828. Certificates of administration | §6829. Interpretation and translation requirements for prescription drugs and standardized medication labeling | §6830. Standardized patient-centered data elements

§6800. Introduction.

This article applies to the profession of pharmacy. The general provisions for all professions contained in article one hundred thirty of this title apply to this article.

§6801. Definition of practice of pharmacy.

1. The practice of the profession of pharmacy is defined as the administering, preparing, compounding, preserving, or the dispensing of drugs, medicines and therapeutic devices on the basis of prescriptions or other legal authority, and collaborative drug therapy management in accordance with the provisions of section sixty-eight hundred one-a of this article.
2. A licensed pharmacist may execute a non-patient specific regimen prescribed or ordered by a licensed physician or certified nurse practitioner, pursuant to rules and regulations promulgated by the commissioner. When a licensed pharmacist administers an immunizing agent, he or she shall:
    a. report such administration to the patient's attending primary health care practitioner or practitioners, if any, pursuant to rules and regulations of the commissioner;
    b. provide information to the patient on the importance of having a primary health care practitioner, developed by the commissioner of health; and
    c. report such administration, absent of any individually identifiable health information, to the department of health in a manner required by the commissioner of health.
3. No pharmacist shall administer immunizing agents without receiving training satisfactory to the commissioner and the commissioner of health which shall include, but not be limited to, techniques for screening individuals and obtaining informed consent; techniques of administration; indications, precautions and contraindications in the use of agent or agents; record keeping of immunization and information; and handling emergencies, including anaphylaxis and needlesticks.
4. The commissioner of health, in consultation with the commissioner, shall prepare and submit a report to the governor and the legislature, on or before December thirty-first, two thousand eleven, reporting the results and evaluating the effectiveness and impact, if any, of implementation of subdivision two of this section upon the supply of such immunizing agents for the prevention of influenza and pneumococcal disease, upon the geographical distribution of such agents, and upon the distribution of such agents among health care providers, including physicians, and pharmacies in New York state.

Effective until March 31, 2016

§6801-a. Collaborative drug therapy management demonstration program.

1. As used in this section, the following terms shall have the following meanings:
    a. "Collaborative drug therapy management" shall mean the performance of services by a pharmacist relating to the review, evaluation and management of drug therapy to a patient, who is being treated by a physician for a specific disease or disease state, in accordance with a written agreement or protocol with a voluntarily participating physician and in accordance with

4. The existence of a written agreement or protocol on collaborative drug therapy management and the patient's right to choose to not participate in collaborative drug therapy management shall be disclosed to any patient who is eligible to receive collaborative drug therapy management. Collaborative drug therapy management shall not be utilized unless the patient or the patient's authorized representative consents, in writing, to such management. If the patient or the patient's authorized representative consents, it shall be noted on the patient's medical record. If the patient or the patient's authorized representative who consented to collaborative drug therapy management chooses to no longer participate in such management, at any time, it shall be noted on the patient's medical record. In addition, the existence of the written agreement or protocol and the patient's consent to such management shall be disclosed to the patient's primary physician and any other treating physician or healthcare provider.
5. Participation in a written agreement or protocol authorizing collaborative drug therapy management shall be voluntary, and no patient, physician, pharmacist, or facility shall be required to participate.
6. Nothing in this section shall be deemed to limit the scope of practice of pharmacy nor be deemed to limit the authority of pharmacists and physicians to engage in medication management prior to the effective date of this section and to the extent authorized by law.

* NB Repealed September 14, 2014

§6802. Definitions.

1. "Pharmacy" means any place, other than a registered store, in which drugs, prescriptions or poisons are possessed for the purpose of compounding, preserving, dispensing or retailing, or in which drugs, prescriptions or poisons are compounded, preserved, dispensed or retailed, or in which such drugs, prescriptions or poisons are by advertising or otherwise offered for sale at retail.
2. [Repealed]
3. "Formulary" means the latest edition of the official national formulary, and its supplement.
4. "Pharmacopeia", when not otherwise limited, means the latest edition of the official United States pharmacopeia, and its supplement.
5. "Homeopathic pharmacopeia" means the official homeopathic pharmacopeia of the United States, and its supplement.
6. "Official compendium" means the official United States pharmacopeia, official homeopathic pharmacopeia of the United States, official national formulary, or their supplements.
7. "Drugs" means:
   a. Articles recognized in the official United States pharmacopeia, official homeopathic pharmacopeia of the United States, or official national formulary.
   b. Articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or animals.
   c. Articles (other than food) intended to affect the structure or any function of the body of man or animals.
   d. Articles intended for use as a component of any article specified in paragraphs a, b, or c; but does not include devices or their components, parts or accessories.
8. "Cosmetics" means:
   a. Articles intended to be rubbed, poured, sprinkled or sprayed on, introduced into or otherwise applied to the human body for cleansing, beautifying, promoting attractiveness, or altering the appearance.
   b. Articles intended for use as a component of any such articles; except that the term shall not include soap.
9. "Poison", where not otherwise limited, means any drug, chemical or preparation likely to be destructive to adult human life in quantity of sixty grains or less.
10. "Label" means a display of written, printed or pictorial matter upon the immediate container of any drug, device or cosmetic. Any requirement made by or under authority of this article, that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement or other information also appears on the outside container or wrapper, if there be any, of the retail package of such drug, device or cosmetic or is easily legible through the outside container or wrapper.
11. "Immediate container" does not include package liners.
12. "Labeling" means all labels and other written, printed or pictorial matter:
    a. Upon any drug, device or cosmetic or any of its containers or wrappers, or
    b. Accompanying such drug, device or cosmetic.
13. "Misbranding". If a drug, device or cosmetic is alleged to be misbranded because the labeling is misleading, or if an advertisement is alleged to be false because it is misleading then in determining whether the labeling or advertisement is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, sound or any combination thereof, but also the extent to which the labeling fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the drug, device, or cosmetic to which the labeling or advertising relates under the conditions of use

b. Any physician, dentist, veterinarian or other licensed health care provider legally authorized to prescribe drugs under this title who is not the owner of a pharmacy, or registered store, or who is not in the employ of such owner, from supplying his patients with such drugs as the physician, dentist, veterinarian or other licensed health care provider legally authorized to prescribe drugs under this title deems proper in connection with his practice, provided, however, that all such drugs shall be dispensed in a container labeled with the name and address of the dispenser and patient, directions for use, and date of delivery, and in addition, such drug shall bear a label containing the proprietary or brand name of the drug and, if applicable, the strength of the contents, unless the person issuing the prescription specifically states on the prescription in his own handwriting, that the name of the drug and the strength thereof should not appear on the label; provided further that if such drugs are controlled substances, they shall be dispensed pursuant to the requirements of article thirty-three of the public health law;
c. Any merchant from selling proprietary medicines, except those which are poisonous, deleterious or habit forming, or materials and devices specifically exempted by regulations of the department or by the public health law;
d. Any personnel in an institution of higher learning from using prescription-required drugs on the premises for authorized research, experiments or instruction, in accordance with the department's regulations and, if such drugs are controlled substances, in accordance with title III of article thirty-three of the public health law; or
e. The necessary and ordinary activities of manufacturers and wholesalers, subject to the provisions of article thirty-three of the public health law.

2.
a. Notwithstanding the provisions of paragraph b of subdivision one of this section, no prescriber who is not the owner of a pharmacy, or registered store, or who is not in the employ of such owner, may dispense more than a seventy-two hour supply of drugs, except for:
1. persons practicing in hospitals as defined in section twenty-eight hundred one of the public health law;
2. the dispensing of drugs at no charge to their patients;
3. persons whose practices are situated ten miles or more from a registered pharmacy;
4. the dispensing of drugs in a clinic, infirmary or health service that is operated by or affiliated with a post-secondary institution;
5. persons licensed pursuant to article one hundred thirty-five of this title;
6. the dispensing of drugs in a medical emergency as defined in subdivision six of section sixty-eight hundred ten of this article;
7. the dispensing of drugs that are diluted, reconstituted or compounded by a prescriber;
8. the dispensing of allergenic extracts; or
9. the dispensing of drugs pursuant to an oncological or AIDS protocol.
b. The commissioner, in consultation with the commissioner of health, may promulgate regulations to implement this subdivision and may, by regulation, establish additional renewable exemptions for a period not to exceed one year from the provisions of paragraph a of this subdivision.

3. A pharmacist may dispense drugs and devices to a registered professional nurse, and a registered professional nurse may possess and administer, drugs and devices, pursuant to a non-patient specific regimen prescribed or ordered by a licensed physician or certified nurse practitioner, pursuant to regulations promulgated by the commissioner and the public health law.

§6808. Registering and operating establishments.

1. No person, firm, corporation or association shall possess drugs, prescriptions or poisons for the purpose of compounding, dispensing, retailing, wholesaling, or manufacturing, or shall offer drugs, prescriptions or poisons for sale at retail or wholesale unless registered by the department as a pharmacy, store, wholesaler, or manufacturer.
2. Pharmacies.
a. Obtaining a registration. A pharmacy shall be registered as follows:
1. The application shall be made on a form prescribed by the department.
2. The application shall be accompanied by a fee of three hundred forty-five dollars.
3. To secure and retain a registration, a pharmacy must be equipped with facilities, apparatus, utensils and stocks of drugs and medicines sufficient to permit the prompt and efficient compounding and dispensing of prescriptions, as prescribed by regulation.
b. Renewal of registration. All pharmacy registrations shall be renewed on dates set by the department. The triennial registration fee shall be two hundred sixty dollars or a pro rated portion thereof as determined by the department At the time of renewal, the owner of every pharmacy shall report under oath to the department any facts required by the board of pharmacy.
c. Display of registration. The registration shall be conspicuously displayed at all times in the pharmacy. The names of the owner or owners of a pharmacy shall be conspicuously displayed upon the exterior of such establishment. The names so displayed shall be presumptive evidence

of ownership of such pharmacy by such person or persons. In the event that the owner of a licensed pharmacy is not a licensed pharmacist, the pharmacy registration issued shall also bear the name of the licensed pharmacist having personal supervision of the pharmacy. In the event that such licensed pharmacist shall no longer have personal supervision of the pharmacy, the owner shall notify the department of such fact and of the name of the licensed pharmacist replacing the pharmacist named on the license and shall apply for an amended registration showing the change. The amended registration must be attached to the original registration and displayed in the same manner. Both the owner and the supervising pharmacist shall be responsible for carrying out the provisions of this article.

d. Change of location. In the event that the location of a pharmacy shall be changed, the owner shall apply to the department for inspection of the new location and endorsement of the registration for the new location. The fee for inspection and endorsement shall be fifty dollars, unless it appears to the satisfaction of the department that the change in location is of temporary nature due to fire, flood or other disaster.
e. Conduct of a pharmacy. Every owner of a pharmacy is responsible for the strength, quality, purity and the labeling thereof of all drugs, toxic substances, devices and cosmetics, dispensed or sold, subject to the guaranty provisions of this article and the public health law. Every owner of a pharmacy or every pharmacist in charge of a pharmacy shall be responsible for the proper conduct of this pharmacy. Every pharmacy shall be under the immediate supervision and management of a licensed pharmacist at all hours when open. No pharmacist shall have personal supervision of more than one pharmacy at the same time.
f. A pharmacy as a department. When a pharmacy is operated as a department of a larger commercial establishment, the area comprising the pharmacy shall be physically separated from the rest of the establishment, so that access to the pharmacy and drugs is not available when a pharmacist is not on duty. Identification of the area within the pharmacy by use of the words "drugs", "medicines", "drug store", or "pharmacy" or similar terms shall be restricted to the area licensed by the department as a pharmacy.
g. Limited pharmacy registration.
    1. When, in the opinion of the department, a high standard of patient safety, consistent with good patient care, can be provided by the registering of a pharmacy within a hospital, nursing home or extended care facility which does not meet all of the requirements for registration as a pharmacy, the department may waive any requirements pertaining to full-time operation by a licensed pharmacist, minimum equipment, minimum space and waiting area, provided that when the waiver of any of the above requirements is granted by the board, the pharmaceutical services to be rendered by the pharmacy shall be limited to furnishing drugs to patients registered for treatment by the hospital, and to in-patients for treatment by the nursing home or extended care facility.
    2. When in the opinion of the department, a high standard of patient safety, consistent with good patient care, can be provided by the registering of a pharmacy within a facility distributing dialysis solutions for patients suffering from end stage renal disease and where the pharmaceutical services to be rendered by the pharmacy shall be limited to furnishing dialysis solutions to patients for whom such has been prescribed by a duly authorized prescriber, the department may waive certain requirements, including, but not limited to, full-time operation by a licensed pharmacist, minimum equipment, and minimum space and waiting area. Such solutions shall only be dispensed by employees who have completed an approved training program and who have demonstrated proficiency to perform the task or tasks of assemblying, labeling or delivering a patient order and who work under the general supervision of a licensed pharmacist who shall be responsible for the distribution, record keeping, labeling and delivery of all dialysis solutions dispensed by the distributor as required by the department.
    3. The department shall promulgate such rules or regulations consistent with this paragraph as are necessary to ensure the safe distribution of such dialysis solution, including establishment registration and proper record keeping, storage, and labeling.
    4. The initial registration fee and renewal fee for a limited pharmacy shall be three hundred forty-five dollars for each triennial registration period.
h. Applicant registration. An applicant for registration as a pharmacy shall be of good moral character, as determined by the department. In the case of a corporate applicant, the requirement shall extend to all officers and directors and to stockholders having a ten percent or greater interest in the corporation.

3. [Repealed]
4. Wholesaler's or manufacturer's registration.
    a. Obtaining a registration. A wholesaler or manufacturer shall be registered as follows:
        1. The application shall be made on a form prescribed by the department.
        2. The application shall be accompanied by a fee of eight hundred twenty-five dollars.

   b. Renewal of registration. All wholesalers' and manufacturers' registrations shall be renewed on dates set by the department. The triennial registration fee shall be five hundred twenty dollars or a pro rated portion thereof as determined by the department
   c. Display of registration. The registration shall be displayed conspicuously at all times in the place of business.
   d. Change of location. In the event that the location of such place of business shall be changed, the owner shall apply to the department for inspection of the new location and endorsement of the registration for the new location. The fee for inspection and endorsement shall be one hundred seventy dollars, unless it appears to the satisfaction of the department that the change in location is of a temporary nature due to fire, flood or other disaster.
5. Inspection. The state board of pharmacy and the department of education, and their employees designated by the commissioner, shall have the right to enter any pharmacy, wholesaler, manufacturer, or registered store, or vehicle and to inspect, at reasonable times, such factory, warehouse, establishment or vehicle and all records required by this article, pertinent equipment, finished and unfinished materials, containers, and labels.
6. Revocation or suspension. A pharmacy, store, wholesaler or manufacturer registration may be revoked or suspended by the committee on professional conduct of the state board of pharmacy in accordance with the provisions of article one hundred thirty.
7. Sale of drugs at auction. No controlled substance or substances and no poisonous or deleterious drugs or drugs in bulk or in opened containers shall be sold at auction unless the place where such drugs are sold at auction shall have been registered by the board, and unless such sale shall be under the personal supervision of a licensed pharmacist. Drugs in open containers shall not be sold at auction unless the seller shall have in his possession a certificate of the board showing that such drugs have been inspected and meet the requirements of this article. In the event that the drug so sold is one as to which this article or any federal statute or any regulation adopted pursuant to this article or an applicable federal statute require that the expiration date be stated on each package, such drug may not be sold at auction after such expiration date or when such expiration date will occur within a period of thirty days or less from the date of sale.

§6808-a. Identification of Pharmacists.

Every pharmacist on duty shall be identified by a badge designed by the state board of pharmacy, which shall contain his name and title.

§6808-b. Registration of nonresident establishments.

1. Definition. The term "nonresident establishment" shall mean any pharmacy, manufacturer or wholesaler located outside of the state that ships, mails or delivers prescription drugs or devices to other establishments, authorized prescribers and/or patients residing in this state. Such establishments shall include, but not be limited to, pharmacies that transact business through the use of the internet.
2. Registration. All nonresident establishments that ship, mail, or deliver prescription drugs and/or devices to other registered establishments, authorized prescribers, and/or patients into this state shall be registered with the department; except that such registration shall not apply to intra-company transfers between any division, affiliate, subsidiaries, parent or other entities under complete common ownership and control. The provisions of this subdivision shall apply solely to nonresident establishments and shall not affect any other provision of this article.
3. Agent of record. Each nonresident establishment that ships, mails or delivers drugs and/or devices into this state shall designate a resident agent in this state for service of process pursuant to rule three hundred eighteen of the civil practice law and rules.
4. Conditions of registration. As a condition of registration, a nonresident establishment shall comply with the following requirements:
   a. Be licensed and/or registered and in good standing with the state of residence;
   b. Maintain, in readily retrievable form, records of drugs and/or devices shipped into this state;
   c. Supply, upon request, all information needed by the department to carry out the department`s responsibilities under the laws and rules and regulations pertaining to nonresident establishments;
   d. Comply with all statutory and regulatory requirements of the state where the nonresident establishment is located, for prescription drugs or devices shipped, mailed or delivered into this state, except that for controlled substances shipped, mailed or delivered into this state, the nonresident pharmacy shall follow federal law and New York law relating to controlled substances;
   e. The application shall be made in the manner and form prescribed by the department;
   f. The application of establishments to be registered as a manufacturer or wholesaler of drugs and/or devices shall be accompanied by a fee as provided in section sixty-eight hundred eight of this article; and

g. The application of establishments to be registered as a nonresident pharmacy shall be accompanied by a fee of three hundred forty-five dollars and shall be renewed triennially at a fee of two hundred sixty dollars.

5. Additional requirements. Nonresident pharmacies registered pursuant to this section shall:
   a. Provide a toll-free telephone number that is available during normal business hours and at least forty hours per week, to enable communication between a patient in this state and a pharmacist at the pharmacy who has access to the patient`s records; and
   b. Place such toll-free telephone number on a label affixed to each drug or device container.
6. Disciplinary action. Except in emergencies that constitute an immediate threat to public health, the department shall not prosecute a complaint or otherwise take formal action against a nonresident establishment based upon delivery of a drug into this state or a violation of law, rule, or regulation of this state if the agency having jurisdiction in the state where the nonresident establishment is based commences action on the violation complained of within one hundred twenty days from the date that the violation was reported; provided however, that the department may prosecute a complaint or take formal action against a nonresident establishment if it determines that the agency having jurisdiction in the state where the nonresident establishment is based has unreasonably delayed or otherwise failed to take prompt and appropriate action on a reported violation.
7. Revocation or suspension. A nonresident establishment that fails to comply with the requirements of this section shall be subject to revocation or suspension of its registration and other applicable penalties in accordance with the provisions of article one hundred thirty of this chapter.
8. Exception. The department may grant an exception from the registration requirements of this section on the application of a nonresident establishment that restricts its sale or dispensing of drugs and/or devices to residents of this state to isolated transactions.
9. Rules and regulations. The department shall promulgate rules and regulations to implement the provisions of this section.

§6810. Prescriptions.

1. *No drug for which a prescription is required by the provisions of the Federal Food, Drug and Cosmetic Act or by the commissioner of health shall be distributed or dispensed to any person except upon a prescription written by a person legally authorized to issue such prescription. Such drug shall be compounded or dispensed by a licensed pharmacist, and no such drug shall be dispensed without affixing to the immediate container in which the drug is sold or dispensed a label bearing the name and address of the owner of the establishment in which it was dispensed, the date compounded, the number of the prescription under which it is recorded in the pharmacist's prescription files, the name of the prescriber, the name and address of the patient, and the directions for the use of the drug by the patient as given upon the prescription. The prescribing and dispensing of a drug which is a controlled substance shall be subject to additional requirements provided in article thirty-three of the public health law. The words "drug" and "prescription required drug" within the meaning of this article shall not be construed to include soft or hard contact lenses, eyeglasses, or any other device for the aid or correction of vision. Nothing in this subdivision shall prevent a pharmacy from furnishing a drug to another pharmacy which does not have such drug in stock for the purpose of filling a prescription.

   * NB Effective until March 30, 2013

   * 1. No drug for which a prescription is required by the provisions of the Federal Food, Drug and Cosmetic Act or by the commissioner of health shall be distributed or dispensed to any person except upon a prescription written by a person legally authorized to issue such prescription. Such drug shall be compounded or dispensed by a licensed pharmacist, and no such drug shall be dispensed without affixing to the immediate container in which the drug is sold or dispensed a label bearing the name and address of the owner of the establishment in which it was dispensed, the date compounded, the number of the prescription under which it is recorded in the pharmacist's prescription files, the name of the prescriber, the name and address of the patient, and the directions for the use of the drug by the patient as given upon the prescription. All labels shall conform to such rules and regulations as promulgated by the commissioner pursuant to section sixty-eight hundred twenty-nine of this article. The prescribing and dispensing of a drug which is a controlled substance shall be subject to additional requirements provided in article thirty-three of the public health law. The words "drug" and "prescription required drug" within the meaning of this article shall not be construed to include soft or hard contact lenses, eyeglasses, or any other device for the aid or correction of vision. Nothing in this subdivision shall prevent a pharmacy from furnishing a drug to another pharmacy which does not have such drug in stock for the purpose of filling a prescription.

   * NB Effective March 30, 2013

2. A prescription may not be refilled unless it bears a contrary instruction and indicates on its face the number of times it may be refilled. A prescription may not be refilled more times than allowed on the prescription. The date of each refilling must be indicated on the original prescription. Prescriptions for controlled substances shall be refilled only pursuant to article thirty-three of the public health law.

PHARMACY LAWS OF NORTH CAROLINA

Current as of March 2012

Chapter 90

MEDICINE AND ALLIED OCCUPATIONS

Article 4A.

North Carolina Pharmacy Practice Act.

§ 90-85.2. Legislative findings.

The General Assembly of North Carolina finds that mandatory licensure of all who engage in the practice of pharmacy is necessary to insure minimum standards of competency and to protect the public from those who might otherwise present a danger to the public health, safety and welfare. (1981 (Reg. Sess., 1982), c. 1188, s. 1.)

§ 90-85.3. Definitions.

(a) "Administer" means the direct application of a drug to the body of a patient by injection, inhalation, ingestion or other means.

(b) "Board" means the North Carolina Board of Pharmacy.

(b1) "Clinical pharmacist practitioner" means a licensed pharmacist who meets the guidelines and criteria for such title established by the joint subcommittee of the North Carolina Medical Board and the North Carolina Board of Pharmacy and is authorized to enter into drug therapy management agreements with physicians in accordance with the provisions of G.S. 90-18.4.

(c) "Compounding" means taking two or more ingredients and combining them into a dosage form of a drug, exclusive of compounding by a drug manufacturer, distributor, or packer.

(d) "Deliver" means the actual, constructive or attempted transfer of a drug, a device, or medical equipment from one person to another.

(e) "Device" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article including any component part or accessory, whose label or labeling bears the statement "Caution: federal law requires dispensing by or on the order of a physician." The term does not include:

(1) Devices used in the normal course of treating patients by health care facilities and agencies licensed under Chapter 131E or Article 2 of Chapter 122C of the General Statutes;

(2) Devices used or provided in the treatment of patients by medical doctors, dentists, physical therapists, occupational therapists, speech pathologists, optometrists, chiropractors, podiatrists, and nurses licensed under Chapter 90 of the General Statutes, provided they do not dispense devices used to administer or dispense drugs.

(f) "Dispense" means preparing and packaging a prescription drug or device in a container and labeling the container with information required by State and federal law. Filling or refilling drug containers with prescription drugs for subsequent use by a patient is "dispensing". Providing quantities of unit dose prescription drugs for subsequent administration is "dispensing".

(g) "Drug" means:

(1) Any article recognized as a drug in the United States Pharmacopeia, or in any other drug compendium or any supplement thereto, or an article recognized as a drug by the United States Food and Drug Administration;

(2) Any article, other than food or devices, intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals;

(3) Any article, other than food or devices, intended to affect the structure or any function of the body of man or other animals; and

(4) Any article intended for use as a component of any articles specified in clause (1), (2) or (3) of this subsection.

(h) "Emancipated minor" means any person under the age of 18 who is or has been married or who is or has been a parent; or whose parents or guardians have surrendered their rights to the minor's services and earnings as

Whenever a pharmacist who has not renewed his license for five or more years seeks to renew or reinstate his license, he must appear before the Board and submit evidence that he can safely and properly practice pharmacy. (1981 (Reg. Sess., 1982), c. 1188, s. 1.)

§ 90-85.20. Licensure without examination.

(a) The Board may issue a license to practice pharmacy, without examination, to any person who is licensed as a pharmacist in another jurisdiction if the applicant shall present satisfactory evidence of possessing the same qualifications as are required of licensees in this State, that he was licensed by examination in such other jurisdiction, and that the standard of competence required by such other jurisdiction is substantially equivalent to that of this State at that time. The Board must be satisfied that a candidate for licensure has a satisfactory understanding of the laws governing the practice of pharmacy and distribution of drugs in this State.

(b) Repealed by Session Laws 1991, c. 125, s. 2. (1905, c. 108, s. 16; Rev., s. 4482; C.S., s. 6660; 1945, c. 572, s. 2; 1971, c. 468; 1977, c. 598; 1981, c. 717, ss. 6, 7; 1981 (Reg. Sess., 1982), c. 1188, s. 1; 1983, c. 196, ss. 6, 7; 1991, c. 125, s. 2.)

§ 90-85.21. Pharmacy permit.

(a) In accordance with Board regulations, each pharmacy in North Carolina shall annually register with the Board on a form provided by the Board. The application shall identify the pharmacist-manager of the pharmacy and all pharmacy personnel employed in the pharmacy. All pharmacist-managers shall notify the Board of any change in pharmacy personnel within 30 days of the change. In addition to identifying the pharmacist-manager, a pharmacy may identify a pharmacy permittee's designated agent that the Board shall notify of any investigation of the pharmacy or a pharmacist employed by the pharmacy. The notice shall include the specific reason for the investigation and be given prior to the initiation of any disciplinary proceedings.

(a1) A mobile pharmacy shall register annually with the Board in the manner prescribed in subsection (a) of this section, and the registration shall be renewed annually. A mobile pharmacy shall be considered a single pharmacy and shall not be required to pay a separate registration fee for each location but shall pay the annual registration fee prescribed in G.S. 90-85.24. A mobile pharmacy shall provide the Board with the address of every location from which prescription drugs will be dispensed by the mobile pharmacy.

(b) Each physician who dispenses prescription drugs, for a fee or other charge, shall annually register with the Board on the form provided by the Board, and with the licensing board having jurisdiction over the physician. Such dispensing shall comply in all respects with the relevant laws and regulations that apply to pharmacists governing the distribution of drugs, including packaging, labeling, and record keeping. Authority and responsibility for disciplining physicians who fail to comply with the provisions of this subsection are vested in the licensing board having jurisdiction over the physician. The form provided by the Board under this subsection shall be as follows:

Application For Registration
With The Pharmacy Board
As A Dispensing Physician

1. Name and Address of Dispensing Physician	2. Affix Dispensing Label Here

3. Physician's North Carolina License Number _____

4. Are you currently practicing in a professional association registered with the North Carolina Medical Board? _____ Yes _____ No. If yes, enter the name and registration number of the professional corporation:

_____

_____

5. I certify that the information is correct and complete.

_____ _____
Signature Date

(1927, c. 28, s. 1; 1953, c. 183, s. 2; 1981 (Reg. Sess., 1982), c. 1188, s. 1; 1987, c. 687; 1995, c. 94, s. 25; 1999-246, s. 2; 2001-375, s. 3; 2005-427, s. 1.)

§ 90-85.21A. Applicability to out-of-state operations.

(a) Any pharmacy operating outside the State which ships, mails, or delivers in any manner a dispensed legend drug into this State shall annually register with the Board on a form provided by the Board. In order to satisfy the registration requirements of this subsection, a pharmacy shall certify that the pharmacy employs a pharmacist who is responsible for dispensing, shipping, mailing, or delivering dispensed legend drugs into this State or in a state approved by the Board and has met requirements for licensure equivalent to the requirements for licensure in this State. In order for the pharmacy's certification of the pharmacists to be valid, a pharmacist shall agree in writing, on a form approved by the Board, to be subject to the jurisdiction of the Board, the provisions of this Article, and the rules adopted by the Board. If the Board revokes this certification, the pharmacy shall no longer have authority to dispense, ship, mail, or deliver in any manner a dispensed legend drug into this State.

(b) Any pharmacy subject to this section shall at all times maintain a valid unexpired license, permit, or registration necessary to conduct such pharmacy in compliance with the laws of the state in which such pharmacy is located. No pharmacy operating outside the State may ship, mail, or deliver in any manner a dispensed legend drug into this State unless such drug is lawfully dispensed by a licensed pharmacist in the state where the pharmacy is located.

(c) The Board shall be entitled to charge and collect not more than five hundred dollars ($500.00) for original registration of a pharmacy under this section, and for renewal thereof, not more than two hundred dollars ($200.00), and for reinstatement thereof, not more than two hundred dollars ($200.00).

(d) The Board may deny a nonresident pharmacy registration upon a determination that the pharmacy has a record of being formally disciplined in its home state for violations that relate to the compounding or dispensing of legend drugs and presents a threat to the public health and safety.

(e) Except as otherwise provided in this subsection, the Board may adopt rules to protect the public health and safety that are necessary to implement this section. Notwithstanding G.S. 90-85.6, the Board shall not adopt rules pertaining to the shipment, mailing, or other manner of delivery of dispensed legend drugs by pharmacies required to register under this section that are more restrictive than federal statutes or regulations governing the delivery of prescription medications by mail or common carrier. A pharmacy required to register under this section shall comply with rules adopted pursuant to this section.

(f) The Board may deny, revoke, or suspend a nonresident pharmacy registration for failure to comply with any requirement of this section. (1993, c. 455, s. 1; 1998-212, s. 12.3B(b); 2004-199, s. 25; 2005-402, s. 3.)

§ 90-85.21B. Unlawful practice of pharmacy.

It shall be unlawful for any person, firm, or corporation not licensed or registered under the provisions of this Article to:

(1) Use in a trade name, sign, letter, or advertisement any term, including "drug", "pharmacy", "prescription drugs", "prescription", "Rx", or "apothecary", that would imply that the person, firm, or corporation is licensed or registered to practice pharmacy in this State.

(2) Hold himself or herself out to others as a person, firm, or corporation licensed or registered to practice pharmacy in this State. (2003-284, s. 10.8D.)

§ 90-85.22. Device and medical equipment permits.

(a) Devices. – Each place, whether located in this State or out-of-state, where devices are dispensed or delivered to the user in this State shall register annually with the Board on a form provided by the Board and obtain a device permit. A business that has a current pharmacy permit does not have to register and obtain a device permit. Records of devices dispensed in pharmacies or other places shall be kept in accordance with rules adopted by the Board.

(b) Medical Equipment. – Each place, whether located in this State or out-of-state, that delivers medical equipment to the user of the equipment in this State shall register annually with the Board on a form provided by the Board and obtain a medical equipment permit. A business that has a current pharmacy permit or a current device permit does not have to register and obtain a medical equipment permit. Medical equipment shall be delivered only in accordance with requirements established by rules adopted by the Board.

(c) This section shall not apply to either of the following:

(1) A pharmaceutical manufacturer registered with the Food and Drug Administration.

(2) A wholly owned subsidiary of a pharmaceutical manufacturer registered with the Food and Drug Administration. (1981 (Reg. Sess., 1982), c. 1188, s. 1; 1993 (Reg. Sess., 1994), c. 692, s. 1; 2001-339, s. 1.)

§ 90-85.23. License and permit to be displayed.

Every pharmacist-manager's license, every permit, and every current renewal shall be conspicuously posted in the place of business owned by or employing the person to whom it is issued. The licenses and every last renewal of

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- **NC Pharmacy Rules -- updated March 2012 (indexed by section below)**

***NC Pharmacy Rules Indexed by Section**

Sections .0100 through .1100 have been repealed effective April 1, 1983.

SECTION .1200 - ORGANIZATION OF THE BOARD
SECTION .1300 - GENERAL DEFINITIONS
SECTION .1400 - HOSPITALS: OTHER HEALTH FACILITIES
SECTION .1500 - ADMISSION REQUIREMENTS: EXAMINATIONS
SECTION .1600 - LICENSES AND PERMITS
SECTION .1700 - DRUGS DISPENSED BY NURSE OR PHYSICIAN'S ASSISTANT
SECTION .1800 - PRESCRIPTIONS
SECTION .1900 - FORMS
SECTION .2000 - ADMINISTRATIVE PROVISIONS
SECTION .2100 - ELECTIONS
SECTION .2200 - CONTINUING EDUCATION
SECTION .2300 - PRESCRIPTION INFORMATION AND RECORDS
SECTION .2400 - DISPENSING IN HEALTH DEPARTMENT
SECTION .2500 - MISCELLANEOUS PROVISIONS
SECTION .2600 - DEVICES
SECTION .2700 - NUCLEAR PHARMACY
SECTION .2800 - STERILE PARENTERAL PHARMACEUTICALS
SECTION .2900 - PRODUCT SELECTION
SECTION .3000 - DISPOSAL OF UNWANTED DRUGS
SECTION .3100 - CLINICAL PHARMACIST PRACTITIONER
SECTION .3200 - PEER REVIEW AGREEMENTS
SECTION .3300 - REGISTRATION OF A PHARMACY TECHNICIAN
SECTION .3400 - AUTOMATED DISPENSING ON DRUG SUPPLY DEVICES

MONDAY, JULY 18, 2011

21 NCAC 46.1418, SUPERVISION OF UNIT DOSE MEDICATION SYSTEMS
General Assembly's regular session adjournment, Board Rule .1418 governing u
dose medication systems is now in effect. Pharmacist managers of in-patient
have not already, review the rule carefully. The text of the rule may be foun
here: http://www.ncbop.org/pdf/21NCAC46.1418SupervisionUnitDoesMedSys.pdf

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WEDNESDAY, JUNE 29, 2011

SECTION .1400 - HOSPITALS: OTHER HEALTH FACILITIES

21 NCAC 46 .1401 REGISTRATION AND PERMITS

(a) Registration Required. All places providing services which embrace the practice of pharmacy shall register with the North Carolina Board of Pharmacy as provided in G.S. 90-85.21 and acquire a permit to do so. Application for such registration and permit shall be on forms provided by the Board. If the Board is satisfied that proper facilities and adequately trained and properly licensed personnel have been obtained which will assure compliance with all laws regulating the compounding and distribution of drugs, the practice of pharmacy and the rules of the Board, a permit shall be issued by the Board attesting such registration.

(b) Exemptions. Nothing in these rules shall be construed to require the registration with the Board of those health care facilities in which there occurs only the administration of drugs.

(c) Separate Registration Required. The dispensing of drugs from separate locations owned by a health care facility, such as satellite pharmacies, outside clinics, health maintenance organizations, or physician's offices owned by the health care facility shall require separate registration if any one of the following criteria exists:

(1) The drugs dispensed at the location are ordinarily and customarily obtained from a source outside of the health care facility;

(2) The pharmacist-manager is controlled and supervised from a source other than the health care facility pharmacy; or

(3) The routine activity at the location is dispensing drugs to outpatients.

(d) Any pharmacy that provides compounding or dispensing services to one or more health care facilities for individual patient administration bearing any labeled name other than that under which it is registered shall require a separate registration.

(e) Health care facilities which do not have a pharmacy permit shall secure their pharmaceutical services through a pharmacist holding a current license from the Board.

History Note: *Authority G.S. 90-85.6; 90-85.21;*
Eff. April 1, 1983;
Amended Eff. May 1, 1997; May 1, 1989; March 1, 1984.

21 NCAC 46 .1402 SUPERVISION OF DRUGS IN AREAS OUTSIDE OF PHARMACY

21 NCAC 46 .1403 INSTITUTIONAL PHARMACY DRUG INVENTORIES AND EMERGENCY KITS

21 NCAC 46 .1404 MEDICATION IN INSTITUTIONAL EMERGENCY DEPARTMENTS

History Note: *Authority G.S. 90-18.1; 90-18.2; 90-85.6; 90-85.21;*
Eff. April 1, 1983;
Amended Eff. April 1, 1992; May 1, 1989; March 1, 1984;
Repealed Eff. May 1, 1997.

21 NCAC 46 .1405 STANDARDS FOR PHARMACY SERVICE

History Note: *Authority G.S. 90-85.2; 90-85.6;*
Eff. March 1, 1984;
Repealed Eff. May 1, 1989.

21 NCAC 46 .1406 AUTOMATIC STOP ORDERS

History Note: *Authority G.S. 90-85.2; 90-85.3(r); 90-85.6;*
Eff. March 1, 1984;
Amended Eff. May 1, 1989;
Repealed Eff. May 1, 1997.

21 NCAC 46 .1407 INSTITUTIONAL FORMULARY

History Note: Authority G.S. 90-85.2; 90-85.3(r); 90-85.6;
Eff. March 1, 1984;
Repealed Eff. May 1, 1989.

21 NCAC 46 .1408 INSTITUTIONAL DISCHARGE MEDICATION OPTION

History Note: Authority G.S. 90-85.6; 90-85.32;
Eff. March 1, 1984;
Amended Eff. May 1, 1989;
Repealed Eff. May 1, 1997.

21 NCAC 46 .1409 RESEARCH PARTICIPATION

History Note: Authority G.S. 90-85.3(r); 90-85.6; 90-85.34;
Eff. March 1, 1984;
Repealed Eff. May 1, 1989.

21 NCAC 46 .1410 PERSONNEL

(a) The health care facility pharmacy must be directed by a legally qualified pharmacist, hereinafter referred to as the pharmacist-manager, who shall be responsible for meeting the requirements set forth by Federal and State law, this Section, 21 NCAC 46.2502, and other applicable Rules of the Board. The pharmacist-manager shall be thoroughly familiar with the specialized functions of health care facility pharmacy practice. The pharmacist-manager shall be an employee of the health care facility or contracted for by the health care facility in which the pharmacy is located.

(b) The pharmacist-manager shall be assisted by a sufficient number of pharmacists and supportive personnel to operate such pharmacy competently, safely, and to meet the needs of the patients of the health care facility.

(c) The pharmacist-manager shall ensure that an adequate number of qualified and trained pharmacists are employed. The pharmacist- manager shall develop and implement written policies and procedures to specify the duties to be performed by such pharmacists.

(d) The pharmacist-manager shall ensure that a sufficient number of qualified, trained, and adequately supervised supportive personnel are employed to provide technical services, as well as ensuring that all such functions and activities are performed competently, safely, and without risk of harm to patients. The relationship between the supervising pharmacist and the supportive personnel shall be such that the pharmacist is fully aware of and responsible for all activities involved in the preparation and dispensing of medications prior to release to the patient, including the maintenance of appropriate records.

(e) Secretarial and clerical support shall be provided to assist with record keeping, report submission and other administrative duties.

History Note: Authority G.S. 90-85.6; 90-85.21;
Eff. May 1, 1997.

21 NCAC 46 .1411 RESPONSIBILITIES OF THE PHARMACIST-MANAGER

(a) The pharmacist-manager shall establish written procedures for the safe and effective distribution of pharmaceutical products. Procedures shall be periodically reviewed to assure they reflect current practice in the facility. A copy of such procedures shall be available in the pharmacy.

(b) The pharmacist-manager shall be responsible for the safe and effective distribution, control, and accountability for drugs, including intravenous and irrigation solutions. The pharmacist-manager may delegate responsibilities to other health care facility staff for ordering, distributing, and accounting for pharmaceutical materials to achieve this purpose. Whenever there is a deviation from this Section, the facility's pharmacy permit is subject to action by the Board. In addition to Rule 21 NCAC 46.2502, the pharmacist-manager shall, at a minimum, be responsible for:

(1) the development of policies and procedures for the compounding, admixture, labeling, and dispensing of parenteral medications in the health care facility, including relevant

education and training of all pharmacy and nursing personnel involved in the preparation of parenteral medications;

(2) the establishment of specifications or use of compendia specifications for procurement of all pharmaceuticals, including drugs, chemicals, and biologicals used in direct patient care, subject to approval of the appropriate committee of the health care facility;

(3) participation in development and maintenance of a drug formulary when required by the health care facility;

(4) participation in those aspects of pharmaceutical care that affect drug distribution and control;

(5) preparing, packaging, compounding and labeling all drugs;

(6) assuring that drugs are dispensed only by a pharmacist or other persons allowed by law to dispense; supportive pharmacy personnel are properly directed and supervised;

(7) the development and implementation of policies and procedures to ensure that discontinued drugs; outdated drugs; drugs recalled; containers with worn, illegible, or missing labels; or products that are otherwise unusable are returned to the pharmacy for proper disposition in a timely manner;

(8) maintaining records and reports as are required to ensure patient health, safety and welfare. These records and reports shall include, at a minimum:

(A) access to medication administration records;

(B) reports of suspected adverse drug reactions and medication variances;

(C) list of contents of ancillary drug cabinets where allowed and emergency kits/crash carts;

(D) the current formulary of drugs where a formulary is required;

(E) a biennial controlled substances inventory;

(F) alcohol and flammable material reports as required by law when such material is procured by the pharmacy; and

(G) such other records and reports as may be required by law and rules of the Board of Pharmacy;

(9) developing and implementing policies and procedures that effectively address the safeguarding and handling of all drugs and devices, as defined in G.S. 90-85.3(e), throughout the health care facility, or other locations where legend drug products are transferred, including medications that originate from a source outside the facility. When discrepancies in controlled substance counts are identified:

(A) they shall be reviewed, and a report of this action, including steps taken to prevent recurrence, where possible, shall be provided to the pharmacist-manager within 24 hours of occurrence. This report shall be maintained by the pharmacist-manager; and

(B) recurring losses or mishandling of significant quantities of controlled substances shall be immediately reported to the Board and the Drug Enforcement Administration;

(10) maintaining policies and procedures which require at least monthly inspections of patient care units or other areas of the health care facility where medications are dispensed, administered, or stored. For long-term care facilities and adult care homes, quarterly inspections are permitted, as defined by state licensure regulations. A record of such inspections shall be maintained to verify that:

(A) antiseptics, other drugs for external use, and disinfectants are stored separately from internal and injectable medications;

(B) drugs requiring special conditions for storage to assure stability are properly stored;

(C) all necessary and required security and storage standards are met;

(D) outdated or otherwise unusable drugs are identified, their distribution and administration prevented, and such are returned to the pharmacy for proper disposition;

(E) the distribution and administration of controlled drugs are adequately documented by pharmacy, nursing, and other involved services or personnel and are in accordance with applicable law;

(F) any investigational drugs in use are properly stored, distributed, and controlled;
(G) emergency drugs, as approved by the medical staff, are in adequate and proper supply in the pharmacy or other designated areas of the health care facility; and
(H) metric-apothecaries' weight and measure conversion tables and charts are available;

(11) all drugs and devices dispensed by the pharmacy as defined in G.S. 90-85.3(e) which are ordered for and used within the health care facility; and

(12) maintaining policies and procedures regarding drug samples and patient's personal medications.

History Note: *Authority G.S. 90-85.6; 90-85.21; 90-85.32; Eff. May 1, 1997.*

21 NCAC 46 .1412 PHYSICAL REQUIREMENTS

A health care facility pharmacy shall have sufficient floor space allocated to it to ensure that drugs are prepared in sanitary, well lighted and enclosed places. It shall have sufficient equipment and physical facilities for proper compounding, dispensing, and storage of drugs, including parenteral preparations. In addition to the requirements of Section .1600 of this Chapter, the equipment and physical facilities shall include the following:

(1) Compounding and dispensing areas;

(2) Physically separate parenteral solution additive area when parenteral solutions are compounded as described in Section .2800 - Sterile Parenteral Pharmaceuticals of this Chapter;

(3) Receiving and storage areas;

(4) Packaging and repackaging areas;

(5) Office space sufficient to allow for administrative functions without interference with the safe compounding and dispensing of medications and security of the pharmacy;

(6) Storage. All drugs shall be stored in designated areas within the pharmacy or decentralized pharmacy sufficient to provide sanitation to prevent contamination, moisture control, and security to prevent access from unauthorized personnel. Controlled substances shall be stored in compliance with applicable Federal and State laws and regulations. Alcohol and flammables shall be stored in areas that shall, at a minimum, meet basic local building code requirements for the storage of volatile substances and such other laws, ordinances, or regulations that may apply.

(7) Security. All areas occupied by the health care facility pharmacy, to include auxiliary drug supplies and unit dose carts, shall remain secured at all times.

History Note: *Authority G.S. 90-85.6; 90-85.21; 90-85.32; Eff. May 1, 1997.*

21 NCAC 46 .1413 ABSENCE OF PHARMACIST

(a) When a health care facility pharmacy is not open 24 hours a day, seven days a week, arrangements shall be made in advance by the pharmacist-manager for provision of drugs and pharmaceutical care to the medical staff, other authorized personnel, and patients of the health care facility after normal working hours by use of an "on call" pharmacist accessible to the facility during all absences, and an ancillary drug cabinet as described in Rule .1414(g) of this section. In addition, one or both of the options in Subparagraphs (a)(1) and (2) may be authorized by the pharmacist-manager to assure access to drugs and pharmaceutical care in the absence of a pharmacist:

(1) a contractual arrangement with another health care facility, pharmacy, or pharmacist;

(2) a nurse trained and authorized by the pharmacist-manager to remove drugs or devices from the pharmacy after hours. Entry into the pharmacy after hours shall occur only if the drug needed is not in the ancillary drug cabinet. The pharmacist-manager shall maintain a current list of authorized persons and document the initial orientation, continuing education, and quality control processes on an ongoing basis. The pharmacist-manager shall maintain a list of restricted medications that cannot be taken from the pharmacy and can only be removed after contacting the "on call" pharmacist to

verify the appropriateness and accuracy of the medication order and medication removed from the pharmacy at the time of removal. For medications not on the restricted list, an "on call" pharmacist must be accessible for questions by the authorized nurse. Within 24 hours, a pharmacist shall verify the accuracy and appropriateness of the medication order and the medication removed from the pharmacy.

(b) A suitable record of drugs or devices removed from ancillary drug cabinets or from pharmacy inventory shall be maintained for three years in the health care facility. The pharmacist-manager shall at least quarterly verify the accuracy of the records.

(c) Supportive personnel approved by the pharmacist-manager may be present in the pharmacy at other than regular service hours to perform certain clerical, repackaging and distributive functions according to written policies and procedures if the drugs so handled are not permitted to leave the pharmacy until all work performed has been checked and certified as being correct by the pharmacist.

(d) Only drugs in unit-of-use packaging shall be removed from the ancillary drug supply or from the pharmacy; they shall be used for administration to a specific patient only, in amounts sufficient to meet the needs for immediate therapeutic requirements. Controlled substances may be stocked and removed from an ancillary drug cabinet; controlled substances may not be removed from the pharmacy in the absence of a pharmacist. Drugs shall be pre-labeled by the pharmacist with drug name, strength, lot number and expiration date. A copy of written orders for new medications shall be provided to the pharmacy.

History Note: Authority G.S. 90-85.6; 90-85.21; 90-85.32; 90-85.33; *90-85.34;*
Eff. May 1, 1997;
Amended Eff. August 1, 2000.

21 NCAC 46 .1414 DRUG DISTRIBUTION AND CONTROL

(a) MEDICATION ORDERS.

(1) Pharmacists shall dispense medications from a health care facility pharmacy only upon receipt of a medication order. A mechanism shall be in place to verify the authenticity of the medication order. Oral orders shall be put in writing immediately and signed within the time frame established by regulatory agencies and health care facility policies and procedures.

(2) All medication orders shall be received and reviewed by a pharmacist and, at a minimum, shall contain the:

(A) patient's name, location and other necessary identifying information such as history or medical records number;

(B) medication name, strength, dosage form, route of and directions for administration. In the absence of a facility policy on interpretation of routes of administration, the route of administration must be specified;

(C) date the order was written; and

(D) prescriber's signature as set out in Subparagraph (a)(1) of this Rule (may include electronic signature or verification).

(3) The health care facility pharmacy and the pharmacist-manager shall ensure that medication orders for patients requiring continuous drug therapy shall be entered into a patient medication profile, either manual or automated. The medication profile shall, at a minimum, contain the:

(A) patient's name, location and important clinical data such as age, height, weight, sex, and allergies;

(B) medication name, strength, dosage form, route of and directions for administration;

(C) medication start date;

(D) medication discontinuance date; and

(E) identification of pharmacist responsible for or verifying technician entry of the medication order.

(4) Abbreviations used in medication orders shall be agreed to, jointly adopted, and published by the medical, nursing, pharmacy, and medical records staff of the health care facility.

(5) Medication orders shall be reviewed and discontinued or suspended, if appropriate, when the patient is transferred to the delivery room, operating room, or is admitted from another facility. A method to protect the patient from indefinite, open-ended drug orders must be provided. The prescriber shall be notified in a timely manner that the order shall be stopped before such action takes place by one or more of the following:

(A) the routine monitoring of patient's drug therapy by a pharmacist;

(B) a health care facility-approved, drug class-specific, automatic stop order policy covering those drug orders not specifying a number of doses or duration of therapy; or

(C) a health care facility-approved automatic cancellation of all drug orders after a predetermined time interval unless rewritten by the prescriber.

(6) Health care facilities which credential practitioners for prescribing privileges within the facility shall provide the health care facility pharmacy with credentialing information annually or immediately upon discharge or when privileges are suspended or terminated.

(b) DEVICES. Devices shall be dispensed in accordance with Section .2600 of this Chapter.

(c) DISPENSING. In health care facilities with 24 hour pharmacy services, all dispensing shall be done by a pharmacist. In health care facilities without 24 hour pharmacy services, Rule .1413 of this Section shall apply in the absence of a pharmacist.

(d) LABELING.

(1) The health care facility pharmacy and the pharmacist dispensing the drug shall ensure that all drugs dispensed from within a health care facility pharmacy are labeled and identified up to the point of administration;

(2) Whenever a drug is added to a parenteral admixture, it shall be labeled with a distinctive supplementary label indicating the name and amount of the drug added, expiration date, and expiration time, if applicable. For admixtures prepared outside the pharmacy, the pharmacist-manager shall develop policies and procedures for preparation and labeling.

(e) PARENTERAL MEDICATIONS. The dispensing of parenteral medications shall be done in accordance with Section .2800 of this Chapter--Sterile Parenteral Pharmaceuticals.

(f) PATIENT CARE UNIT MEDICATION INVENTORIES. This Paragraph does not apply to nursing facilities, assisted living facilities, and adult care homes.

(1) The pharmacist-manager shall develop an approved drug list for each health care facility location. Non-controlled drugs may be stocked on a health care facility patient care unit in quantities limited to not more than five dosage units per drug when immediate availability is deemed essential to the patient's health and well-being. Drugs shall be stored in a manner that prevents unauthorized access and shall only be administered to a patient of the health care facility pursuant to a medication order.

(2) All controlled substances stocked within a health care facility that are not located within the facility's pharmacy or automated dispensing device must be accompanied by a disposition form issued from the pharmacy. This document shall at a minimum contain:

(A) the product name, strength, dosage form, and quantity supplied;

(B) the date transferred to the patient care unit by the pharmacy;

(C) the name of the pharmacy representative supplying, and the patient care unit representative receiving the drug;

(D) the date, time, and amount of the drug removed from the patient care unit stock for administration; and

(E) the patient name and identification of the person acquiring the product.

(3) Exceptions to this Paragraph shall be made for use of automated dispensing devices provided that these devices meet all applicable rules for controlled substances contained therein.

(4) When a dose of a controlled substance has been prepared for a patient but not used (i.e., refused, order canceled, or contaminated), it may be destroyed at the patient care unit. The destruction must be witnessed by a health care provider, such as a pharmacist, registered nurse, or licensed practical nurse. The pharmacist-manager shall ensure that details of the event, along with the identification of the two who effected and witnessed the destruction, are documented. If such record is separate from the disposition form, it shall be maintained uniformly with the corresponding disposition form.

(g) ANCILLARY DRUG CABINET INVENTORIES. (This Paragraph does not apply to nursing facilities, assisted living facilities, and adult care homes.) Drugs that are routinely prescribed by the medical staff in a health care facility shall be maintained in quantities limited to not more than five dosage units per drug as a supplementary inventory for use only when the pharmacy is closed. The pharmacist-manager shall, in connection with the appropriate committee of the health care facility, develop listings of those drugs to be included in such inventories. The pharmacist-manager shall, at a minimum, assure that:

(1) access to such drug inventories is by locked cabinet(s) or other enclosure(s) constructed and secured to deny access to unauthorized persons;

(2) only authorized personnel, as indicated by written policies and procedures, shall obtain access to the drug inventories;

(3) only pre-packaged drugs are available therein, in amounts sufficient for immediate therapeutic requirements. Drugs shall be properly labeled, with drug name, strength, lot number and expiration date. Whenever access to such inventory is gained, a copy of the record of withdrawal and a copy of the written order for new drug orders shall be provided to the pharmacy. The record of withdrawal shall contain the following:

(A) the date of removal of the drug;

(B) the name, strength, dosage form, and quantity of drug removed;

(C) the name of the patient for whom the drug was ordered;

(D) the name or identification code of the authorized personnel removing the drug from inventory;

(4) all drugs are reviewed no less often than quarterly to ensure their purity, potency, and integrity; and

(5) written policies and procedures are established to implement the requirements of this Rule.

(h) AUTOMATED DISPENSING OR DRUG SUPPLY DEVICES. Automated Dispensing or Drug Supply Devices such as but not limited to Pyxis machines may be utilized in health care facility pharmacies and where a pharmacy permit exists in accordance with 21 NCAC 46 .1814.

(i) EMERGENCY KITS. (This Paragraph does not apply to adult care homes or assisted living facilities) Drugs and devices may be provided in emergency kits for use by authorized personnel provided the pharmacist-manager, in conjunction with the medical staff of the health care facility, develop and implement written policies and procedures to ensure compliance with the following provisions:

(1) the pharmacist-manager, or designee, and the medical staff of the health care facility jointly determine the drugs and devices, by identity and quantity, to be included in the kit. Drugs and devices included in the kit shall be limited to those for emergency use only and are not to be used for any other purpose.

(2) the emergency kit contains those drugs and devices which may be required to meet the immediate therapeutic needs of patients and which are not available from any other authorized source in sufficient time to prevent prolonged discomfort or risk of harm to patients;

(3) the emergency kit shall be stored in a secure, readily available location under the supervision of the nursing staff and sealed with a non-reusable, removable seal to prevent unauthorized access, and to ensure a proper environment for preservation of the drugs and devices within them. Policies and procedures shall be established to ensure the integrity of the kit at all times;

(4) the exterior of the emergency kit shall be labeled so as to clearly and unmistakably indicate that it is an emergency drug kit and is for use in emergencies only. In addition, a listing of the drugs and devices contained therein, including name, strength, and quantity of each drug or device shall be attached. Each emergency kit shall be inspected by a pharmacist or his designee every 30 days (90 days for long-term care facilities) to check for expiration dates and the integrity of the seal;

(5) all drugs and devices contained within the emergency kit shall be labeled, if applicable, with, at a minimum, the name, strength, lot number, manufacturer, and expiration date;

(6) drugs and devices shall be removed from the emergency kit for administration to a patient only pursuant to a valid physician's order, by personnel authorized by the facility;

(7) whenever an emergency kit is opened, the pharmacy shall be notified. The pharmacist-manager or designee shall re-stock, re-seal, and return the kit to the unit within a

reasonable length of time in order to prevent risk of harm to patients. The emergency drug kits shall be checked by an authorized person in accordance with written policies and procedures of the health care facility. In the event the kit is opened in an unauthorized manner, the pharmacy and other personnel designated by the pharmacist-manager of the facility shall be notified; and

(8) Emergency drugs that are controlled substances must be stored in compliance with 10A NCAC 26E .0408.

(j) RECORDS.

(1) The pharmacist-manager shall, in addition to the requirements for preserving prescription orders as set forth in G.S. 90-85.26, develop a system of daily accountability for medication compounding and dispensing that shall permit the identification of the responsible pharmacists and pharmacy technicians. Readily retrievable records of accountability shall be maintained for at least 30 days. At a minimum, this system shall identify all personnel who perform these activities and the pharmacist responsible for:

(A) interpretation and appropriateness of new medication orders;

(B) profile entry of new medication orders;

(C) dispensing of new medication orders including stat doses;

(D) daily cart fills;

(E) intravenous admixtures;

(F) compounded medications; and

(G) periodically assessing the quality of pharmacy procedures for preparation and release of drugs and devices for replenishment of floor stock, ancillary drug supplies, and automated dispensing devices in locations outside the pharmacy.

(2) Upon notification of medication errors resulting from the administration of an incorrect medication or dose, the pharmacist-manager shall document such medication error. Documentation shall include pertinent chronological information and include documentation on health care facility forms. These documents shall be archived in a readily retrievable manner, open for inspection, for a period of three years.

(3) Upon notification of information that reasonably suggests that there is a probability a prescription drug or device dispensed from a location holding a permit has caused or contributed to the death of a patient (see 21 NCAC 46 .2502(k) RESPONSIBILITY OF PHARMACIST-MANAGER), the pharmacist-manager shall retain all documents, labels, vial, supplies, substances and internal investigative reports relating to the event. All such items shall be maintained by the health care facility, accessible to the pharmacist-manager, and open to the Board of Pharmacy.

(4) The pharmacist-manager shall maintain records of ordering, receiving, dispensing or transfer of controlled substances. These records shall include, but are not limited to the following:

(A) Invoices or other such documents verifying the ordering and receipt of controlled substances;

(B) Perpetual inventories of controlled substances transferred to patient care units and other sites as allowed by this Rule (i.e., automated dispensing devices, emergency kits, etc.). These inventories shall record the transfer date; location transferred to; the identity of the drug; strength, dosage form, and quantity transferred; transferring pharmacist's name;

(C) Disposition records required by Paragraph (f)(4) of this Rule;

(D) A record of controlled substances dispensed directly to the patient to include the patient's name; date dispensed; dispensing pharmacist's name; name, strength, dosage form, and quantity of the drug dispensed. The records shall also document drugs returned and credited; and

(E) A perpetual inventory shall be maintained on all controlled substances awaiting destruction or return to a vendor.

(5) Automated systems may be used to collect and store information required by Subparagraph (j)(4) of this Rule provided such system allows for the immediate retrieval (via CRT display and hard-copy printout) of original medication order information and dispensing history consistent with criteria cited in 21 CFR .1306.

(6) With the exception of Subparagraph (j)(l) of this Rule, all records required by this Section shall be maintained for a period of three years. Such records shall be archived in a uniform manner, retrievable to the pharmacy within 48 hours, and open for review, copying, or seizure by a member or designated employee of the Board.

History Note: *Authority G.S. 90-85.6; 90-85.21; 90-85.32; 90-85.33; 90-85.34;*
Eff. May 1, 1997;
Amended Eff. February 1, 2005; April 1, 2003; April 1, 1999; August 1, 1998

21 NCAC 46 .1415 MEDICATION IN HEALTH CARE FACILITY EMERGENCY DEPARTMENTS

(a) In those health care facilities having 24 hour outpatient pharmacy service, all drugs dispensed to outpatients including emergency department patients must be dispensed by a pharmacist.

(b) When drugs are not otherwise available from a pharmacist, drugs may be dispensed for use outside the emergency department by the physician, registered nurse under physician supervision, or a person authorized to prescribe and dispense drugs pursuant to G.S. 90-18.1 or 90-18.2 subject to the following:

(1) Drugs shall only be dispensed to a registered patient of the emergency department;

(2) The pharmacist-manager shall develop and supervise a system of control and accountability of all drugs administered in, or dispensed from the emergency department;

(3) The pharmacist-manager, in conjunction with the appropriate committee responsible for policy in the emergency department, shall develop an emergency department formulary which may be dispensed from the emergency department for patients receiving care in that department. This formulary shall consist of drugs of the nature and type to meet the immediate needs of emergency department patients, and quantities in each container shall be limited to not more than a 24 hour supply or the smallest commercially-available quantity;

(4) Such drugs shall be prepackaged in safety closure containers and shall be appropriately pre-labeled by the pharmacist to comply with 21 NCAC 46.1414(i)(5) of this Chapter. Prior to dispensing, the following information shall be placed on the label:

(A) name, address, and telephone number of the health care facility pharmacy;

(B) dispensing date;

(C) full name of patient;

(D) generic or trade name, or in the absence of a brand name, the established name of the product dispensed;

(E) directions for use to the patient;

(F) name of physician prescribing and dispensing the product; and

(G) required precautionary or further accessory cautionary information as may be desirable for proper use and safety to the patient;

(5) A perpetual record of dispensing of all drugs, including drug samples and starter packages, shall be maintained as part of the pharmacy's records for three years. The pharmacist-manager or designee shall verify the accuracy of these records at least once a month. Such record shall, at a minimum, contain the following:

(A) date dispensed;

(B) patient's name;

(C) physician's name; and

(D) name of drug dispensed, strength, dosage form, quantity dispensed, and dose.

(6) The physician shall sign all orders for medication within the time frame established by regulatory agencies and health care facility policies and procedures.

(c) The physician, registered nurse under physician supervision, or person who is authorized to prescribe and dispense drugs pursuant to G.S. 90-18.1 or 90-18.2 shall comply with all regulations governing the dispensing of medications including patient counseling as defined in 21 NCAC 46 .2504 Patient Counseling.

History Note: *Authority G.S. 90-85.6; 90-18.1; 90-18.2; 90-85.21; 90-85.32; 90-85.33;*
Eff. May 1, 1997.

21 NCAC 46 .1416 REPACKAGING

(a) Drugs which are prepackaged from within a health care facility pharmacy for subsequent dispensing or administration shall be labeled to include:

(1) the generic or trade name, strength, and quantity of drug;
(2) identification of the manufacturer, and lot or control number;
(3) the expiration date of the drug being repackaged; and
(4) cautionary notations, if applicable.

(b) A batch number assigned by the pharmacy may be placed on the label in lieu of the manufacturer's name and lot number, provided that the pharmacy maintains a readily retrievable record which identifies, by batch number, the manufacturer, manufacturer's expiration date, and lot number of the drug.

(c) The pharmacy shall have and use facilities, personnel, operational practices, packaging material, and control procedures to assure that the purity, integrity, safety, and effectiveness of the drugs are not affected by such repackaging. All repackaging must be performed by or under the supervision of a pharmacist.

History Note: Authority G.S. 90-85.6; 90-85.21; 90-85.32; 90-85.33; Eff. May 1, 1997.

21 NCAC 46 .1417 REMOTE MEDICATION ORDER PROCESSING SERVICES

(a) Purpose. The purpose of this Section is to set out requirements for health care facility pharmacies providing remote medication order processing services and facilities contracting with remote medication order processing services.

(b) Definition. Medication order processing does not include the dispensing of a prescription drug but includes any of the following:

(1) receiving, interpreting, or clarifying medication orders;
(2) data entry and transferring of medication order information;
(3) performing drug regimen review;
(4) interpreting clinical data;
(5) performing therapeutic interventions; and
(6) providing drug information concerning medication orders or drugs.

(c) Outsourcing. A pharmacy may outsource medication order processing to another pharmacy provided the pharmacies have the same owner or the pharmacy has entered into a written contract or agreement with an outsourcing company that outlines the services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with federal and state laws and regulations. The pharmacy providing the remote processing of medication orders must notify the Board of Pharmacy prior to providing such services.

(d) Training. A pharmacy providing remote medication order processing must ensure that all pharmacists providing such services have been trained on each pharmacy's policies and procedures relating to medication order processing. The training of each pharmacist shall be documented by the pharmacist-manager to ensure competency and to ensure that performance is at least at the same level of performance as pharmacists in the outsourcing pharmacy. Such training shall include policies on drug and food allergy documentation, abbreviations, administration times, automatic stop orders, substitution, and formulary compliance. The pharmacies shall jointly develop a procedure to communicate changes in the formulary and changes in policies and procedures related to medication order processing.

(e) Access. The pharmacies must share common electronic files or have appropriate technology to allow secure access to the pharmacy's information system and to provide the remote pharmacy with access to the information necessary or required to process a medication order.

(f) Communication. The pharmacies must jointly define the procedures for resolving problems detected during the medication order review and communicating these problems to the prescriber and the nursing staff providing direct care.

(g) Recordkeeping. A pharmacy using remote order entry processing services is responsible for maintaining records of all orders entered into their information system including orders entered from a remote location. The system shall have the ability to audit the activities of the individuals remotely processing medication orders.

(h) Licensure. All pharmacies providing remote order processing services must be permitted by the Board. An out-of-state pharmacy providing remote order processing services must be registered with the Board as an out-of-state pharmacy. All pharmacists located in this State or employed by an out-of-state pharmacy

providing remote order processing services to health care facilities in this State, shall be licensed by the Board.
(i) Policy and Procedure Manual. All pharmacies involved in remote order processing shall maintain a policy and procedure manual. Each remote pharmacy is required to maintain those portions of the policy and procedure manual that relate to that pharmacy's operations. The manual shall:

(1) outline the responsibilities of each of the pharmacies;
(2) include a list of the name, address, telephone numbers, and all license/registration numbers of the pharmacies involved in remote order processing; and
(3) include policies and procedures for:
  (A) protecting the confidentiality and integrity of patient information;
  (B) maintaining appropriate records to identify the name(s), initials, or identification code(s) and specific activity(ies) of each pharmacist who performed any processing;
  (C) complying with federal and state laws and regulations;
  (D) 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;
  (E) annually reviewing the written policies and procedures and documenting such review; and
  (F) annually reviewing the competencies of pharmacists providing the remote order review service.

History Note: *Authority G.S. 90-85.6; 90-85.21; 90-85.21A; 90-85.26; 90-85.32; 90-85.34; Eff. February 1, 2006.*

21 NCAC 46 .1418 SUPERVISION OF UNIT DOSE MEDICATION SYSTEMS

(a) The purpose of this Section is to set out requirements in the event that pharmacists elect to supervise designated pharmacy technicians' validation of stocking and prepackaging functions in acute care hospital pharmacy practice settings as a means of facilitating pharmacists' delivery of clinical services.
(b) A Hospital's pharmacist-manager is responsible for the oversight of all validation of floor stock and unit dose distribution systems, and that responsibility may not be delegated pursuant to 21 NCAC 46 .1411. In the event that the Hospital's pharmacist-manager elects to utilize Validating Technicians in the filling of floor stock and unit dose distribution systems, the pharmacist-manager shall develop written policies and procedures that:

(1) permit a Validating Technician to validate only the following functions of other registered pharmacy technicians in filling floor stock and unit dose distribution systems for inpatients in a Hospital:
  (A) stocking of patient care unit medication inventories;
  (B) stocking of ancillary drug cabinet inventories;
  (C) stocking of automated dispensing or drug supply devices;
  (D) stocking of emergency kits; and
  (E) prepackaging of prescription drugs within the Hospital pharmacy;
(2) establish the parameters for pharmacist supervision of pharmacy technician validation functions;
(3) establish facility-specific training for pharmacy technician validation functions;
(4) establish an ongoing evaluation and assessment program to ensure that pharmacy technician validation functions are performed safely and accurately; and
(5) establish a recordkeeping system that shall permit the identification of the Validating Technician who performs activities authorized by this Rule. Readily retrievable records generated by this system shall be maintained for the period of time specified in 21 NCAC 46 .1414(j)(1) and (2).

(c) With respect to compounded or admixed prescription drugs (whether sterile or non-sterile), a Validating Technician may validate the filling of floor stock and unit dose distribution systems only after a pharmacist has verified that the compounded or admixed prescription drugs have been prepared correctly.
(d) This Rule does not authorize a pharmacy technician to perform any act requiring the exercise of professional judgment by a pharmacist.
(e) Validating Technician. For the purposes of this Rule, a Validating Technician shall be a pharmacy technician who:

(1) is registered with the Board and trained as specified in G.S. 90-85.15A;

(2) is a certified technician;

(3) holds either:

(A) an associate's degree in pharmacy technology conferred by either an institution within the North Carolina Community College System or System;

(B) an associate's degree in pharmacy technology conferred by an institution accredited by one of the regional accrediting agencies recognized by the United States Department of Education; or

(C) an associate's degree in pharmacy technology conferred by a program accredited by the American Society of Health System Pharmacists; and

(4) assists pharmacists with the preparation, dispensing and distribution of prescription medications that will be administered by a licensed health care provider to an inpatient in a Hospital under this Rule.

(f) Hospital. For the purposes of this Rule, a Hospital is either:

(1) a hospital licensed by the North Carolina Medical Care Commission; or

(2) a psychiatric hospital operated by the Secretary of the Department of Health and Human Services.

(g) Pursuant to G.S. 90-85.15A(c), the Board approves a pharmacist's supervision of more than two pharmacy technicians where the additional technicians are Validating Technicians. This Rule does not relieve the pharmacist-manager of the obligation to request and receive written Board approval for a pharmacist's supervision of more than two pharmacy technicians where the additional technicians are certified pharmacy technicians but are not Validating Technicians.

(h) A pharmacy technician performing validation functions described in this Rule as part of a Board-approved 21 NCAC 46 .2510 pilot project at Broughton State Hospital or Wake Forest University Baptist Medical Center may continue to perform such functions for a period of three years from this Rule's original effective date, after which time the pharmacy technician must meet all of the requirements specified in Paragraph (e) of this Rule to continue performing such functions.

History Note: *Authority G.S. 90-85.6; 90-85.15A; 90-85.21; 90-85.26; 90-85.32; 90-85.33; 90-85.34; Eff. June 18, 2011.*

43-15-08. Oaths - President may administer.
The president of the board may administer oaths to applicants for registration and to any witness in hearings, investigations, or proceedings pending before the board.

43-15-09. Meetings - When held - Notice - Quorum.
The board shall hold at least two and not more than four meetings in each calendar year for the examination of applicants for licensure. The board may hold such other meetings as may be necessary for the performance of its duties. A special meeting must be held at such time and place as a majority of the members agree upon, or may be called by the secretary, at the request of the president or any two members, by giving such notice to the members as the board may prescribe by its rules and regulations. A majority of the board constitutes a quorum for the transaction of business.

43-15-10. Powers of board.
In addition to other powers provided by law, the board shall have the following powers and duties, which shall be exercised in conformity with chapter 28-32 in order to protect the public health, welfare, and safety:

1. To place on probation, reprimand, or fine any pharmacy, pharmacist, or pharmacy intern or pharmacy technician; or refuse to issue or renew, or suspend, revoke, restrict, or cancel, the license, permit, or registration of any pharmacy, pharmacist, or pharmacy intern or pharmacy technician, if any of the following grounds apply and the pharmacy, pharmacist, or pharmacy intern or pharmacy technician:
   a. Is addicted to any alcohol or drug habit.
   b. Uses any advertising statements of a character tending to deceive or mislead the public.
   c. Is subject to drug or alcohol dependency or abuse.
   d. Permits or engages in the unauthorized sale of narcotic drugs or controlled substances.
   e. Permits or engages an unauthorized person to practice pharmacy.
   f. Is mentally or physically incompetent to handle pharmaceutical duties.
   g. Is guilty of fraud, deception, or misrepresentation in passing the pharmacist examination.
   h. Is found by the board in violation of any of the provisions of the laws regulating drugs, pharmacies, and pharmacists or interns and technicians or the rules and regulations established by the board.
   i. Is found to have engaged in unprofessional conduct as that term is defined by the rules of the board.
   j. Is subject to incapacity of a nature that prevents a pharmacist from engaging in the practice of pharmacy with reasonable skill, competence, and safety to the public.
   k. Is found guilty by a court of competent jurisdiction of one or more of the following:
      (1) A felony, as defined by the statutes of North Dakota.
      (2) Any act involving moral turpitude or gross immorality.
      (3) Violations of the pharmacy or the drug laws of North Dakota or rules and regulations pertaining thereto, or of statutes, rules or regulations of any other state, or of the federal government.
   l. Commits fraud or intentional misrepresentation in securing the issuance or renewal of a license or pharmacy permit.
   m. Sells, dispenses, or compounds any drug while on duty and while under the influence of alcohol or while under the influence of a controlled substance without a practitioner's prescription.
   n. Discloses confidential information to any person, except as authorized by law.

2. To prescribe rules and regulations not inconsistent with this chapter governing the cancellation or suspension of a license.

3. To examine and license as pharmacist any applicant found entitled to such license.

4. To prescribe rules and regulations for the guidance of its members, officers, and employees, and to ensure the proper and orderly dispatch of its business.

5. To employ and pay such persons as it may deem necessary to inspect pharmacies in this state, investigate pharmacies for the information of the board, procure evidence in any proceeding pending before the board, or procure evidence in aid of any prosecution or action in any court

commenced or about to be commenced by or against the board in relation to any matter in which the board has any duty to perform.

6. To employ and pay counsel to advise the board or to prosecute or defend any action or proceeding commenced by or against the board or pending before it.

7. To grant permits and renewals thereof for the establishment and operation of pharmacies.

8. Only for good cause to cancel, revoke, or suspend permits and renewals thereof for the establishment and operation of pharmacies.

9. To prescribe reasonable and nondiscriminatory rules and regulations in regard to granting, renewing, canceling, revoking, or suspending permits and renewals for establishing and operating pharmacies.

10. Action by the board canceling, revoking, suspending, or refusing to renew a permit to establish or operate a pharmacy shall not be enforced for thirty days after notice has been given an aggrieved party by the board, nor during the time that an appeal by such aggrieved party is pending and until such appeal is finally determined.

11. To prescribe reasonable rules and regulations relating to the physical design of space occupied by a pharmacy to ensure appropriate control of and safeguards over the contents of such pharmacy.

12. To regulate and control the practice of pharmacy in North Dakota.

13. To adopt, amend, and repeal rules for the regulation of pharmacies and pharmacists providing radiopharmaceutical services, including special training, education, and experience for pharmacists and physical design of space, safeguards, and equipment for pharmacies.

14. To adopt, amend, and repeal rules determined necessary by the board for the proper administration and enforcement of this chapter, chapter 19-02.1 as that chapter pertains to drugs, subject to approval of the director of the state department of health, and chapter 19-03.1.

15. The board or its authorized representatives may investigate and gather evidence concerning alleged violations of the provisions of chapter 43-15, chapter 19-02.1 that pertains to drugs, chapters 19-03.1, 19-03.2, and 19-04, or of the rules of the board. Board investigative files are confidential and may not be considered public records or open records for purposes of section 44-04-18, until a complaint is filed or a decision made by the board not to file a complaint.

16. In addition to other remedies, the board may apply to the district court in the jurisdiction of an alleged violation, and that court has jurisdiction upon hearing and for cause shown, to grant a temporary or permanent injunction restraining any person from violating any provision of chapter 43-15, chapter 19-02.1 pertaining to drugs, and chapter 19-03.1, whether or not there exists an adequate remedy at law. Whenever a duly authorized representative of the board finds or has probable cause to believe that any drug or device is adulterated, misbranded, mislabeled, or improperly identified, within the meaning of chapter 19-02.1, the representative shall affix to that drug or device a tag or other appropriate marking giving notice that the article is or is suspected of being adulterated, misbranded, mislabeled, or improperly identified, has been detained or embargoed and warning all persons not to remove or dispose of such article by sale or otherwise until provision for removal or disposal is given by the board or its agents or the court. No person may remove or dispose of such embargoed drug or device by sale or otherwise without the permission of the board or its agent, or, after summary proceedings have been instituted, without permission from the court.

17. When a drug or device detained or embargoed has been declared by such representative to be adulterated, misbranded, mislabeled, or improperly identified, the board shall, as soon as practical thereafter, petition the district court in whose jurisdiction the article is detained or embargoed for an order for condemnation of such article. If the judge determines that the drug or device so detained or embargoed is not adulterated, misbranded, mislabeled, or improperly identified, the board shall direct the immediate removal of the tag or other marking. If the court finds the detained or embargoed drug or device is adulterated, misbranded, mislabeled, or improperly identified, such

drug or device, after entry of the decree, shall be destroyed at the expense of the owner under the supervision of a board representative and all court costs and fees, storage, and other proper expense shall be borne by the owner of such drug or device. When the adulteration, misbranding, mislabeling, or improper identification can be corrected by proper labeling or processing of the drug or device, the court, after entry of the decree and after such costs, fees, and expenses have been paid and a good and sufficient bond has been posted, may direct that such drug or device be delivered to the owner for labeling or processing under the supervision of a board representative. Expense of supervision shall be paid by the owner. Bond posted shall be returned to the owner of the drug or device on representation to the court by the board that the drug or device is no longer in violation of the embargo and the expense of supervision has been paid. Nothing in this section shall be construed to require the board to report violations whenever the board believes the public's interest will be adequately served in the circumstances by a suitable written notice or warning.

18. The board shall establish a bill of rights for patients concerning the health care services a patient may expect in regard to pharmaceutical care.

19. To adopt, amend, and repeal rules as may be deemed necessary by the board to register pharmacy technicians pursuant to qualifications established by the board, to charge a pharmacy technician an annual registration fee not to exceed fifty dollars, to specify tasks associated with and included in the practice of pharmacy which may be delegated by a licensed pharmacist to a registered pharmacy technician, to provide for suspension or revocation of a pharmacy technician's registration, and to regulate and control pharmacy technicians. The board may allocate up to fifty percent of the amount of the registration fee to an appropriate pharmacy technician association for its general operating expenses, including pharmacy technician education and development standards.

20. To require the self-reporting by an applicant or a licensee of any information the board determines may indicate possible deficiencies in practice, performance, fitness, or qualifications.

21. To require information regarding an applicant's or licensee's fitness, qualifications, and previous professional record and performance from recognized data sources, including the national association of boards of pharmacy data bank, other data repositories, licensing and disciplinary authorities of other jurisdictions, professional education and training institutions, liability insurers, health care institutions, and law enforcement agencies be reported to the board. The board may require an applicant for licensure or a licensee who is the subject of a disciplinary investigation to submit to a statewide and nationwide criminal history record check. The nationwide criminal history record check must be conducted in the manner provided by section 12-60-24. All costs associated with obtaining a background check are the responsibility of the licensee or applicant.

22. To adopt, amend, and repeal rules as may be deemed necessary by the board to register veterinary dispensing technicians pursuant to qualifications established by the board, to charge a veterinary dispensing technician an annual registration fee not to exceed fifty dollars, to provide for suspension or revocation of a veterinary dispensing technician's registration, to provide for suspension or revocation of a veterinary retail facility's license, to regulate and control veterinary retail facilities, and to regulate and control veterinary dispensing technicians.

43-15-11. Fees deposited with state treasurer - Separate fund - Vouchers.
Repealed by S.L. 1971, ch. 510, § 15.

43-15-12. State board of pharmacy - Report.
The board may submit a biennial report to the governor and the secretary of state in accordance with section 54-06-04.

43-15-13. State board of pharmacy - When members may teach pharmacy.
Repealed by S.L. 1995, ch. 407, § 1.

43-15-13.1. North Dakota pharmaceutical association - How governed.
Repealed by S.L. 2009, ch. 365, § 5.

43-15-13.2. Membership of North Dakota pharmaceutical association.
Repealed by S.L. 2009, ch. 365, § 5.

rules to implement this section must be jointly adopted by the board of medical examiners and the board of pharmacy.

43-15-31.5. Injection of drugs - Rules.
Any pharmacist who administers drugs by injection must have a certificate of authority from the board. The authority to administer a drug by injection may not be delegated. The board shall adopt rules to establish educational and operational requirements for a pharmacist to obtain and maintain a certificate of authority to administer drugs by injection. Rules adopted by the board under this section must include:

1. Educational requirements of a minimum of twenty hours, which include, at a minimum:
   a. Basic immunology, including the human immune response;
   b. The mechanism of immunity, adverse effects, dose, and administration schedule of available vaccines and approved medication and immunization;
   c. Current immunization guidelines and recommendations of the centers for disease control and prevention;
   d. Management of adverse events, including identification, appropriate response, documentation, and reporting;
   e. How to educate patients on the need for immunizations;
   f. Physiology and techniques for subcutaneous, intradermal, and intramuscular injection; and
   g. Recordkeeping requirements established by law, rule, and regulation or established standards of care.
2. A requirement that an authorized pharmacist must obtain and maintain current certification in cardiopulmonary resuscitation or basic cardiac life support.
3. Requirements to maintain continuing competency with completion of a minimum of six hours of education dedicated to this area of practice every two years.
4. Requirements for content of physician orders and protocols.
5. Requirements relating to the reporting of the administration by injection to a patient's primary health care provider and to the state department of health.
6. Requirements relating to environments in which injections may be administered.

43-15-32. Who may engage in drug business.
Every store, dispensary, pharmacy, laboratory, or office, selling, dispensing, or compounding drugs, medicines, or chemicals, or compounding or dispensing prescriptions of medical practitioners in the state, and every business carried on under a name which contains the words "drugs", "drugstore", or "pharmacy", or which is described or referred to in such terms by advertisements, circulars, posters, signs, or otherwise, must be in charge of a registered pharmacist.

43-15-33. License to sell emergency medicines.
Repealed by S.L. 1999, ch. 379, § 8.

43-15-34. Operation of pharmacy - Permit required - Application - Fee.
No person, copartnership, association, corporation, or limited liability company shall open, establish, operate, or maintain any pharmacy within this state without first obtaining a permit so to do from the board. Application for the permit shall be made upon a form to be prescribed and furnished by the board and shall be accompanied by a fee to be set by the board not to exceed three hundred dollars. A like fee shall be paid upon each annual renewal thereof. Separate applications shall be made and separate permits required for each pharmacy opened, established, operated, or maintained by the same owner and for the change of location, name, or ownership of an existing pharmacy.

43-15-34.1. Out-of-state pharmacies.
Any pharmacy operating outside the state which ships, mails, or delivers in any manner a dispensed prescription drug or legend drug into North Dakota shall obtain and hold a pharmacy permit issued by the North Dakota state board of pharmacy and that part of the pharmacy operation dispensing the prescription for a North Dakota resident shall abide by state law and rules of the board.

43-15-35. Requirements for permit to operate pharmacy - Exceptions.
1. The board shall issue a permit to operate a pharmacy, or a renewal permit, upon satisfactory proof of all of the following:
   a. The pharmacy will be conducted in full compliance with existing laws and with the rules and regulations established by the board.

KEY= 43 – 15 NORTH DAKOTA CENTURY CODE {LAW}
19 STATUTE {LAW}
61 ADMINISTRATIVE CODE {RULE/REGULATION}

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Law Implemented: NDCC 43-15-10(9), 43-15-10(12), 43-15-10(14)

ARTICLE 61-07
HOSPITAL PHARMACY

Chapter
61-07-01 Hospital Pharmacy

CHAPTER 61-07-01
HOSPITAL PHARMACY

Section
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61-07-01-01. Definitions. For purposes of this chapter, the following definitions apply:

1. The terms "hospital" and "medical center" are synonymous.

2. "Hospital pharmacy" is defined as those portions of a hospital where drugs, medications, devices, and other materials used in the diagnosis and treatment of injury, illness, and disease (hereinafter referred to as "drugs") are manufactured, produced, sold, or distributed.

History: Effective April 1, 1988.
General Authority: NDCC 28-32-02
Law Implemented: NDCC 43-15-10(9), 43-15-10(12), 43-15-10(14)

61-07-01-02. Applicability. This chapter is applicable to all hospital pharmacies as defined by section 61-07-01-01.

History: Effective April 1, 1988.
General Authority: NDCC 28-32-02
Law Implemented: NDCC 43-15-10(9), 43-15-10(12), 43-15-10(14)

61-07-01-03. Registration. All hospital pharmacies shall register annually with the board of pharmacy; certificates of registration may be issued only to those hospital pharmacies which satisfy the provisions of all rules of the board and laws of North Dakota.

History: Effective April 1, 1988.
General Authority: NDCC 28-32-02
Law Implemented: NDCC 43-15-10(9), 43-15-10(12), 43-15-10(14)

61-07-01-04. Personnel.

1. Director. Each hospital pharmacy must be directed by a pharmacist-in-charge, hereinafter referred to as the director of pharmacy, who is licensed to engage in the practice of pharmacy in this state, and who is knowledgeable in and thoroughly familiar with the specialized functions of hospital pharmacies. The director of pharmacy is responsible for all activities of the hospital pharmacy, and for meeting the requirements of the North Dakota pharmacy practice act and this chapter. Contractual providers of pharmacy services shall meet the same requirements as director of pharmacy services.

2. Supportive personnel. The director of a hospital pharmacy must be assisted by a sufficient number of additional pharmacists and ancillary personnel as may be required to operate such pharmacy competently, safely, and adequately to meet the needs of the patients of the hospital.

   a. Pharmacy technicians may be employed provided they have been approved by the director. The director shall develop and implement written policies and procedures to specify the duties to be performed by such technical personnel. These policies and procedures shall, at a minimum, specify that ancillary technical personnel are properly or adequately supervised by a registered pharmacist and that ancillary technical personnel are not assigned duties which may be performed only by pharmacists.

   b. Secretarial support should be provided as required to assist with recordkeeping, report submission, and other administrative duties.

3. Supervision. All of the activities and operations of each hospital pharmacy must be personally and directly supervised by its director or pharmacist's designee. All functions and activities of ancillary personnel must be personally and directly supervised by a sufficient number of registered pharmacists to ensure that all such functions and activities are performed competently, safely, and without risk of harm to patients.

History: Effective April 1, 1988.
General Authority: NDCC 28-32-02
Law Implemented: NDCC 43-15-10(9), 43-15-10(12), 43-15-10(14)

61-07-01-05. Absence of pharmacist.

1. General. During such times as a hospital pharmacy may be unattended by a pharmacist, arrangements must be made in advance by the director for the provision of drugs to the medical staff and other authorized personnel of the hospital, by use of night cabinets or floor stock, or both, and in emergency circumstances, by access to the pharmacy. A pharmacist must be available for consultation during all absences; this protocol can be accomplished by telephone.

2. Night cabinets. If night cabinets are used, the following should prevail: absence of a pharmacist, must be by locked cabinets or other enclosures constructed and located outside of the pharmacy area, to which only specifically authorized personnel may obtain access by key or combination, and which is sufficiently secure to deny access to unauthorized persons by force or otherwise. The director shall, in conjunction with the appropriate committee of the hospital, develop inventory listings of those drugs to be included in such cabinets and shall ensure that:
   a. Such drugs are available therein, properly labeled.
   b. Only prepackaged drugs are available therein, in amounts sufficient for immediate therapeutic requirements.
   c. Whenever access to such cabinets shall have been gained, written physician's orders and proofs of use, if applicable, are provided.
   d. Written policies and procedures are established to implement the requirements of this subsection.

3. Access to pharmacy. Whenever any drug is not available from floor supplies or night cabinets, and such drug is required to treat the immediate needs of a patient whose health would otherwise be jeopardized, such drug may be obtained from the pharmacy in accordance with the requirements of this section. One supervisory registered professional nurse and only one in any given eight-hour shift is responsible for removing drugs there from. The responsible nurse, in times of emergency, may delegate this duty to another nurse. The responsible nurse must be designated by position, in writing, by the appropriate committee of the hospital and, prior to being permitted to obtain access to the pharmacy, shall receive thorough education and training in the proper methods of access, removal of drugs, and records and procedures required. Such education and training must be given by the director of pharmacy, who shall require, at a minimum, the following records and procedures:

   a. Removal of any drug from the pharmacy by an authorized nurse must be recorded on a suitable form showing patient name, room number, name of drug, strength, amount, date, time, and signature of nurse.

b. Such form must be left with the container from which the drug was removed, both placed conspicuously so that it will be found by a pharmacist and checked properly and promptly; or, in the case of a unit dose, place an additional dose of the drug, or the box, on the form.

4. Emergency kits. Emergency drugs, as approved by the medical staff, must be in adequate and proper supply in the pharmacy and in designated hospital areas. The pharmacist is responsible both for the contents of emergency medication carts, kits, and for the inspection procedure to be used.

History: Effective April 1, 1988.
General Authority: NDCC 28-32-02
Law Implemented: NDCC 43-15-10(9), 43-15-10(12), 43-15-10(14)

61-07-01-06. Physical requirements.

1. Area. A hospital pharmacy shall have within the hospital it services, sufficient floor space allocated to it to ensure that drugs are prepared in sanitary, well-lighted, and enclosed places, and which meet the other requirements of this section.

2. Equipment and materials. Each hospital pharmacy shall have sufficient equipment and physical facilities for proper compounding, dispensing, and storage of drugs, including parenteral preparations, and, as a minimum, access to the references for the following subjects:
   a. Drug interactions.
   b. Drug compatibility.
   c. Poison and antidote information.
   d. Chemistry:
      (1) Organic;
      (2) Pharmaceutical; and
      (3) Biological.
   e. Toxicology.
   f. Pharmacology.
   g. Bacteriology.
   h. Sterilization and disinfection.
   i. Pharmacy technology.
   j. Patient counseling.
   k. Rational therapy.
   l. Pathology.
   m. Current United States Pharmacopeia and National Formulary dispensing information.
   n. Current state and federal regulations applicable to controlled substances.

The technical equipment required by section 61-02-01-03 may be either at the hospital pharmacy or the community pharmacy servicing the hospital pharmacy.

3. Storage. All drugs must be stored in designated areas within the hospital pharmacy which are sufficient to ensure proper sanitation, temperature, light, ventilation, moisture control, segregation, and security.

4. Alcohol and flammables. Alcohol and flammables must be stored in areas that shall meet, at a minimum, basic local building code requirements for the storage of volatiles and such other laws, ordinances, regulations as may apply.

5. Unattended areas. In the absence of authorized personnel, and whenever any area of a hospital pharmacy is not under the personal and direct supervision of authorized personnel, such area must be locked.

6. Security. All areas occupied by a hospital pharmacy must be capable of being locked by key or combination, so as to prevent access by unauthorized personnel. The director shall designate, in writing, by title and specific area, those persons who shall have access to particular areas within the pharmacy.

History: Effective April 1, 1988.
General Authority: NDCC 28-32-02
Law Implemented: NDCC 43-15-10(9), 43-15-10(11), 43-15-10(12), 43-15-10(14)

61-07-01-07. Drug distribution and control.

1. General. The director of pharmacy services shall establish written procedures for the safe and efficient distribution of pharmaceutical products. An annual updated copy of such procedures must be on hand for inspections.

2. Responsibility. The director is responsible for the safe and efficient distribution of, control of, and accountability for drugs. The other professional staff of the hospital shall cooperate with the director in meeting this responsibility and in ordering, administering, and accounting for pharmaceutical materials so as to achieve this purpose. Accordingly, the director is responsible for, at a minimum, the following:

   a. Preparation and sterilization of parenteral medications manufactured within the hospital.
   b. Admixture of parenteral products, including education and training of nursing personnel concerning incompatibility and provision of proper incompatibility information when the admixture of parenteral products is not accomplished within the hospital pharmacy.
   c. Manufacture of drugs, if applicable.
   d. Establishment of specifications for procurement of all materials, including drugs, chemicals, and biologicals, subject to approval of the appropriate committee of the hospital.
   e. Participation in development of a formulary for the hospital.
   f. Filling and labeling all containers from which drugs are to be administered.
   g. Maintaining and making available a sufficient inventory of antidotes and other emergency drugs, both in the pharmacy and inpatient care areas, as well as current antidote information, telephone numbers of regional poison control centers, and other emergency assistance organizations, and such other materials and information as may be deemed necessary by the appropriate committee of the hospital, if any.
   h. Records of all transactions of the hospital pharmacy as may be required by applicable law, state and federal, and as may be necessary to maintain accurate control over and accountability for all pharmaceutical materials.
   i. Participation in drug usage evaluation activities.
   j. Fullest cooperation with teaching or research programs, or both, in the hospital, if any.
   k. Implementation of the policies and decisions of the appropriate committees of the hospital.
   l. Effective and efficient messenger and delivery service to connect the pharmacy with appropriate parts of the hospital on a regular basis throughout the normal workday of the hospital.
   m. Meeting all compliance and other requirements of the North Dakota board of pharmacy rules and laws and this chapter.

3. Labeling.
   a. For use inside the hospital. All drugs dispensed by a hospital pharmacy, not on an individual prescription, intended for use within the hospital, must be dispensed in appropriate containers and adequately labeled so as to identify, at a minimum, brand name or generic name, strength, quantity, source, and expiration date.
   b. For use outside the pharmacy. All drugs dispensed by a hospital pharmacy to patients about to be discharged or to whom it is certain will carry the item dispensed outside of the hospital, in compliance with pharmacy practice act and rules, must be labeled with the following information:
      (1) Name, address, and telephone number of the hospital pharmacy.
      (2) Date and identifying serial number.
      (3) Full name of patient.
      (4) Name of drug strength, and number of units.
      (5) Directions for use to the patients.
      (6) Name of physician prescribing.
      (7) Required precautionary information regarding controlled substances.
      (8) Such other and further accessory cautionary information as may be required or desirable for proper use and safety to the patient.

c. Drugs added to parenteral admixtures. Whenever any drugs are added to parenteral admixtures, whether within or outside the direct and personal supervision of a pharmacist, such admixtures must be labeled with a distinctive supplementary label indicating the name and the amount of the drug added, date and time of addition and expiration, and name of person so adding.

4. Discontinued drugs. The director shall develop and implement policies and procedures to ensure that discontinued and outdated drugs and containers with worn, illegible, or missing labels are returned to the pharmacy for proper disposition or that the director or the director's designee make proper disposition or dispose of such drugs at the storage site.

5. Physician's orders. Drugs may be dispensed from the hospital pharmacy only upon written or verbal orders, direct copies or facsimiles thereof, of authorized physicians. Verbal orders for drugs are accepted only by personnel so designated in accordance with applicable law and regulations governing such acts and in accordance with the approved medical staff rules and regulations.
   a. Authorization. The appropriate committee of the hospital shall designate, from time to time as appropriate, those physicians who are authorized to issue orders to the pharmacy.
   b. Abbreviations. Orders employing abbreviations and chemical symbols may be utilized and filled only if such abbreviations and symbols appear on a published list of accepted abbreviations developed by the appropriate committee of the hospital.
   c. Requirements - Orders for drugs for use by inpatients. Orders for drugs for use by inpatients shall contain, at a minimum: patient name and room number, drug name, strength, directions for use, date, and physician's signature or that of the physician's authorized representative.
   d. Requirements - Orders for drugs for use by outpatients. Orders for drugs for use by outpatients become prescriptions and must meet all requirements of the law.
   e. Pharmacist review. The pharmacist shall review the prescriber's order, or a direct copy thereof, before the initial dose of medication is dispensed (with the exception of emergency orders when time does not permit). In cases when the medication order is written when the pharmacy is "closed" or the pharmacist is otherwise unavailable, the medication order should be reviewed by the pharmacist as soon thereafter as possible, preferably within twenty-four hours.
   f. Signature. A means of identifying the signatures of all practitioners authorized to use the pharmaceutical services, as well as a listing of their drug enforcement administration numbers, must be maintained.

6. Controlled drug accountability. The hospital shall establish effective procedures and maintain adequate records regarding use and accountability of controlled substances and such other drugs as the appropriate hospital committee may designate which may specify at least the following:
   a. Name of drug.
   b. Dose.
   c. Physician.
   d. Patient.
   e. Date and time of administration.
   f. Person administering the drug.

7. Recall. The director shall develop and implement a recall procedure that can be readily activated to assure the medical staff of the hospital that all drugs included on the recall, whether within or outside the hospital, are returned to the pharmacy for proper disposition.

8. Suspected adverse drug reactions. Any and all suspected adverse drug reactions must be reported orally immediately to the ordering physician and in writing to the pharmacy, and to the appropriate committee of the hospital. Appropriate entry on the patient's record must also be made. The director may, at the director's discretion, make further reports of such suspected reactions to the hospital reporting program of the United States food and drug administration, to the manufacturer, and to the United States pharmacopeia.

9. Records and reports. The director shall maintain and submit, as appropriate, such records and reports as are required to ensure patient health, safety, and welfare, and, at a minimum, the following:
   a. Physician's orders, direct copies, or facsimiles thereof.
   b. Controlled drug accountability report.
   c. Reports of suspected adverse drug reactions.
   d. Inventories of night cabinets and emergency kits.
   e. Inventories of the pharmacy.
   f. Biennial controlled substances inventories.
   g. Alcohol and flammables reports.
   h. Such other and further records and reports as may be required by law and this chapter.

10. Distribution systems.
   a. Floor or ward stock system. In this system, all but the most unusual drug items are stocked on the nursing stations. Drug products which require special control (e.g., antineoplastic agents) are often omitted from floor stock, and are sent to the nursing unit upon receipt of a prescription order for the individual patient. All containers used for floor stock must meet specific labeling requirements as addressed in these rules.
   b. Individual prescription order system. In this system, all medications are dispensed by the pharmacist on individual prescription orders.
   c. Combination of floor stock and the individual prescription order system. In this system, most drugs are dispensed on an individual prescription basis. The remaining drugs are obtained via limited floor stock.
   d. Unit dose. In this system, medications are contained in single unit packages; they are dispensed in as ready-to-administer form as possible, for most medications. All doses will be labeled properly to include name, strength, expiration date, or lot number or control number, or both.

History: Effective April 1, 1988.
General Authority: NDCC 28-32-02
Law Implemented: NDCC 43-15-10(9), 43-15-10(12), 43-15-10(14)

61-07-01-08. Nondistributive roles of the pharmacist. These functions include, but are not limited to, chart review; audits; clinical tasks; committee participation; drug information; in service training of the pharmacists, the pharmacy staff, and other health professionals; poison control; nursing unit inspections; preparation of medication histories; monitoring of drug therapy; patient education; detection and reporting of adverse drug reactions; drug therapy selection; participation in drug usage evaluation; and other quality assurance programs.

History: Effective April 1, 1988.
General Authority: NDCC 28-32-02
Law Implemented: NDCC 43-15-10(9), 43-15-10(12), 43-15-10(14)

61-07-01-09. Administration of drugs.

1. General. Drugs may be administered at a hospital only upon the orders of those members of the medical staff who have been granted clinical privileges or who are authorized members of the house staff and, by authorized licensed hospital personnel in accordance with policies and procedures specified by the appropriate committee of the facility, under applicable law and rules, and by usual and customary standards of good medical practice.

2. Self-administration. Self-administration of drugs by patients may be permitted only when specifically authorized by the treating or ordering physician; provided, however, the patient has been educated and trained in the proper manner of self-administration and there is no risk of harm to the patient or others. The label should contain patient's name, room number, date directions, and name and strength of medication, at a minimum.

History: Effective April 1, 1988.
General Authority: NDCC 28-32-02
Law Implemented: NDCC 43-15-10(9), 43-15-10(12), 43-15-10(14)

61-07-01-10. Drugs from outside sources.

1. Outside pharmacies. Whenever drugs or pharmaceutical services are obtained from outside of a hospital, arrangements must be made to ensure that such outside pharmacist provides services with sufficient professionalism, quality, and availability to adequately protect the safety of the patients and to properly serve the needs of the hospital. Such arrangements must be made in writing and must, at a minimum, specify that:
   a. The outside pharmacist shall act in the capacity of the director (subsection 1 of section 61-07-01-04) and, therefore, is subject to this chapter.
   b. Such arrangement is contingent upon approval of the board of pharmacy.
   c. The pharmacist must be available for consultation during all absences, or provide a protocol to contact another pharmacist.
   d. Adequate storage facilities for drugs will be provided.
   e. All drugs supplied must be labeled so as to ensure that recalls can be effected and that proper control and supervision of such drugs may be exercised.

2. Brought by patients. Whenever patients bring drugs into a hospital, such drugs may not be administered unless they can be precisely identified; administration must be pursuant to a physician's order only. The director of pharmacy will specify the policy and procedure for handling these medications.

History: Effective April 1, 1988.
General Authority: NDCC 28-32-02
Law Implemented: NDCC 43-15-10(9), 43-15-10(12), 43-15-10(14)

61-07-01-11. Quality assurance. The director of pharmacy services is responsible for developing procedures for an ongoing quality assurance program of pharmaceutical services that includes a mechanism for reviewing and evaluating drug-related patient care, as well as an appropriate response to findings. This written plan should clearly establish responsibility and the need for documentation of an effective program. The director of pharmacy services is responsible for developing procedures for quality assurance in centralized intravenous admixture services. Such procedures must encompass selection, education, and training of personnel, in process controls, end-product testing, and sampling guidelines. Cautionary measures for the safe admixture of parenteral products must be developed.

History: Effective April 1, 1988.
General Authority: NDCC 28-32-02
Law Implemented: NDCC 43-15-10(9), 43-15-10(12), 43-15-10(14)

61-07-01-12. Investigational drugs. Investigational drugs must be properly labeled and may be administered only under the personal and direct supervision of the principal physician-investigator or physician-investigator's authorized clinician with prior approval of the appropriate committees of the hospital. Nurses may administer such drugs only after they have been educated and trained concerning relevant pharmacologic information about such drugs by the clinician or the pharmacist. A central unit must be maintained wherein essential information regarding such drugs may be obtained. Patients' or representatives' informed consent must be obtained prior to investigational drug therapy. Investigational drugs must be stored under the same regulations as Schedule II controlled substances.

History: Effective April 1, 1988.
General Authority: NDCC 28-32-02
Law Implemented: NDCC 43-15-10(9), 43-15-10(12), 43-15-10(14)

61-07-01-13. Inspection.

1. Monthly. The director of pharmacy shall inspect, no less than once a month, personally or by qualified designee, all matters within the director's jurisdiction and responsibility and make appropriate written records and notations of such inspections. Such inspections shall verify, at a minimum, that:
   a. Drugs are dispensed only by pharmacists.

   b. Ancillary pharmacy personnel are properly directed and supervised.

c. Disinfectants and drugs for external use are stored separately and apart from drugs for internal use or injection.
d. Drugs requiring special storage conditions to ensure their stability are properly stored.
e. Outdated drugs or otherwise unusable drugs have been identified and their distribution and administration prevented. An area must be designated for authorized storage of such drugs prior to their proper disposition.
f.. Distribution and administration of controlled substances are properly and adequately documented and reported by both pharmacy and medical personnel.

g. Emergency drugs designated pursuant to subsection 4 of section 61-07-01-05 are adequate and in proper supply both within the pharmacy and at outside storage locations.

h. All necessary and required security and storage standards are met.

i. Metric-apothercaries' weight and measure conversion tables and charts are reasonably available to all medical personnel.
j. All policies and procedures of the director and of appropriate committees of the hospital relevant to pharmacy are followed.
k. The telephone number of the regional poison control information center should be posted by all telephones in the nursing stations where drugs are stored.

2. Annual. The board of pharmacy shall inspect, no less than once a year, by one of its members or by its qualified designee, all aspects of the management and operation of all hospital pharmacies in the state, to verify compliance with the law, this chapter, and such other standards as may be appropriate to ensure that the health, safety, and welfare of patients of the hospital serviced by the pharmacy are protected. Written reports of an inspection must be filed with the board and the director. Any discrepancies or deficiencies noted must be corrected within a reasonable time. Written notice of such corrections must be filed with the board. Board recommendations may be questioned by written notice to the executive secretary of the board of pharmacy. Consideration must be given by the board's inspector or designee to giving thirty days' notice of an inspection to the director of the pharmacy to be visited. Consideration must also be given to any recent survey by the joint commission on accreditation of health care organizations.

History: Effective April 1, 1988.
General Authority: NDCC 28-32-02
Law Implemented: NDCC 43-15-10(9), 43-15-10(12), 43-15-10(14)

Home Ohio State Board of Pharmacy

Rules

Ohio Administrative Code

(Promulgated under Chapter 119. of the Ohio Revised Code)

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DEFINITIONS; INSTITUTIONAL FACILITY

Rule 4729-17-01 [Update Effective 01/01/2011]

As used in Chapter 4729-17 of the Administrative Code:

(A) "Institutional facility" means a hospital as defined in section 3727.01 of the Revised Code, or a facility licensed by the Ohio state board of pharmacy and the Ohio department of health, the Ohio department of rehabilitation and correction, or the Ohio department of developmental disabilities at which medical care is provided on site and a medical record documenting episodes of care, including medications ordered and administered, is maintained, including but not limited to:

(1) Convalescent homes;

(2) Developmental facilities;

(3) Long term care facilities;

(4) Nursing homes;

(5) Psychiatric facilities;

(6) Rehabilitation facilities;

(7) Developmental disability facilities.

(B) "Inpatient" means any person who receives drugs for use while within the institutional facility.

(C) "Inpatient prescription" means a written, electronic, or oral order for a drug to be dispensed for use in treating an inpatient.

(D) "Dispensing of a drug pursuant to an inpatient prescription" means the professional review by a pharmacist required to place a specific drug in final association with the name of a particular inpatient pursuant to the lawful order of a prescriber. In the case of an automated drug delivery system meeting the requirements of rule 4729-5-35 of the Administrative Code, the final association with the name of a particular inpatient will be deemed to have occurred when the pharmacist has given final approval to the patient specific order in the system.

(E) "Contingency drugs" are those drugs which may be required to meet the therapeutic needs of inpatients when a licensed pharmacist is not available and personally in full and actual charge of the institutional pharmacy.

(F) "Emergency drugs" are those drugs which are required to meet the immediate therapeutic needs of inpatients in order to sustain life in an emergency crisis.

(G) "Outpatient" means any person who receives drugs for use outside of the institutional facility.

(H) "Electronic drug record keeping system" means a system of storing drug records electronically and capturing the positive identification of the person responsible for a specific drug transaction including, but not limited to, the prescribing, administering, or dispensing of a drug.

(I) "Positive identification" has the same meaning as paragraph (N) of rule 4729-5-01 of the Administrative Code except that a specific hospital having a closed electronic drug record

keeping system may be permitted to use identifiers utilizing both a password combined with a personal identifier to document the positive identification of each user for, but not limited to, the prescribing and administration of a drug if approved by the board of pharmacy.

(1) At a minimum, the following items will be considered during the approval process:

(a) Adequate audit controls are in place to detect and deter drug diversion;

(b) Adequate access controls are in place to assure the identity of a user and to assign accountability of the user for any drug transaction;

(c) Adequate safeguards are in place to prevent and detect the unauthorized use of an individual's password and personal identifier;

(d) An ongoing quality assurance program is in place to ensure that paragraphs (I)(1)(a) to (I)(1)(c) of this rule are being fulfilled and reviewed; and

(e) Appropriate policies and procedures are in place to address all of the items in paragraphs (I)(1)(a) to (I)(1)(d) of this rule.

(2) Positive identification pursuant to paragraph (N) of rule 4729-5-01 of the Administrative Code shall always be used to document the:

(a) Dispensing, compounding, or repackaging of a drug;

(b) Removal and possession of a controlled substance to administer to a patient;

(c) Waste of a controlled substance.

(J) "Password" means a private identification that is created by a user to obtain access to an electronic drug record keeping system.

(K) "Personal identifier" means a unique user name or number for identifying and tracking a specific user's access to an electronic drug record keeping system such as social security number, user identification number, or employee number.

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RESPONSIBLE PERSON FOR AN INSTITUTIONAL PHARMACY

Rule 4729-17-02 [Update Effective 01/01/2011]

Each institutional pharmacy shall be directed by a pharmacist who holds a current identification card to practice pharmacy in Ohio pursuant to the provisions of section 4729.12 of the Revised Code.

(A) The institutional pharmacy director or designated pharmacist shall be the pharmacist-in-charge pursuant to section 4729.27 of the Revised Code, the responsible person pursuant to rule 4729-5-11 of the Administrative Code, and the pharmacist responsible for maintaining supervision and control over the possession and custody of all dangerous drugs acquired by the institutional facility pursuant to division (B) of section 4729.55 of the Revised Code.

(B) A pharmacist shall be the responsible person for no more than one pharmacy except with written permission from the state board of pharmacy. A written request shall be submitted outlining the circumstances requiring a pharmacist to be responsible for more than one pharmacy and the period of time during which the circumstances will exist. A pharmacist shall not be designated the responsible person for a pharmacy unless he/she will be physically present in the pharmacy a sufficient amount of time to provide supervision and control.

(C) The terminal distributor of dangerous drugs license issued to the institutional facility shall be signed by the responsible person and maintained in a readily available place in the pharmacy.

(D) The responsible person shall:

(1) Be responsible for the practice of pharmacy performed within the institution;

(2) Develop, implement, supervise, and coordinate all services provided by the pharmacy;

(3) In conjunction with the appropriate interdisciplinary committees, be responsible for the development of written policies and procedures which are consistent with this chapter of the Administrative Code and other applicable federal and state laws and rules governing the legal distribution of drugs, assure adherence to these policies and procedures in order to provide for the safe and efficient distribution of drugs in all areas of the institution, and make available a current copy of these written policies and procedures for inspection and/or copying by an employee of the state board of pharmacy;

(4) Be responsible for the security and control of all drugs within the institution;

(5) Be responsible for the maintenance of all records, required by state or federal law to be kept at the licensed location, of the acquisition, use, distribution, and disposition of all drugs.

(E) An institutional pharmacy director or designated pharmacist, who becomes the responsible person shall:

(1) File a written notice to the state board of pharmacy by regular mail, or by verified facsimile transmission within thirty days. This notice shall include:

(a) The name, address, and dangerous drug distributor license number(s) of the institutional pharmacy;

(b) His/her name and pharmacist registration identification number; and

(c) The date on which he/she became the responsible person.

(2) Take a complete inventory, pursuant to federal regulations, of the controlled substances on hand at the pharmacy with the old or previous responsible person at the time he/she ceases to be the responsible person.

(a) The original copy of the inventory shall be maintained in the pharmacy with all other required controlled substance records;

(b) This inventory shall serve as the inventory of controlled substances for which the new or acting responsible person is responsible.

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SECURITY AND CONTROL OF DRUGS IN AN INSTITUTIONAL FACILITY

Rule 4729-17-03 [Update Effective 01/01/2011]

(A) In the absence of a licensed pharmacist, drugs ordered by a prescriber for patient treatment may be obtained in the following manner:

(1) Where a licensed pharmacist is not present twenty-four hours-a-day, drugs for patient treatment may be made available to licensed health care professionals authorized pursuant to the Revised Code to administer drugs in the course of their professional practice by the use of contingency drug supplies pursuant to the provisions of paragraph (A)(2) of this rule. A licensed pharmacist shall be available for emergencies when the institutional pharmacy is closed.

(2) Contingency drugs shall be used only in the absence of a licensed pharmacist, and shall be stored in a locked cabinet(s) or other enclosure(s) constructed and located outside of the institutional pharmacy. The storage area must be sufficiently secure to deny access, without obvious damage, to unauthorized persons. The responsible person shall:

(a) Designate those who may obtain access to the drug supply;

(b) Determine, in conjunction with the appropriate interdisciplinary committees, the drugs that are to be included in the contingency drug supply;

(c) Ensure that such drugs are properly labeled and packaged in sufficient quantities to provide drug therapy during the period when the institutional pharmacy is not open;

(d) Provide controls adequate to prevent diversion of the drugs, and institute record keeping procedures to account adequately for the drugs when used and the positive identification of the person who obtained the drugs from the drug supply;

(e) Provide procedures for the inspection of the contingency drug inventory to assure proper utilization and replacement of the drug supply.

(3) For a pharmacy located on the premises of the institutional facility, when a drug is not available from the contingency drug supply and such drug is required to treat the immediate needs of an inpatient or outpatient whose health would otherwise be jeopardized, such drug may be obtained from the institutional pharmacy pursuant to written policies and procedures implemented by the responsible person.

(a) The policies and procedures shall:

(i) Identify the personnel authorized to access the pharmacy and the conditions under which access may be gained to the pharmacy;

(ii) Ensure a minimum of two employees of the institution, one of whom shall be a health care professional licensed pursuant to Chapter 4723. (Nursing Practice Act) or 4731. (Medical Practice Act) of the Revised Code and authorized by such chapter to administer drugs in the course of their professional practice, to accompany each other when accessing the pharmacy;

(iii) Provide a written record documenting emergency access to the pharmacy. Such record shall include the names, titles, and positive identification of all institutional personnel accessing the pharmacy, date and time of access, the name and quantity of drugs obtained, the name of the patient, and the name of the ordering prescriber.

(b) The written record of each access to the institutional pharmacy when it is closed and a pharmacist is not present shall be filed, within twenty-four hours, with the responsible person and maintained in the pharmacy for three years

(B) Supplies of dangerous drugs may be maintained in patient care areas according to written policies and procedures developed and implemented by the responsible person. The policies and procedures shall:

(1) Provide for a limited quantity of dangerous drugs to be maintained at any one location;

(2) Provide for the proper storage and labeling of all such drugs;

(3) Provide for storage in a secure area. If dangerous drugs cannot be stored in a secure area, they shall be stored in a container which is sealed with a tamper-evident seal that must be broken to gain access to the drugs;

(4) Provide for notification of the responsible person, or designated pharmacist, when the dangerous drug supply has been accessed and/or drugs used;

(5) Provide for replacement of the drugs used, and the dangerous drug supply to be resealed;

(6) Provide for inspection of the dangerous drug supply, on a regular basis, to detect unauthorized use of such drugs and which drugs have exceeded their expiration or beyond use date;

(7) Provide adequate record keeping procedures to document the disposition of drugs from the supply.

(C) Security

(1) All areas occupied by an institutional pharmacy shall be capable of being secured by key, or other effective mechanism, so as to prevent access by unauthorized personnel.

(2) In the absence of a licensed pharmacist, all areas occupied by an institutional pharmacy shall be secured so as to prevent access by unauthorized personnel.

(3) The responsible person shall develop and implement policies and procedures which will detect and deter the diversion and/or adulteration of drugs.

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RECORDS; INSTITUTIONAL PHARMACY

Rule 4729-17-04 [Update Effective 01/01/2009]

All drug records shall be maintained for a period of three years pursuant to section 4729.37 of the Revised Code. All drug records must be readily retrievable within three working days, excluding holidays and weekends, of all drug transactions within the previous three years. Electronic drug record keeping systems, computerized record keeping systems, or subsequent storage of such records, must be readily retrievable via CRT display, hard copy printout, or other mutually agreeable transfer medium. If an electronic drug record keeping system is being utilized as defined in paragraph (H) of rule 4729-17-01 of the Administrative Code the method(s) of achieving positive identification must be approved by the state board of pharmacy prior to implementation pursuant to paragraph (I) of rule 4729-17-01 of the Administrative Code. The responsible person shall be responsible for maintaining the following records:

(A) A record of all drugs purchased, the quantity received, and the name, address, and wholesale distributor registration number of the person from whom the drugs were purchased.

(B) All drug orders and records relating to the practice of pharmacy.

(1) Records of drugs dispensed shall include, but are not limited to:

(a) The name, strength, and quantity of drugs dispensed;

(b) The date of dispensing;

(c) The name of the inpatient to whom, or for whose use, the drug was dispensed; and

(d) Positive identification of all pharmacists involved in the dispensing.

(2) All other records relating to the practice of pharmacy other than dispensing shall include, but are not limited to:

(a) The name of the inpatient to whom, or for whose benefit, the activity was performed;

(b) The practice of pharmacy activity performed;

(c) The results of the activity, if applicable; and

(d) Positive identification of all pharmacists involved in the activity, identifying the function performed by each pharmacist.

(3) Records of drugs dispensed for outpatients shall be maintained pursuant to rule 4729-5-27 of the Administrative Code.

(C) A record of all drugs compounded or repackaged for use only within the institution, which shall include at least the following:

(1) Name of drug, strength, quantity, and dosage form;

(2) Manufacturer's or distributor's control number;

(3) Manufacturer's or distributor's name, if a generic drug is used;

(4) Pharmacy control number;

(5) Manufacturer's or distributor's expiration date;

(6) The pharmacy's expiration date or beyond-use date;

(7) Positive identification of the pharmacist responsible for the compounding or repackaging of the drug.

(D) A record of the distribution of dangerous drugs to other areas of the institution for administration or use as described in paragraph (B) of rule 4729-17-03 of the Administrative Code, which shall include at least the following:

(1) The name, strength, dosage form, and amount of drug distributed;

(2) The area receiving the drug;

(3) The date distributed;

(4) Positive identification of the individual receiving the drug if it is a controlled substance;

(5) The area of the institution receiving the dangerous drug shall make a record of all such drugs administered to patients. Such records shall include at least the following:

(a) Name of the patient;

(b) Name, dosage form, and strength when applicable of the drug;

(c) Date and time the drug was administered;

(d) Quantity administered;

(e) Positive identification of the personnel administering the drug.

(E) A log that must be maintained of all changes made to a drug record in an electronic drug record keeping system or a computerized record keeping system after a drug transaction has been made. Such log may be accessible for review, but shall be protected from being altered in any way. The log must contain at least, but is not limited, to the following:

(1) Date and time of change;

(2) Changes made;

(3) Person making the change.

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CONTROLLED SUBSTANCE RECORDKEEPING

Rule 4729-17-05 [Update Effective 01/01/2011]

(A) All controlled substances dispensed to inpatients in an institutional facility in quantities exceeding a seventy-two-hour supply shall be dispensed and maintained according to the following requirements:

(1) All controlled substances dispensed in quantities exceeding a seventy-two-hour supply shall be packaged in tamper-evident, unit-of-use containers except multidose liquids and injectables where unit-of-use packaging is not available;

(2) The drugs shall be stored in a secure location with access limited to authorized individuals;

(3) A proof-of-use sheet or other board-approved recordkeeping system shall be maintained for each drug and shall include at least, but is not limited to, the following information:

(a) Patient name,

(b) Date and time of access,

(c) Drug name, strength, and quantity obtained,

(d) The positive identification of the person doing the administration, and, if applicable,

(e) The positive identification of both the person and the witness who waste a partial dose of a controlled substance;

(4) At every change of shift, a reconciliation must be conducted by both the leaving and arriving licensed health care professional responsible for the security of these drugs in the area in which they are stored and must include at least the following:

(a) A physical count and reconciliation of the controlled substances and proof-of-use sheets, if applicable, to ensure the accountability of all doses,

(b) An inspection of the packaging to ensure its integrity,

(c) The positive identification of the persons conducting the reconciliation, and

(d) The immediate reporting of any unresolved discrepancy to the appropriate people within the institution. A pharmacist at the pharmacy department responsible for the terminal distribution of dangerous drugs license must be one of those notified.

(B) All controlled substances maintained as stock in areas outside of the pharmacy pursuant to paragraph (B) of rule 4729-17-03 of the Administrative Code shall meet the following requirements, unless they are stored in a secure, automated storage system that meets the requirements of paragraph (C) of this rule:

(1) The drugs shall be stored in a secure location with access limited to authorized individuals;

(2) A proof-of-use sheet or other board approved recordkeeping system shall be maintained for each drug and shall include at least, but is not limited to, the following information:

(a) Patient name,

(b) Date and time of access,

(c) Drug name, strength, and quantity obtained,

(d) The positive identification of the person doing the administration, and, if applicable,

(e) The positive identification of both the person and the witness who waste a partial dose of a controlled substance;

(3) At every change of shift, a reconciliation must be conducted by both the leaving and arriving licensed health care professional responsible for the security of these drugs in the area in which they are stored and must include at least the following:

(a) A physical count and reconciliation of the controlled substances and proof-of-use sheets, if applicable, to ensure the accountability of all doses,

(b) An inspection of the packaging to ensure its integrity,

(c) The positive identification of the persons conducting the reconciliation, and

(d) The immediate reporting of any unresolved discrepancy to the appropriate people within the institution. A pharmacist at the pharmacy department responsible for the terminal distributor of dangerous drugs license must be one of those notified;

(4) All controlled substances shall be packaged in tamper-evident containers except multidose liquids and injectables where unit-of-use packaging is not available.

(C) All controlled substances maintained as stock in areas outside of the pharmacy pursuant to paragraph (B) of rule 4729-17-03 of the Administrative Code that are stored in a secure, automated storage system shall be handled as in paragraph (B) of this rule unless the automated storage system meets all of the following requirements:

(1) The drugs shall be stored in a secure location with access limited to authorized individuals;

(2) The system shall document the positive identification of every person accessing the system and shall record the date and time of access;

(3) A recordkeeping system shall be maintained that shall include at least, but is not limited to, the following information:

(a) Patient name,

(b) Date and time of access,

(c) Drug name, strength, and quantity removed,

(d) The positive identification of the person removing the drug, and, if applicable,

(e) The positive identification of both the person and the witness who waste a partial dose of a controlled substance;

(4) Periodically, the responsible person shall cause a reconciliation of the automated storage system to be conducted which must include at least the following:

(a) A physical count and reconciliation of the controlled substances to ensure the accountability of all doses,

(b) An inspection of the packaging to ensure its integrity,

(c) The positive identification of the persons conducting the reconciliation, and

(d) The immediate reporting of any unresolved discrepancy to the appropriate people within the institution. A pharmacist at the pharmacy department responsible for the terminal distributor of dangerous drugs license must be one of those notified;

(5) Access to all controlled substances stored in the automated storage system shall be limited to one drug and strength at a time;

(6) All controlled substances stored in the automated storage system shall be packaged in tamper-evident containers, unless the system only allows access to one dose at a time.

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MINIMUM STANDARDS FOR AN INSTITUTIONAL PHARMACY

Rule 4729-17-08 [Update Effective 01/01/2009]

(A) Library

(1) All pharmacists working in a pharmacy must be able to access all current federal and state laws, regulations, and rules governing the legal distribution of drugs in Ohio;

(2) The pharmacy shall carry and utilize the references necessary to conduct a pharmacy in a manner that is in the best interest of the patients served and to comply with all state and federal laws; and

(3) Telephone number of a poison control center.

(B) Drug inventory, fixtures, and space

(1) The inventory of drugs and equipment shall be commensurate with the scope of pharmacy services provided, and housed in suitable, well-lighted and well-ventilated room(s), in a clean and sanitary area.

(2) All areas where drugs are stored shall be maintained at temperatures which will ensure the integrity of the drugs prior to their dispensing or administration as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling.

(3) All areas where drugs are stored shall provide adequate physical security to deter and detect their diversion and/or adulteration.

(C) Personnel

The pharmacy shall be appropriately staffed to operate in a safe and effective manner pursuant to section 4729.55 of the Revised Code. An employee of a pharmacy that may have contact with patients or the general public must be identified by a nametag that includes the employee's job title.

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DRUG ORDERS FOR PATIENTS OF AN INSTITUTIONAL FACILITY

Rule 4729-17-09 [Update Effective 01/01/2011]

(A) Drugs shall be dispensed by a pharmacist for inpatients pursuant to an original patient specific order issued by a prescriber.

(1) Oral orders issued by a prescriber for inpatients of an institutional facility may be transmitted to a pharmacist by personnel authorized by, and in accordance with, written policies and procedures of the facility. Such orders shall be recorded by the pharmacist, noting the full name(s) of the authorized personnel transmitting the order. Oral orders issued by a prescriber and transmitted by authorized personnel shall be verified by the prescriber using positive identification within a reasonable time and as required by the written policies and procedures of the facility.

(2) Drug orders for inpatients of an institutional facility transmitted to a pharmacist by use of a facsimile machine to facsimile machine transfer shall be transmitted by personnel authorized by, and in accordance with, written policies and procedures of the facility. The pharmacist receiving the facsimile shall have in place written policies and procedures allowing only authorized personnel access to the drug order facsimile. The pharmacist shall maintain the facsimile showing the origin of the order as a part of the drug order record. This facsimile must be maintained if it is the only record showing the pharmacist responsible for dispensing the drug.

(3) Drug orders for inpatients of an institutional facility transmitted to a pharmacist by use of an electronic drug record keeping system may be considered an original order for the dispensing of drugs. Access to such system for entering and transmitting original orders shall be restricted to licensed health care professionals using positive identification. If the licensed health care professional entering the order into the system is not the prescriber, there shall be a system in place requiring the positive identification of the prescriber for each order within a reasonable period of time which shall be available in a readily retrievable fashion.

(B) All orders for drugs for inpatients shall include, but are not limited to, at least the following:

(1) Name of patient;

(2) Name, strength, and dosage form of drug;

(3) Directions for use, including route of administration;

(4) Date prescribed; and

(5) Prescriber's positive identification.

(C) Drugs shall be dispensed for outpatients pursuant to an original order of a prescriber. All orders for the dispensing of drugs to outpatients shall, at a minimum, conform to rule 4729-5-30 of the Administrative Code, shall be labeled in accordance with rule 4729-5-16 of the Administrative Code, and the records shall be maintained in accordance with rule 4729-5-27 of the Administrative Code.

(D) An original signed prescription for a schedule II controlled substance prepared in accordance with federal and state requirements and issued for a resident in a long term care facility may be transmitted by the prescriber or the prescriber's agent to the dispensing pharmacy by

facsimile. The facsimile shall serve as the original written prescription and shall be received and maintained pursuant to rules 4729-5-21 and 4729-5-30 of the Administrative Code. The original signed prescription must remain with the patient's records at either the prescriber's office or the long term care facility.

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LABELING OF PRESCRIPTIONS FOR PATIENTS OF AN INSTITUTIONAL FACILITY

Rule 4729-17-10 [Update Effective 01/01/2010]

(A) All dangerous drugs dispensed for use by inpatients in an institutional facility, whereby the drug is not in the possession of the ultimate user prior to administration, shall meet the following requirements:

(1) The label of a single unit package of an individual-dose or unit-dose system of packaging of drugs shall include:

(a) The non-proprietary or proprietary name of the drug;

(b) The route of administration, if other than oral;

(c) The strength and volume, where appropriate, expressed in the metric system whenever possible;

(d) The control number and expiration date;

(e) Identification of the manufacturer, packer or distributor, or if the repackager is the dispensing pharmacy identification of the repackager, shall be by name or by the final seven digits of their terminal distributor of dangerous drugs license number, and such identification shall be clearly distinguishable from the rest of the label;

(f) Special storage conditions, if required.

(2) When a multiple-dose drug distribution system is utilized, including dispensing of single unit packages, the drugs shall be dispensed in a container to which is affixed a label containing the following information:

(a) Identification of the dispensing pharmacy;

(b) The patient's full name;

(c) The date of dispensing;

(d) The non-proprietary and/or proprietary name of the drug;

(e) The strength, expressed in the metric system whenever possible.

(3) Multiple drugs may be packaged in the same container such that the different drugs are in contact with each other only under the following conditions:

(a) The number of drugs placed in one package cannot exceed the capability of the receptacle to prevent damage to the dosage forms.

(b) The quantity dispensed may not be more than a thirty-one-day supply.

(c) The labels must be of sufficient size to properly and clearly label a thirty-one-day or less supply with all information required by state and federal law including accessory labels.

(d) Each individual package must include a beyond-use date of not more than sixty days from the date the drugs were placed in the package.

(e) Medications which have been packaged in multi-dose packaging may not be returned to stock or redispensed when returned to the pharmacy for any reason.

(f) When the drugs are not in the possession of the ultimate user and any one drug within each individual package has been discontinued, all drugs in the individual package are deemed adulterated and they may not be administered unless otherwise approved by the board of pharmacy.

(g) The packaging is tamper-evident.

(h) Any pharmacist/pharmacy using multi-dose packaging must implement policies and procedures which will exclude drugs having the following characteristics from such packaging:

(i) The U.S.P. monograph or official labeling requires dispensing in the original container;

(ii) The drugs or dosage forms are incompatible with packaging components or each other;

(iii) The drugs are therapeutically incompatible when administered simultaneously;

(iv) The drug products require special packaging.

(4) At least the name of the patient must be placed on all medication containers too small to bear a complete label and dispensed in a container bearing a complete label.

(B) All drugs dispensed to inpatients for self-administration shall be labeled in accordance with paragraphs (A), (B), and (C) of rule 4729-5-16 of the Administrative Code.

(C) Whenever any drugs are added to parenteral solutions, such admixtures shall bear a distinctive label indicating:

(1) The patient's full name;

(2) The name and amount of the parenteral solution;

(3) The name and amount of the drug(s) added;

(4) The expiration date or beyond-use date;

(5) The name and address of the institutional facility pharmacy;

(6) Cautionary statements, if required.

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LABELING OF PRESCRIPTIONS FOR OUTPATIENTS

Rule 4729-17-11 [Update effective 01/10/1996]

All drugs dispensed for use by outpatients of an institutional facility shall be labeled in accordance with paragraphs (A), (B), and (C) of rule 4729-5-16 of the Administrative Code except as noted in paragraph (A) of rule 4729-17-10 of the Administrative Code.

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D.E.A. NUMBERS FOR HOSPITAL EMPLOYED PRESCRIBERS

Rule 4729-17-13 [Update effective 01/01/2006]

(A) A person authorized to write prescriptions pursuant to rule 4729-5-15 of the Administrative Code who is employed as a staff prescriber of a hospital, is not individually registered under the provisions of the controlled substances act and, therefore, does not possess a "Drug Enforcement Administration" (D.E.A.) number, may administer, dispense, and prescribe controlled substances under the registration of the hospital.

(B) A person pursuing an approved training program within the jurisdiction of the hospital and authorized to write prescriptions pursuant to paragraph (B) of rule 4729-5-15 of the Administrative Code may administer, dispense, or prescribe controlled substances under the registration of the hospital. Persons pursuing such approved training programs may function in sites outside the physical confines of the hospital only if such sites are part of the training program and the persons are under the employment and jurisdiction of the hospital administering the approved program. While functioning in the outside sites, such persons may continue to use the internal code assigned by the hospital administering the approved program, upon mutual agreement of the hospital and the outside site.

(C) The administering, dispensing, or prescribing must be done in the usual course of his/her professional practice and only within the scope of his/her employment.

(D) Each person so authorized must be assigned a specific internal code number by the hospital which will be used as a suffix to the hospital D.E.A. registration number. Such internal code number shall consist of numbers, letters, or a combination thereof and shall be preceded by a hyphen. A list of the internal codes and the corresponding individual prescriber must be kept by the hospital and made available at all times to other registrants, state board of pharmacy designated agents, investigators of the state medical board, and federal, state, county, or municipal law enforcement agencies for verification.

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PROFESSIONS AND OCCUPATIONS
TITLE 59, OKLAHOMA STATUTES
CHAPTER 8. – Drugs and Pharmacy
Oklahoma Pharmacy Act

353. Short title - Purpose - Declaration of pharmacy as a profession

A. Sections 353 through 366 of Title 59 of the Oklahoma Statutes shall be known and may be cited as the "Oklahoma Pharmacy Act".

B. It is the purpose of the Oklahoma Pharmacy Act to promote, preserve and protect the public health, safety and welfare by and through the effective control and regulation of the practice of pharmacy and of the registration of drug outlets engaged in the manufacture, production, sale and distribution of dangerous drugs, medication, devices and such other materials as may be used in the diagnosis and treatment of injury, illness and disease.

C. In recognition of and consistent with the decisions of the appellate courts of this state, the practice of pharmacy is hereby declared to be a profession.

353.1. Definitions

For the purposes of the Oklahoma Pharmacy Act:

1. **"Pharmacy"** means a place regularly licensed by the Board of Pharmacy in which prescriptions, drugs, medicines, chemicals and poisons are compounded or dispensed;

2. **"Doctor of Pharmacy"** means a person registered by the Board of Pharmacy to engage in the practice of pharmacy. The terms "pharmacist" and "Doctor of Pharmacy" shall be interchangeable and shall have the same meaning wherever they appear in the Oklahoma Statutes and the rules promulgated by the Board of Pharmacy;

3. **"Drugs"** means all medicinal substances and preparations recognized by the United States Pharmacopoeia and National Formulary, or any revision thereof, and all substances and preparations intended for external and internal use in the cure, diagnosis, mitigation, treatment or prevention of disease in humans and all substances and preparations, other than food, intended to affect the structure or any function of the body of a human;

4. **"Medicine"** means any drug or combination of drugs which has the property of curing, preventing, treating, diagnosing or mitigating diseases, or which is used for that purpose;

5. **"Poison"** means any substance which when introduced into the system, either directly or by absorption, produces violent, morbid or fatal changes, or which destroys living tissue with which such substance comes into contact;

6. **"Chemical"** means any medicinal substance, whether simple or compound or obtained through the process of the science and art of chemistry, whether of organic or inorganic origin;

7. **"Prescription"** means and includes any order for drug or medical supplies written or signed, or transmitted by word of mouth, telephone or other means of communication by a licensed practitioner of allopathic or osteopathic medicine, including physician assistants under the supervision of a licensed physician, dentistry, optometry certified by the Board of Examiners in Optometry, podiatry, or veterinary medicine, licensed by law to prescribe such drugs and medical supplies intended to be filled, compounded, or dispensed by a pharmacist, or by a wholesaler or distributor as authorized in subsection G of Section 353.13 of this title;

Agency Note: *Physician Assistants and Certified Optometrists have restrictions and limits on their prescribing of certain drugs under their practice act and rules.* ***Only Oklahoma licensed.*** *[Certified Optometrist prescribing must be for abnormalities of the eye only.] (see Appendix E)*

8. **"Filled prescription"** means a packaged prescription medication to which a label has been affixed, which shall contain such information as is required by the Oklahoma Pharmacy Act;

9. **"Nonprescription drugs"** means medicines or drugs, which are sold without a prescription and which are prepackaged for use by the consumer and labeled in accordance with the requirements of the statutes and regulations of this state and the federal government. Such items shall also include medical and dental supplies, and bottled or nonbulk chemicals which are sold or offered for sale to the general public, if such articles or preparations meet the requirements of the Federal Food, Drug and Cosmetic Act, 21 U.S.C.A., Section 321 et seq.;

10. **"Hospital"** means any institution licensed by this state for the care and treatment of patients;

11. **"Person"** means every individual, copartnership, corporation or association, unless the context otherwise requires;

12. **"Board"** or **"State Board"** means the Board of Pharmacy;

13. **"Administer"** means the direct application of a drug, whether by injection, inhalation, ingestion or any other means, to the body of a patient;

14. **"Dispense"** includes sell, distribute, leave with, give away, dispose of, deliver, or supply;

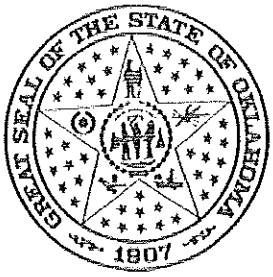
15. **"Wholesaler"** or **"Distributor"** means a person engaged in the business of distributing dangerous drugs or medicines at wholesale to pharmacies, hospitals, practitioners, government agencies, or other lawful drug outlets permitted to sell or use drugs or medicines, or as authorized in subsection G of Section 353.13 of this title;

16. **"Dangerous drug"**, **"legend drug"**, **"prescription drug"** or **"Rx Only"** means a drug which:
    a. under federal law, is required, prior to being dispensed or delivered, to be labeled with one of the following statements:

OKLAHOMA PHARMACY LAWBOOK

2010

Laws and Rules Pertaining to the Practice of Pharmacy



Oklahoma Statutes, Title 59, Chapter 8.
- Drugs and Pharmacy

UNOFFICIAL

and

Title 535. Oklahoma State Board of Pharmacy

UNOFFICIAL

*Official copies of the laws may be obtained from the statute books. Official copies of the rules may be obtained from the Oklahoma Secretary of State, Office of Administrative Rules.

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December 2010

(B) The records required in Section 535:15:5.5-5(a)(4)(A) above may be kept at either the remote medication order processing pharmacy or the hospital so long as the records are maintained and readily available.

(C) A hospital utilizing a remote pharmacist shall maintain a record of the name and address of such pharmacist(s), evidence of current pharmacist licensure in Oklahoma, and the address of each location where records of any and all orders processed for the hospital will be maintained.

[Source: Added at 27 Ok Reg 2256, eff 7-11-10]

535:15-4-6. Governing body

The pharmacy and pharmacist will recognize the Board as the governing body of the practice of pharmacy and any violations of pharmacy laws or rules that may come to the attention of the pharmacy and/or pharmacist must be reported to the Board.

[Source: Added at 27 Ok Reg 2256, eff 7-11-10]

535:15-4-7. Unlawful acts and violations

(a) Unlawful acts and violations are described in the Oklahoma Pharmacy Act and this Title.

(b) Remote medication order processing pharmacy rules for conduct, violations of conduct and rules for applicants are found in 535:25.

(c) Rules for conduct and violations of conduct for pharmacists are found in 535:10-3-1.1, 535:10-3-1.2, 535:15-3-2, 535:15-3-4-2; and rules for applicants are found in 535:25.

(d) Remote medication order processing pharmacies are subject to rules in 535:15-3 unless they clearly do not apply to RMOP pharmacies.

(e) Penalties for violations of this Title, the Oklahoma Pharmacy Act and federal and state laws and rules are listed in Title 59 O.S. Section 353.26.

[Source: Added at 27 Ok Reg 2256, eff 7-11-10]

SUBCHAPTER 5. HOSPITAL PHARMACIES

Section

535:15-5-1. Purpose
535:15-5-2. Definitions
535:15-5-3. Applicability
535:15-5-4. Registration
535:15-5-5. Director and pharmacy manager
535:15-5-6. Staff pharmacists [Revoked]
535:15-5-7. Supportive personnel
535:15-5-7.1. Pharmacy technician qualifications and training
535:15-5-7.2. Supervision of pharmacy technicians
535:15-5-7.3. Auxiliary supportive personnel tasks
535:15-5-7.4. Pharmacy technician tasks
535:15-5-7.5. Prohibited duties
535:15-5-7.6. Pharmacy technician annual permit requirement
535:15-5-7.7. Permit display
535:15-5-7.8. Change of address and employment location notification
535:15-5.7.9. Multiple employment locations
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535:15-5-7.11. Technician training
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535:15-5-8. Absence of pharmacist
535:15-5-9. Hospital pharmacy physical requirements
535:15-5-10. Director of Pharmacy responsibilities
535:15-5-10.1. Labeling
535:15-5-10.2. Physician's medication orders
535:15-5-11. Non-distributive roles of pharmacists
535:15-5-12. Administration of drugs to patients
535:15-5-13. Medications from other sources
535:15-5-14. Performance improvement
535:15-5-15. Investigational drugs
535:15-5-16. Monthly inspections
535:15-5-17. Board of Pharmacy inspections
535:15-5-18. Drug rooms
535:15-5-19. Remote medication order processing (RMOP)
[**Source:** Amended at 27 Ok Reg 2256, eff 7-11-2010]

535:15-5-1. Purpose

The rules of this Subchapter are to accomplish the purposes of the Oklahoma Pharmacy Act, as specified in 59 O.S., Section 353.18(A), by implementing the rules and regulations of a licensed hospital pharmacy and a hospital drug room, and as specified in 59 O.S., Section 353.29 by implementing rules regarding supportive personnel.

[**Source:** Amended at 11 Ok Reg 545, eff 11-03-93 (emergency); Amended at 11 Ok Reg 3431, eff 6-27-94; Amended at 20 Ok Reg 2982, eff 9-2-03 (emergency); Amended at 20 Ok Reg 2479, eff 1-1-04; Amended at 21 Ok Reg 2452, eff 7-1-04]

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 facility" or **"Hospital"** means any institution licensed as a hospital by this state for the care and treatment of patients.

"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 medical practitioner who has privileges to practice in the hospital facility.

"Medication order" means a prescription as defined in Title 59 O.S. Section 353.1(7).

"Pharmacist" means any person licensed to practice pharmacy by the Oklahoma State Board of Pharmacy.

"Pharmacy technician", "Tech", "Technician" or **"RxTech"** means a person who has been issued a permit by the Board to assist the pharmacist and performs non-judgmental, technical, manipulative, non-discretionary 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 technicians and auxiliary supportive persons, who are regularly paid employees of the hospital pharmacy and who work or perform tasks in the hospital pharmacy.

[**Source:** Amended at 11 Ok Reg 545, eff 11-3-93 (emergency); Amended at 11 Ok Reg 3431, eff 6-27-94; Amended at 18 Ok Reg 2738, eff 7-1-01; Amended at 20 Ok Reg 2982, eff 9-2-03 (emergency); Amended at 20 Ok Reg 2479, eff 1-1-04; Amended at 21 Ok Reg 2452, eff 7-1-04; Amended at 27 Ok Reg 2256, eff 7-11-10]

535:15-5-3. Applicability

The rules of this Subchapter are applicable to all hospitals and hospital pharmacies, as defined by 535:15-5-2 and may, if specified, apply to drug rooms. Compliance with the rules of this Subchapter is the responsibility of the hospital pharmacy, and the Director of Pharmacy, and may be for the individual pharmacist employed in the hospital pharmacy.
[**Source:** Amended at 11 Ok Reg 3431, eff 6-27-94; Amended at 18 Ok Reg 2738, eff 7-1-01; Amended at 27 Ok Reg 2249, eff 7-11-10]

535:15-5-4. Registration

(a) **Registration.** All hospital pharmacies shall register annually with the Board of Pharmacy; hospital pharmacy licenses shall be issued only to those hospital pharmacies that satisfy the provisions of Section 353.18(A) of the Oklahoma Pharmacy Act, and all rules of this Title.
(b) **Minimum hours.** A hospital pharmacy shall be staffed with licensed pharmacist and be open for a minimum of four days a week and for a minimum of at least 32 hours per week to the standards listed in 535:15-5-10 (j).
[**Source:** Amended at 11 Ok Reg 545, eff 11-3-93 (emergency); Amended at 11 Ok Reg 3431, eff 6-27-94; Amended at 18 Ok Reg 2738, eff 7-1-01; Amended at 27 Ok Reg 2249, eff 7-11-10]

535:15-5-5. Director and pharmacy manager

(a) Each hospital pharmacy shall be directed by a pharmacist hereinafter referred to as the Director of Pharmacy. The Director of Pharmacy shall be responsible for all activities of the hospital pharmacy, and for meeting the requirements of the Oklahoma Pharmacy Act and the rules of this Title.
(b) A hospital pharmacy manager's responsibilities are the same as those set out in Section 535:15-3-2 and the rules of this Subchapter.
(c) When the Director of Pharmacy and the pharmacy manager are separate individuals and the pharmacy manager is under the direction of the Director of Pharmacy, both individuals will be cited when action is taken against the pharmacy and/or the pharmacy manager.
[**Source:** Amended at 9 Ok Reg 2141, eff 6-11-92; Amended at 14 Ok Reg 3024, eff 7-11-97; Amended at 18 Ok Reg 2738, eff 7-1-01]

535:15-5-7. Supportive personnel

The rules from 535:15-5-7.1 through 535:15-5-7.12, et seq. describe the rules for pharmacy supportive personnel in a licensed hospital pharmacy facility and may include references to the rules in 535:15-13, and other rules of this Title.
[**Source:** Amended at 11 Ok Reg 545, eff 11-3-93 (emergency); Amended at 11 Ok Reg 3431, eff 6-27-94; Amended at 18 Ok Reg 2738, eff 7-1-01; Amended at 20 Ok Reg 2982, eff 9-24-03; Amended at 21 Ok Reg 2454, eff 7-1-04]

535:15-5-7.1. Pharmacy technician qualifications and training

(a) A pharmacy technician must have completed a high school education or G.E.D. equivalence, be of good moral character, be non-impaired (e.g. alcohol or drugs) and have adequate education to perform assigned duties.
(b) The pharmacy technician must, at a minimum, satisfactorily complete a pharmacy technician on-the-job training (OJT) program as described in 535:15-13-13.
(c) The Director of Pharmacy must demonstrate that the pharmacy technician has been given additional training before being allowed to prepare sterile products and

that the training given is at a level consistent with the scope of pharmaceutical product being prepared.
(d) A pharmacy technician, to be eligible for a technician permit, must comply with the requirements in this Title and 535:25.
[Source: Added at 18 Ok Reg 2738, eff 7-1-01]

535:15-5-7.2. Supervision of pharmacy technicians
(a) All tasks performed by pharmacy technicians in the pharmacy must be accomplished under the immediate supervision of an Oklahoma currently licensed pharmacist.
(b) Non-dispensing and non-compounding tasks performed in the floor stock or "satellite" areas must be under the supervision of the pharmacist.
(c) A pharmacy technician may perform certain non-judgmental tasks of dispensing as enumerated in this Subchapter provided that whenever the pharmacist leaves the pharmacy, all dispensing shall cease. Certified medical orders may be delivered during a pharmacist's absence.
(d) The pharmacist shall include in the Policy and Procedure Manual the specific scope of responsibilities or procedures delegated to pharmacy technicians and the in-service training of pharmacy technicians.
(e) The ratio of pharmacy technicians to supervising pharmacists shall be set by the Director of Pharmacy and should be a ratio that would be considered safe and reasonable by the certifying pharmacist. The ratio shall not exceed two pharmacy technicians to one supervising pharmacist.
(f) A pharmacy intern working in the pharmacy will not affect or change this ratio.
(g) A licensed pharmacy intern shall not supervise pharmacy technicians.
(h) The pharmacist shall do the final check and certification of the technical tasks performed by technicians. This certification shall be by means of the certifying pharmacist's signature, initial or other identifying mark on a record, the medication order and/or label.
[Source: Added at 18 Ok Reg 2738, eff 7-1-01]

535:15-5-7.3. Auxiliary supportive personnel tasks
Auxiliary supportive personnel may perform the following tasks:
(1) Retrieve prescriptions or files as necessary;
(2) Clerical tasks such as data entry, typing labels and maintaining patient profiles;
(3) Secretarial tasks such as telephoning, filing, and typing;
(4) Accounting tasks such as record keeping, maintaining accounts receivables, third party billing and posting;
(5) Inventory control tasks including monitoring, pricing, dating, invoicing, stocking pharmacy, and preparation of purchase orders; and,
(6) Help maintain a clean and orderly pharmacy.
[Source: Added at 18 Ok Reg 2738, eff 7-1-01; Amended at 20 Ok Reg 2982, eff 9-2-03 (emergency); Amended at 21 Ok Reg 2452, eff 7-1-04]

535:15-5-7.4. Pharmacy technician tasks

Pharmacy technicians may perform the following tasks in a licensed hospital pharmacy facility in accordance with 535:15-7.2:

(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 parenteral products utilizing a policy and procedure that addresses the verification of the pharmaceutical constituents, the prepared label and the final product by the pharmacist.

(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 parenteral products.

(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.

[Source: Added at 18 Ok Reg 2738, eff 7-1-01; Amended at 20 Ok Reg 2982 eff 9-2-03 (emergency); Amended at 21 Ok Reg 2452, eff 7-1-04]

535:15-5-7.5. Prohibited duties

These prohibited duties shall be performed by a pharmacist and shall not be performed by supportive personnel:

(1) Final interpretation of the prescriber's original order.

(2) Performance of the prospective drug utilization review and determination of action to be taken when there is an indication of a drug interaction.

(3) Receipt of new phone-in prescriptions from prescribers or their agents.

(4) Determination of product selection if substitution is requested or approved.

(5) Certification of the completed prescription or medication order for accuracy and completeness before dispensing from the pharmacy department.

(6) Provision of patient counseling or drug information as necessary.

[Source: Added at 18 Ok Reg 2738, eff 7-1-01; Amended at 20 Ok Reg 2984, eff 9-2-03 (emergency); Amended at 21 Ok Reg 2452, eff 7-1-04]

535:15-5-7.6. Pharmacy technician annual permit requirement

(a) Annual permit requirements for pharmacy technicians are set forth in this Title, in 535:15-13-8 and in 535:25.

(b) No pharmacy technician permit shall be issued or continued for an applicant or permit holder who fails to meet and maintain the requirements in 535:25-3 and 535:25-7 or who violates the rules in 535:25-9.

(c) A pharmacy technician must be employed in a licensed pharmacy to be eligible to renew their pharmacy technician permit.

[Source: Added at 18 Ok Reg 2738, eff 7-01-01; Amended are 24 Ok Reg 2261, eff 7-1-07]

535:15-5-7.7. Permit display

Each pharmacy technician permit issued by the Board shall be displayed as set forth in 535:15-13-9.

[Source: Added at 18 Ok Reg 2738, eff 7-1-01]

535:15-5-7.8. Change of address and employment location notification

A pharmacy technician must notify the Board of change of address or

employment location as set forth in 535:15-13-10.
[Source: Added at 18 Ok Reg 2738, eff 7-1-01]

535:15-5.7.9. Multiple employment locations

A pharmacy technician may work in more than one pharmacy location provided the tech has been "trained" for each location and the training is documented in each pharmacy.
[Source: Added at 18 Ok Reg 2738, eff 7-1-01]

535:15-5-7.10. Work schedule display

A pharmacy shall display a work schedule as required by 535:15-13-12.
[Source: Added at 18 Ok Reg 2738, eff 7-1-01]

535:15-5-7.11. Technician training

Pharmacy technicians shall meet the training requirements as set forth in 535:15-13-13.
[Source: Added at 18 Ok Reg 2738, eff 7-1-01]

535:15-5-7.12. Identification of Pharmacy technicians

Pharmacy technicians practicing in a hospital shall be distinctly identifiable from practicing pharmacists.
[Source: Added at 18 Ok Reg 2738, eff 7-1-01]

535:15-5-8. Absence of pharmacist

During such times as a hospital pharmacy may be unattended by a registered pharmacist, arrangements shall be made in advance by the Director of Pharmacy for provision of drugs to the medical staff and other authorized personnel of the hospital facility by use of night cabinets and in emergency circumstances, by access to the pharmacy. A pharmacist must be "on call" during all absences. Written policies and procedures shall be established to implement the requirements of this section and shall be available for Board review.

(1) **Night cabinets.** IF NIGHT CABINETS ARE USED THE FOLLOWING SHOULD PREVAIL: In the absence of a registered pharmacist, controlled drugs shall be kept in locked cabinet(s) or other enclosure(s) constructed and located outside of the pharmacy area, to which only specifically authorized personnel may obtain access by key or combination, and which is sufficiently secure to deny access to unauthorized person by force or otherwise. The Director shall, in conjunction with the appropriate committee of the hospital facility, develop inventory listings of those drugs to be included in such cabinet(s) and shall insure that:

(A) such drugs available therein are properly labeled;

(B) only prepackaged drugs are available therein, in amounts sufficient for immediate therapeutic requirements;

(C) whenever access to such cabinet(s) shall have been gained, written physician's orders and proofs of use, if applicable, are provided; and,

(D) proper inventories and a complete review of all activity concerning such cabinet(s) are conducted no less than once per month.

(2) **Access to pharmacy.** Whenever any drug is not available from floor supplies or night cabinets, and such drug is required to treat the immediate needs of a patient whose health would otherwise be jeopardized, such drug may be obtained from the pharmacy in accordance with the requirements of this paragraph. One supervisory nurse and only one in any given shift is responsible for removing drugs therefrom. The responsible nurse may, in time of emergency, delegate this duty to another nurse. The responsible nurse shall be designated by position in writing by the appropriate committee of the hospital facility, and shall, prior to being permitted to obtain access to the pharmacy, receive thorough education and training in the proper methods of access, removal of drugs, and records and procedures required. Such education and training shall be conducted by the Director of Pharmacy, or a pharmacist designee. Access to the pharmacy as described above shall require, at a minimum, the following records and procedures:

(A) a record of the removal of any drug from the pharmacy by an authorized nurse on a suitable form showing patient name, room number, name of drug, strength, amount, date, time and signature of nurse; and,

(B) such form shall be left with the container from which the drug was removed, both placed conspicuously so that it will be found by a pharmacist and checked properly and promptly.

[Source: Amended at 11 Ok Reg 3431, eff 6-27-94; Amended at 18 Ok Reg 2738, eff 7-1-01]

535:15-5-9. Hospital pharmacy physical requirements

A hospital pharmacy shall have sufficient facilities to insure that drugs are prepared in sanitary, well-lighted and enclosed places, and which meet the other requirements of this Chapter. The following are in addition to the equipment and library requirements listed in 535:15-3-4 and 535:15-3-6.

(1) **Equipment and materials.** Each hospital pharmacy shall have sufficient equipment and physical facilities for proper compounding, dispensing and storage of drugs.

(A) For parenteral preparations a hospital must comply with 535:15-9-6 and 535:15-9-10, 1 through 5.

(B) A library shall be maintained which includes four of the following current references (not more than 2 years old or most recent). Current electronic sources may be substituted for two hard copy information sources:

(i) Drug interactions;
(ii) Drug compatibility;
(iii) Poison and antidote information;
(iv) Toxicology;
(v) Pharmacology;
(vi) Bacteriology;
(vii)Patient counseling;
(viii) Rational therapy;
(ix) Dispensing information; and,
(x) U.S.P.

(C) The library shall include the latest copy of Oklahoma State Laws and Rules Pertaining to the Practice of Pharmacy and a recent copy of Oklahoma State Bureau of Narcotics & Dangerous Drugs Control Rules.

(2) **Storage.** All pharmaceuticals bearing a federal legend such as "RX Only" and medications administered in the hospital shall be stored in designated areas within the hospital which are sufficient to insure proper sanitation, temperature, light, ventilation, moisture control, segregation and security. The storage shall be as directed by the Director of Pharmacy and shall remain under the direct supervision of a pharmacist.

(3) **Alcohol and flammables.** Alcohol and flammables shall be stored in areas that shall, at a minimum, meet basic local building code requirements for the storage of volatiles and such other laws, ordinances or regulations as may apply.

(4) **Unattended areas.** In the absence of authorized personnel in a hospital medication area, such area shall be locked and inspected on a regular schedule of at least monthly as directed by the Director of Pharmacy.

(5) **Security**. All areas occupied by a hospital pharmacy shall be capable of being locked by key or combination to prevent access by unauthorized personnel.

[Source: Amended at 9 Ok Reg 2141, eff 6-11-92; Amended at 10 Ok Reg 3171, eff 6-25-93; Amended at 18 Ok Reg 2738, eff 7-1-01; Amended at 22 Ok Reg 2172, eff 7-1-05]

535:15-5-10. Director of Pharmacy responsibilities

(a) **Written procedures.** The Director of Pharmacy shall establish written procedures for the safe and efficient acquisition, distribution, storage, and utilization of pharmaceutical products with any of the federal legends such as "Rx Only" and medications administered or used in the hospital system. Such procedures shall be annually reviewed and a current copy shall be on hand for Board inspection.

(b) **General responsibilities.** The Director of Pharmacy shall be responsible for the safe and efficient purchasing, acquisition, monitoring, distribution, control, security, and accountability of all drugs including, but not limited to, federal legend drug products used in diagnostic procedures, I.V. fluids, or contained in supply kits. The other professional staff of the hospital facility shall cooperate with the Director in meeting this responsibility. The Director shall be responsible for, at a minimum, the following:

(1) Preparing and sterilizing parenteral medications prepared within the hospital facility.

(2) Admixing parenteral products, including education and training of nursing personnel concerning incompatibility and provision of proper incompatibility information when the admixture of parenteral products is not accomplished within the hospital pharmacy.

(3) Preparing drug products including unit dose.

(4) Establishing specifications for procurement of all materials, including drugs, chemicals and biologicals used within pharmacy practice, subject to approval of the appropriate committee of the hospital facility.

(5) Participating in the development and maintenance of a formulary for use

within the hospital facility.

(6) Filling and dispensing all drugs which are to be administered within the hospital facility.

(7) Maintaining and making available a sufficient inventory of pharmaceuticals, including antidotes and other emergency drugs, for use within the hospital facility. In addition, current references, antidote information, and telephone numbers of regional reference centers such as Poison Centers and Drug Information Centers shall be maintained and readily available throughout the hospital.

(8) Maintaining records of all transactions of the hospital pharmacy required by applicable local, state, and federal law, and necessary to maintain accurate control and accountability for all pharmaceutical materials.

(9) Participating in those aspects of the hospital facility's patient care evaluation programs that relate to pharmaceutical material utilization and effectiveness.

(10) Cooperating fully with teaching and/or research programs in the hospital facility, if any.

(11) Implementing the policies and decisions of the appropriate committees of the hospital, which deal with drug distribution and drug utilization.

(12) Meeting all inspection and other requirements of the Oklahoma Pharmacy Act, and the rules and regulations governing the practice of pharmacy within a hospital facility.

(13) Establishing guidelines for the safe and effective distribution of drugs intended for floor stock, and their subsequent administration.

(14) Initial and continuing training of pharmacy technicians.

(c) **Confidentiality.** The Director of Pharmacy shall have direct responsibility for the security and integrity of any patient pharmacy information, confidential and non-confidential, and must comply with all federal and state laws and regulations applicable to the hospital pharmacy.

(1) Rules regarding confidentiality of patient records are described in 535:15-3-14(e); and,

(2) Responsibilities for confidentiality shall be as set forth in 535:10-3-1.1 and 535:10-3-1.2 and the rules of this Title.

(d) **Adverse Drug Events program.** The Director of Pharmacy shall develop and maintain a program to monitor the actual and potential adverse drug events including pharmacist interventions, medication errors, and adverse drug reactions for all medications utilized in the hospital to include system wide programs if an integrated system is involved.

(1) Policies indicating the tracking, review, and outcome of the adverse drug events shall be kept current and available for Board inspection.

(2) Sentinel events, direct impact findings, and root cause analyses involving drugs and/or Medication Management Standards of The Joint Commission shall be maintained and be available for Board inspection.

(e) **Investigational drug programs.** The Director of Pharmacy shall maintain a file for review by the Board of all investigational drug protocols open and closed that have been approved by the hospital Investigational Review Board.

(f) **Discontinued drug orders.** The Director of Pharmacy shall develop and implement policies and procedures to insure that discontinued drugs, outdated drugs, and containers with worn, illegible or missing labels are returned to the pharmacy for proper disposition.

(g) **Controlled drug accountability.** The hospital facility shall maintain adequate records regarding the use and accountability of controlled substances and such other drugs as the hospital may designate; and as directed by the Oklahoma State Bureau of Narcotics and the Federal Drug Enforcement Administration. The Director of Pharmacy shall establish effective written procedures to implement this requirement.

(h) **Drug recall procedures.** The Director of Pharmacy shall develop and implement a written recall procedure that can be readily activated which assures that drugs involved, inside or outside of the facility, are returned to the pharmacy for proper disposition. All actions taken in this area are to be properly documented and maintained for 36 months for Board review.

(i) **Records and reports.** The Director of Pharmacy shall maintain and submit, as appropriate, such records and reports as are required to insure patient health, safety and welfare. These should include the following:

(1) Adverse drug reaction reports.
(2) Floor stock inventories of night cabinets and emergency boxes.
(3) Inventory listing of the pharmacy.
(4) Controlled substance inventory.
(5) Ethyl alcohol inventory.
(6) Pharmacy and therapeutic committee minutes.
(7) Reports and records as required by law and/or rules.
(8) Outpatient prescriptions shall contain all information required by pharmacy law and rule.

(j) **Pharmacist staffing.** The Director of Pharmacy shall maintain adequate staffing levels of pharmacist to insure pharmaceutical patient-focused care support. This staffing shall be a sufficient number of additional registered pharmacists as may be required to operate such a pharmacy competently, safely and adequately to meet the needs of the patients of the hospital facility as to meet requirements described in 535:15-5-4.

(k) **Automated dispensing systems.** The Director of Pharmacy shall maintain control to insure that direct pharmacist intervention and responsibility (and certification of medication order) is present and consistent in any cycle of automated dispensing from acquisition of product through the terminal dispensing act prior to administration to the patient of any medication as described in these rules.

(1) The Board must be provided with prior written notice of the installation or removal, or major upgrade that physically changes the operation of automated dispensing systems.
(2) Such notice must include, but is not limited to the:
    (A) name and address of the pharmacy;
    (B) location of the automated equipment;
    (C) identification of the pharmacist-in-charge; and
    (D) name of manufacturer and model of system;

(3) Along with such notice, submit a copy of the automated dispensing system quality assurance plan to the Board for review.

(4) The terminal act of automated dispensing must be to a licensed caregiver (nurse or practitioner not intended to include medication technician's or CMA's) in the hospital facility in no more than a 24-hour supply of medication that has been reviewed by a pharmacist.

[Source: Amended at 9 Ok Reg 2141, eff 6-11-92; Amended at 10 Ok Reg 3171, eff 6-25-93; Amended at 18 Ok Reg 2738, eff 7-1-01; Amended at 20 Ok Reg 2479, eff 1-1-04; Amended at 27 Ok Reg 2249, eff 7-11-10]

535:15-5-10.1. Labeling

Hospital pharmacies shall label drugs in the following manner:

(1) **For use inside the hospital facility**. All drugs dispensed by a hospital pharmacy to any department of the hospital system, intended for use within the facility, shall be adequately labeled.

(2) **For use outside the hospital facility**. All drugs dispensed by a hospital pharmacy whose patients are about to be discharged, or patients that receive emergency treatment, or to whom it is certain will take the drug dispensed outside of the facility, shall be labeled with the following information:

(A) Name and address of the hospital pharmacy,

(B) Date and identifying serial number,

(C) Name of the patient,

(D) Directions for use to the patient,

(E) Name of the prescribing practitioner,

(F) Initials of the dispensing pharmacist,

(G) Required precautionary information regarding controlled substances,

(H) Such other accessory or cautionary information as may be required or desirable for proper use and safety to the patient, and

(I) The name of the drug, its strength, and the number of units dispensed.

(3) **Drugs added to parenteral admixtures.** Whenever any drugs are added to parenteral solutions, whether within or outside the direct and personal supervision of a registered pharmacist, such admixtures shall be labeled with a distinctive supplementary label. This label shall indicate the name and amount of the drug added, date and time of such addition, expiration date and time of the admixture, and the initials of the persons (preparer and verifier) responsible for the admixture.

[Source: Added at 18 Ok Reg 2738, eff 7-1-01]

535:15-5-10.2. Physician's medication orders

The following rules apply to hospital pharmacies regarding practitioner (physician) medication orders:

(1) Drugs may be dispensed to specific patients only upon the written or verbal prescription or medication order of an authorized physician. A pharmacist or other authorized individual in a patient care area of the hospital facility must commit verbal orders to writing.

(A) **Authorization**. The appropriate hospital committee shall

designate the practitioners authorized to issue orders for hospital patients.

(B) **Requirements**. Orders for drugs for use by inpatients of the facility shall, at a minimum, contain the patient name and room number, drug name, strength, directions for use, any relevant stop date or time, order date, and the physician's signature. A direct copy or facsimile of the order is to be provided to the pharmacy from which the order is to be processed.

(2) Orders for drugs for outpatients shall be considered prescriptions and must fulfill all of the requirements of a prescription identified within the Pharmacy Practice Act of the State of Oklahoma and the rules of this Title.

[Source: Added at 18 Ok Reg 2738, eff 7-1-01]

535:15-5-11. Non-distributive roles of pharmacists

(a) Written policies and procedures of the Department of Pharmacy shall reflect the scope of non-distributive roles carried out by the pharmacists of the institution and be readily available for inspection by the Board.

(b) These policies shall include a description of the credentials and certifications required of pharmacists by the appropriate hospital committees.

(c) These policies shall include the process for pharmacist credentialing and/or certifying and must comply with state and federal regulation.

[Source: Amended at 18 Ok Reg 2738, eff 7-1-01]

535:15-5-12. Administration of drugs to patients

(a) **General provisions.** Drugs shall be administered at a hospital facility in accordance with the policies and procedures of that facility.

(b) **Self-administration.** Self-administration of drugs by patients shall be permitted only when specifically authorized by the prescribing physician, provided a pharmacist or physician has identified the drugs.

[Source: Amended at 18 Ok Reg 2738, eff 7-1-01]

535:15-5-13. Medications from other sources

(a) **Drugs from outside pharmacies.** Whenever drugs or pharmaceutical services are obtained from outside of a hospital facility, arrangements shall be made to insure that such outside pharmacies provide their services in a manner which assures the safety of the patients and properly serves the need of the hospital facility. Such arrangements shall be made in writing and shall at a minimum specify that:

(1) A pharmacist shall act in the capacity of a Director of Pharmacy, and therefore, shall be subject to these rules and regulations.

(2) A pharmacist shall provide on-call services at all times.

(3) The hospital will provide adequate storage facilities for these drugs.

(4) All drugs supplied shall be labeled so as to insure that recalls can be effected and that proper control and supervision of such drugs may be exercised. (Unit dose packaging is recommended).

(b) **Emergency sources of medications.** Procedures shall be made, in writing, for the hospital facility to obtain emergency items from a neighboring facility, retail

pharmacy, or other source of pharmaceuticals. (Unit dose packaging is recommended).
(c) **Medications from home.** Whenever patients bring drugs into a hospital facility, such drugs shall not be administered unless they can be precisely identified and the physician has specifically indicated on the patient chart that the patient is to take their own medication.
[Source: Amended at 18 Ok Reg 2738, eff 7-1-01]

535:15-5-14. Performance improvement
(a) **Purpose.** As a part of the hospital or health system's performance improvement program, the quality and appropriateness of patient care services provided by the Department of Pharmacy shall be monitored and evaluated through a planned and systematic approach to improving performance.
(b) **Responsibility.** The Director of Pharmacy is responsible for assuring that the process described in this Section is implemented to assure safe use of drugs for good patient outcomes.

(1) The Board recommends the Director of Pharmacy serve as a voting member of the hospital wide Performance Improvement Committee.

(2) The Board recommends the Director of Pharmacy assume a leadership role within the hospital or health system for the medication-use process performance improvement (including dispensing, administration, monitoring, prescribing, and education) across the continuum of care.

(3) The Director of Pharmacy shall work in collaboration with patients, prescribing practitioners, nurses, and other health care providers in improving the medication use process.

(c) **Measurement.** The pharmacy department shall have a systematic process in place to collect data and measure performance related to the medication-use process.
(d) **Assessment.** The Pharmacy Department shall assess data to identify ways to improve the medication-use process.
(e) **Performance improvement.** The Pharmacy Department shall monitor, achieve and sustain improved performance in the medication-use process towards safe drug use with good patient medication-use outcomes.
(f) **Documentation.** The process described in (a) through (e) of this Section is recorded and documented in a manner consistent with the facility's overall performance improvement program.
[Source: Amended at 18 Ok Reg 2738, eff 7-1-01]

535:15-5-15. Investigational drugs
(a) **Use within hospital.** Policies and procedures of the Department of Pharmacy shall reflect the use of investigational drugs within the hospital facility. The Director of Pharmacy shall maintain a list of investigational drug protocols and agents being used in the hospital readily available for review by the Board.
(b) **Approval for use.** The appropriate committee of the hospital shall approve all investigational drugs for use within a hospital.
(c) **Labeling and administration.** All investigational drugs shall be labeled in accordance with this Chapter with the drug's investigational status identified on the

label. In addition, the individual responsible for the administration of the drug must be provided with complete information regarding its use.
(d) **Storage.** Investigational drugs shall be stored in an area separated from approved pharmaceuticals and shall have the capacity to be locked and secured.
[**Source:** Amended at 18 Ok Reg 2738, eff 7-1-01]

535:15-5-16. Monthly inspections

The Director of Pharmacy, or his appropriate designee, shall conduct an inspection of all areas of the hospital on at least a monthly basis. This inspection shall include, but not be limited to, the following (see 535:15-5-10 for additional requirements):

(1) Drugs for internal use are stored separately from drugs and disinfectants for external use.
(2) Drugs requiring special storage conditions to insure their stability are properly stored.
(3) No outdated drugs are stocked in the facility.
(4) Distribution, administration, and wastage of controlled substances are properly and adequately documented and reported.
(5) Emergency drugs, designated pursuant to 535:15-5-8, are adequate and in proper supply.
(6) All necessary and required security and storage standards are met.
(7) Metric-apothecaries' weight and measure conversion tables and charts are reasonably available to all medical personnel.
(8) Policies and procedures of the Department of Pharmacy of the hospital facility are followed.

[**Source:** Amended at 9 Ok Reg 2141, eff 6-11-92; Amended at 18 Ok Reg 2738, eff 7-1-01]

535:15-5-17. Board of Pharmacy inspections

The Oklahoma Board of Pharmacy's qualified designee shall inspect all aspects of the management and operation of all hospital pharmacies in the State of Oklahoma, to verify compliance with the law, the rules of this Title, and such other standards as may be appropriate to insure that the health, safety and welfare of patients of the facility serviced by the pharmacy are protected. Any discrepancies or deficiencies shall be corrected.

535:15-5-18. Drug rooms

(a) A drug room, as defined in 535:15-5-2, shall comply with all federal, state and local rules for drug rooms.
(b) At a minimum there shall be a consultant pharmacist on duty as required by the rules of the Oklahoma State Department of Health.
(c) The drugs dispensed from a drug room shall be for administration only to patients in the facility hospital.
[**Source:** Added at 11 Ok Reg 3431, eff 6-27-94; Amended at 20 Ok Reg 2479, eff 1-1-04]

535:15-5-19. Remote medication order processing (RMOP)

(a) Hospitals, the pharmacist manager and the director of pharmacy at the hospital that allow remote medication order processing shall establish and maintain policies and procedures related to remote medication order processing.

(1) Such registrants remain responsible to assure the hospital pharmacy meets requirements under Oklahoma laws and rules.

(2) Such registrants shall be responsible to assure RMOP, if used, is reviewed at least annually and that proper credentialing, review and that oversight is established, maintained and exercised.

(b) Prior to implementation of RMOP services, training shall be provided by the hospital, and the relevant portions of the hospital pharmacy's policy and procedure manual shall be established and maintained on RMOP; and such shall be reviewed by the Pharmacist providing RMOP entry services at least annually.

(c) All pharmacists involved in RMOP entry services are responsible for ensuring the confidentiality, privacy and security of patient health care information. At a minimum, the following conditions must be met:

(1) Pharmacists performing RMOP entry must be licensed by the Board.

(2) Pharmacists performing RMOP entry must adhere to the hospital's confidentiality policy and are responsible for ensuring the confidentiality of patient information as described in 535:10-3-1-1(6) and 535:10-3-1-2.(14).

(3) The hospital shall ensure the pharmacist performing remote medication order processing has individual, pharmacist-specific access to the hospital pharmacy's patient information system and to other electronic systems that on-site pharmacists have access to during the hours of operation of the hospital pharmacy.

(d) The hospital will make available to the pharmacist(s) performing RMOP entry, access to either hard-copy or online references as described in 535:15-5-9(1)(B) and 535:15-5-9(1)(C).

(e) The hospital's computer system shall have the ability to audit the activities of each pharmacist(s) remotely processing the RMOP orders.

(f) A hospital pharmacy may allow RMOP for the patient population served under the hospital's pharmacy license by a pharmacist employed by the same licensed hospital pharmacy. Remote medication order processing performed for patients served under a different hospital pharmacy licensure requires a contractual arrangement fulfilling the responsibilities as outlined in 535:15-4-5.

(g) All Pharmacists who engage in RMOP shall ensure the following minimum information technology standards and specifications are met and maintained at the remote site:

(1) Availability of internet, phone, and scan or fax access to the hospital.

(2) Ability to access the hospital facility via the hospital's information system.

(3) To the extent possible, have redundant systems in place to ensure remote medication order processing service availability (e.g. internet connectivity, other information systems used to facilitate remote medication order processing.

(4) Have secure electronic access to the hospital's patient information system and to all other electronic systems that the on-site pharmacist has access to

when the pharmacy is open.(5) Use of a computer workstation e.g. with passwords, firewalls and encryption.

(h) The record of each patient-specific RMOP drug or device order processed pursuant to this rule shall identify, by name or other unique identifier, each pharmacist involved in the review and verification of the order.

(i) Remote medication order processing by a pharmacist shall not relieve the hospital pharmacy from employing or contracting with pharmacist(s) to provide routine pharmacy services within the facility. The activities authorized by this rule are intended to supplement hospital pharmacy services when the pharmacy is closed or additional pharmacist assistance is needed and are not intended to eliminate the need for an on-site hospital pharmacy or pharmacist(s).

(j) Pharmacists performing remote medication order processing shall not be included in the ratio of the pharmacist and technician as outlined in 535:15-5-7.2.(e).

(k) A pharmacist employed by or contracting with a hospital pharmacy for on-site services may also provide remote medication order processing services when the hospital pharmacy is closed or additional pharmacist assistance is needed through a remote medication order processing pharmacy.

[**Source:** Added at 27 Ok Reg 2256, eff 7-11-10]

SUBCHAPTER 6. HOSPITAL DRUG ROOM

Section

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[**Source:** Added at 20 Ok Reg 2482, eff 1-01-04; Amended 27 Ok Reg 2256, eff 7-11-2010]

535:15-6-1. Purpose

The rules of this Subchapter, as authorized under Title 59 O.S. Section 353.7 and 353.18(a) establish the rules for all hospital drug rooms. Compliance with these rules are the responsibility of the hospital drug room, the pharmacist in charge, and may be for pharmacists working in the drug room.

[**Source:** Added at 20 Ok Reg 2479, eff 1-1-04; Amended at 27 Ok Reg 2249, eff 7-11-10]

535:15-6-2. Definitions

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

"Adverse Drug Event" or **"ADE"** means an injury from a medicine or lack of an intended medicine.

"Authorized licensed independent practitioner" or **"ALI Practitioner"** or **"Licensed independent practitioner"** means an individual permitted by Oklahoma law and by the hospital to provide care and services, without direct supervision, within the scope of the individual's license and consistent with individually granted clinical privileges. Licensed independent practitioners may include physicians, advanced practice nurses with prescriptive authority, physician assistants, dentists, podiatrists, and optometrists.

"Contract employee" means any person who performs services or labor for a hospital, and whose compensation may or may not be reflected on the payroll records of a hospital. Examples of pharmacy contract employees are consultant D.Ph., relief D.Ph. and/or volunteer D.Ph.

"Drug room" or **"Hospital drug room"** means a secured room where drug inventories are maintained for use in a hospital, with less than 100 licensed beds including bassinets, licensed and regulated by the Oklahoma Health Department and by the Oklahoma State Board of Pharmacy.

"Drug room supervisor" means an Oklahoma registered nurse, licensed practical nurse, or registered pharmacist (D.Ph.) as described in OAC 310:667-21-2 (c).

"Pharmacist-in-Charge" or "PIC" means an Oklahoma licensed pharmacist director or consultant of the hospital drug room, either employed or a contract employee.

"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 or District of Columbia that is electronically linked to the hospital site via a computer for the purposes of remote medication order processing to a remote medication order processing pharmacy.

[**Source:** Added at 20 Ok Reg 2479, eff 1-1-04; Amended at 27 Ok Reg 2256, eff 7-11-10]

535:15-6-3. Registration

(a) All Oklahoma hospital drug rooms shall be licensed annually with the Board of Pharmacy at a fee set by the Board.

(b) A hospital drug room license shall be issued only to those drug rooms that satisfy and maintain compliance with the provisions of Title 59 O.S. Section 353.18 (a), OAC Title 535, 535:25 for rules regarding registrants, and the rules of this

Subchapter.
(c) Each drug room, in order to obtain and maintain a hospital drug room license shall have an Oklahoma D.Ph. as the PIC.
[Source: Added at 20 Ok Reg 2479, eff 1-1-04]

535:15-6-4. Staffing requirements
(a) The PIC shall be assisted by a sufficient number of additional pharmacists (D.Ph.s) to operate such a drug room competently, safely and adequately to meet the needs of the patients of the hospital facility.
(b) Each hospital drug room shall have oversight by a PIC who shall be responsible for certifying that the drug room meets the requirements of the Oklahoma Pharmacy Act and the rules of this Title. The PIC shall notify the Board, in writing, within 10 days of any change of employment.
(c) A drug room supervisor must be assigned as designated in the rules of the Oklahoma Department of Health under OAC 310:667-21-2(c) et seq.
[Source: Added at 20 Ok Reg 2479, eff 1-1-04; Amended at 26 Ok Reg 2274, eff 7-1-09]

535:15-6-5. Drug room and PIC responsibilities and duties
(a) **Responsibilities.** Responsibilities of the hospital drug room and PIC include drug purchasing, acquisition, preparation, distribution, monitoring, security, storage and control.

(1) **Written procedures.** The hospital drug room and PIC shall establish written procedures for the safe and efficient acquisition, distribution, and utilization of all medicine products with any of the Federal legends such as "RX only" and medications administered or distributed in the hospital system. A current copy of such procedures shall be available for review by the Board.
(2)**General Responsibility.** The hospital drug room and PIC shall be responsible for the safe and efficient monitoring, distribution, control, purchasing, acquisition and accountability of all drugs including but not limited to Federal legend drug products used in diagnostic procedures, I.V. fluids, or contained in supply kits excluding blood bank products and reagents controlled by the laboratory. The other professional staff of the hospital facility shall cooperate with the pharmacist in meeting this responsibility.
(3) **Confidentiality.** The hospital drug room and PIC shall have responsibility for establishing policies for the security and integrity of any patient information, confidential and non-confidential, and must abide by all relevant State and Federal regulations applicable to the hospital system.
(4) **Adverse Drug Events Program.** The hospital drug room and PIC shall develop and maintain a program to monitor the actual and potential adverse drug events including pharmacist interventions, medication errors, and adverse drug reactions for all medications utilized in the hospital to include system wide programs if an integrated system is involved. Records indicating the tracking, review, and outcome of the Adverse Drug Events shall be kept current and available for Board inspection.
(5) **Investigational drug programs.** The PIC shall establish a policy for investigational drug use.

(6) **Review of medication orders.** The PIC shall cause medication orders to be reviewed by a pharmacist in a timely manner.

(7) **Pharmacists Visits.** The hospital drug room and PIC shall cause and document a minimum of 52 routine in-house visits per year to be made to a hospital with a drug room as required by health department rule OAC 310:667-21-2(a) et seq.

(A) No more than 2 visits in any 7-day period shall be counted towards this minimum.

(B) Visits in any calendar month shall be no less than 2.

(C) The PIC shall submit a report outlining issues encountered and decisions made during visits. A copy of this report shall be available in the hospital drug room for inspection by the Board.

(D) A licensed hospital drug room employing a full-time pharmacist is not required to document the 52 routine in-house visits since daily work is done, interventions are documented, and audit systems are maintained.

(8) **Pharmacy and Therapeutics (P&T) Committee.** The PIC shall be a participating member in the Pharmacy and Therapeutics Committee.

(9) **Effective Controls.** The hospital drug room and 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.

(b) **Duties.** The duties of a PIC in a licensed hospital drug room, at a minimum, shall be the following:

(1) The training duties of the PIC are:

(A) Competency training regarding preparation and sterilization of parenteral medications prepared by appropriate hospital staff;

(B Competency training of personnel concerning medicine incompatibilities and providing incompatibility information; and

(C) Training personnel in confidentiality of protected health and proprietary information and regarding the compliance with all federal and state laws and regulations applicable to the hospital drug room.

(i) Such rules regarding confidentiality of patient records are described in 535:15-3-14(e), the federal HIPAA regulations; and,

(ii) Such responsibilities for confidentiality shall be as set forth in 535:10-3-1.1 (a) (6) and 535:10-3-1.2 (a) (14) and the rules of this Title.

(D) Conducting initial and continuing competency training of all drug room personnel.

(2) Repackaging drug products including unit dose.

(3) Establishing procedures for procurement of all medicines used within the hospital system subject to approval of the medical and professional staff.

(4) Participating in the development and maintenance of a formulary for use within the hospital system.

(5) Maintaining and making available a sufficient inventory of medicines including antidotes and other emergency drugs approved by the medical and professional staff, for use within the hospital facility. In addition, current references, antidote information, and telephone numbers of regional reference centers such as Poison Centers and Drug Information Centers shall be maintained and readily available throughout the hospital.

(6) Maintaining oversight of the records of all transactions of the drug room required by applicable local, state, and federal law, and necessary to maintain accurate control and accountability for all medications.

(7) Participating in those aspects of the hospital facility's patient care evaluation programs that relate to medicine utilization and effectiveness.

(8) Cooperating fully with teaching and/or research programs in the hospital facility, if any.

(9) Implementing the policies and decisions of the appropriate committees of the medical and professional staff that deal with drug distribution.

(10) Meeting all inspection and other requirements of the Oklahoma Pharmacy Act, and those rules and regulations governing the practice of pharmacy within a hospital facility.

(11) Establishing guidelines for the safe and effective distribution of medicines intended for floor stock, and their subsequent administration.

[**Source:** Added at 20 Ok Reg 2479, eff 1-1-04; Amended at 27 Ok Reg 2249, eff 7-11-10]

535:15-6-6. Physical and library requirements

A hospital drug room shall have sufficient facilities to insure that drugs are prepared in sanitary, well-lighted and enclosed places, and which meet the other requirements of this Chapter.

(1) **Equipment and materials.** Each hospital drug room shall have sufficient equipment and physical facilities for proper compounding, dispensing and storage of drugs.

(A) For parenteral preparations:

(i) If a laminar hood is used, a hospital drug room shall comply with 535:15-9-6 and 535:15-9-10, 1 through 5.

(ii) If a laminar hood is not used, a closed system for parenteral admixtures should be utilized. If parenteral compounding must be done, an area must be designated for that activity. This area must be at least a counter used for only this purpose and be away from patient care areas. Acceptable aseptic techniques shall be used.

(B) A library shall be maintained which includes four of the following current references (not more than 2 years old or most recent). Current electronic sources may be substituted for two hard copy information sources:

(i) Drug interactions;

(ii) Drug compatibility;

(iii) Poison and antidote information;

(iv) Toxicology;

(v) Pharmacology;

(vi) Microbiology;
(vii) Patient counseling;
(viii) Rational therapy;
(ix) Dispensing information; and,
(x) U.S.P.

(C) The library shall include the latest copy of Oklahoma State Laws and Rules Pertaining to the Practice of Pharmacy and a recent copy of Oklahoma State Bureau of Narcotics & Dangerous Drugs Control Rules.

(2) **Storage.** All drugs bearing a federal legend such as "RX Only" and medications administered in the hospital shall be stored in designated areas within the hospital which are sufficient to insure proper sanitation, temperature, light, ventilation, moisture control, segregation and security. The storage shall be as directed by the PIC and shall remain under the supervision of such pharmacist.

(3) **Alcohol and flammables.** Alcohol and flammables shall be stored in areas that shall, at a minimum, meet basic local building code requirements for the storage of volatiles and such other laws, ordinances or regulations as may apply.

(4) **Unattended areas.** In the absence of authorized personnel in a hospital medication area, such area shall be locked.

(5) **Security**. All areas occupied by a hospital drug room shall be capable of being locked by key or combination to prevent access by unauthorized personnel.

[Source: Added at 20 Ok Reg 2479, eff 1-1-04: Amended at 22 Ok Reg 2172; eff 7-1-05]

535:15-6-7. Drug distribution and control

(a) **General**. The PIC shall establish written procedures for the safe and efficient distribution of medicine products. A copy of such procedures shall be on hand for inspection by the Board.

(b) **Responsibility.** The PIC shall be responsible for the safe and efficient distribution, control, and accountability of drugs. The other professional staff of the hospital facility shall cooperate with the PIC in meeting this responsibility. The PIC shall be responsible for, at a minimum, the following:

(1) Competency education and training of nursing personnel concerning admixture of parenteral products, and incompatibility and provision of proper incompatibility information.

(2) Prepackaging and/or preparing of drug products including certification of unit dose.

(3) Establishing of specifications for procurement of all materials, including drugs, chemicals, and biologicals used within the hospital system, subject to approval of the appropriate committee of the hospital system.

(4) Participating in the development and maintenance of a formulary for use within the hospital facility.

(5) Maintaining and making available a sufficient inventory of medicines, including antidotes and other emergency drugs, for use within the hospital facility. In addition, current references, antidote information, and telephone

numbers of regional reference centers such as Poison Centers and Drug Information Centers shall be maintained and readily available throughout the hospital.

(6) Reviewing records of all transactions of the hospital drug room required by applicable local, state, and federal law, necessary to maintain accurate control and accountability for all medicine materials.

(7) Participating in those aspects of the hospital facility's patient care evaluation programs that relate to drug utilization and effectiveness.

(8) Developing a mechanism to implement the policies and decisions of the appropriate committees of the hospital that deal with drug distribution and drug utilization.

(9) Meeting all inspection and other requirements of the Oklahoma Pharmacy Act, and those rules and regulations applying to hospital drug rooms.

(10) Establishing floor stock guidelines for the safe and effective distribution of drugs intended for floor stock, and their subsequent administration.

(11) Fully cooperating with teaching and/or research programs in the hospital facility, if any.

(12) Prepackaging medications included in the hospital drug room formulary in 535:15-6-9.

(c) **Labeling.** Hospital drug room labeling requirements shall be as follows:

(1) **Labeling for use inside the hospital facility**. All drugs outside of the drug room intended for use within the facility shall be adequately labeled by the pharmacist or in their original container.

(2) **Labeling for use outside the hospital facility**. All drugs labeled by the pharmacist or licensed practitioner for after hours dispensing to discharged or emergency room patients shall be labeled with the following:

(A) Name and address of the hospital facility,

(B) Date and identifying number,

(C) Name of the patient,

(D) Directions for use to the patient,

(E) Name of the prescribing practitioner,

(F) Initials of the dispenser,

(G) Required precautionary information regarding controlled substances,

(H) Such other accessory or cautionary information as may be required or desirable for proper use and safety to the patient, and

(I) The name of the drug, its strength, and the number of units dispensed.

(3) **Drugs added to parenteral admixtures**. Whenever any drugs are added to parenteral solutions, whether within or outside the direct and personal supervision of a pharmacist (D.Ph.), such admixtures shall be labeled with a distinctive supplementary label indicating the name and amount of the drug added, date and time of such addition, expiration date and time of admixture, and the initials of the persons (preparer and the verifier) responsible for the admixture.

(d) **Discontinued and outdated drugs.** The PIC shall develop and implement policies and procedures to insure that discontinued and outdated drugs, and containers with worn, illegible or missing labels are returned to the drug room for

proper disposition.

(e) **Practitioner's orders.** Hospital drug room requirement regarding practitioner's orders shall be as follows:

(1) Drugs may be dispensed to specific patients only upon the written or verbal order of an authorized practitioner. A pharmacist or other authorized individual in a patient care area of the hospital facility must commit verbal ALI practitioner's orders to writing.

(A) **Authorization.** The appropriate hospital committee shall designate those ALI practitioners authorized to issue and accept orders for hospital patients.

(B) **Requirements**. Orders for drugs for use by inpatients of the facility shall, at a minimum, contain the patient name and room number, drug name, strength, directions for use, any relevant stop date or time, order date and time, and ALI practitioner's signature. A direct copy or facsimile of the order is to be provided to the drug room from which the order is to be processed.

(2) Orders for drugs for outpatients shall be considered prescriptions and must fulfill all of the requirements of a prescription identified within the Pharmacy Practice Act; and state and federal law and rules.

(f) **Controlled drug accountability.** The hospital facility shall establish effective written procedures and maintain adequate records as required by law and rule regarding the use and accountability of controlled substances and such other drugs as the hospital may designate.

(g) **Drug recall procedures.** The PIC shall develop and implement a written recall procedure that can be readily activated which assures that drugs involved, inside or outside the facility, are returned to the hospital drug room for proper disposition. All actions taken in this area are to be properly documented.

(h) **Records and reports**. The PIC shall develop a mechanism for maintaining and submitting as appropriate, such records and reports as are required to insure patient health, safety, and welfare. These should include the following:

(1) Adverse drug reaction reports,

(2) Floor stock inventories of night cabinets and emergency boxes,

(3) Drug list or formulary of the hospital drug room as required by state health department rules,

(4) Controlled substance inventory,

(5) Ethyl alcohol inventory,

(6) Pharmacy and therapeutics committee minutes; and

(7) Reports and records as may be required by law, and the rules of this chapter.

[Source: Added at 20 Ok Reg 2482, eff 1-1-04]

535:15-6-8. Emergency dispensing and pre-packaged medications

(a) **Emergency dispensing.** A pharmacist or ALI practitioner on duty may label and dispense an appropriate supply of a medication from the hospital drug room when ordered by an ALI practitioner for a patient of the hospital to take with them when dismissed. An appropriate supply would include only sufficient doses required from the time of dismissal until resumption of normal business hours of local pharmacies.

(b) **Pre-packaged medications.** A pharmacist may pre-package medications in sufficient amounts to meet the immediate needs of patients of the hospital. The pre-dispensed medications must be labeled and packaged properly as required under sub-section 535:15-6-7 (c) Labeling, excepting items B, C, D, and E, and adding the medication expiration date and lot number. Such pre-packaged medications shall be securely stored, and an accurate accounting of their use shall be kept.

(1) When such medications are ordered by an ALI practitioner, to be used after dismissal from the hospital, the prescribing ALI practitioner [with dispensing privileges] shall complete the medication label with the appropriate information including the patient's name, the ALI practitioner's name, appropriate directions for use, the date the medication is distributed to the patient, and an identifying number.

(2) The ALI practitioner who orders the medication shall be responsible for appropriate patient counseling and drug information dissemination.

[Source: Added at 20 Ok Reg 2482, eff 1-1-04]

535:15-6-9 Emergency room pre-packaged medications formulary

(a) Each hospital drug room may choose the medicines to be included in their emergency room (ER) pre-packaged medications formulary within the requirements and limits listed below. This formulary shall be included within the policies and procedures of the hospital drug room. These pre-packaged medications shall be administered only as allowed in 535:15-6-8 for a maximum of a 72-hour supply.

(b) Type of Medication defined or parameters for choice		[Limits]
(1) Controlled Dangerous Substances (CDS):		
(A)Hydrocodone / acetaminophen combination		[one]
(B)Codeine/acetaminophen combination		[one]
(C)Propoxyphene/acetaminophen combination		[one]
(D)Hydrocodone containing antitussive preparation		[one]
(2) ACE inhibitor:	per ER formulary	[two]
(3) Anti-nausea:	per ER formulary	[two]
(4) Anti-viral:	per ER formulary	[two]
(5) Anti-coagulant:	per ER formulary	[two]
(6) Antihistamine:	per ER formulary	[two]
(7) Anti-hypertensive:	per ER formulary	[three]
(8) Antimicrobial:	per ER formulary	[unlimited]
(9) Asthma:	per ER formulary	[one]
(10) Beta blocker:	per ER formulary	[two]
(11) Diuretic:	per ER formulary	[two]
(12) Ear: antibiotic/steroid or antibiotic/ steroid/pain combination		
(13) Eye: antibiotic or antibiotic/steroid combination		
(14) Miscellaneous:		
(A) terbutaline		
(B) oral contrast media		
(15) Muscle relaxant:	per ER formulary	[two non-CDS]
(16) Pain:	per ER formulary	[two non-CDS]
(17) Proton pump inhibitor	per ER formulary	[one]

(18) Steroid: per ER formulary [three]

[Source: Added at 20 Ok Reg 2482, eff 1-1-04; Amended at 24 Ok Reg 2261, eff 7-1-07]

535:15-6-10. Access to drugs in absence of PIC or drug room supervisor

(a) **Absence of the PIC or the drug room supervisor.** During such times as the drug room may be unattended, advance arrangements shall be made for provision of drugs to the medical staff and other authorized personnel of the hospital facility by use of night cabinets and in emergency circumstances, by access to the drug room by authorized personnel.

(b) **Night cabinets**. IF NIGHT CABINETS ARE USED THE FOLLOWING SHOULD PREVAIL:

(1) In the absence of a pharmacist (D.Ph.), a supply of controlled dangerous substances may be kept in locked cabinet(s) or other enclosure(s) constructed and located outside of the hospital drug room area, to which only specifically authorized personnel may obtain access by key or combination, and which is sufficiently secure to deny access to an unauthorized person by force or otherwise.

(2) The PIC shall, in conjunction with the appropriate committee of the hospital facility, develop inventory listings of those drugs to be included in such cabinet(s) and shall insure that:

(A) Such drugs, available therein, are properly labeled;

(B) Only prepackaged drugs are available therein, in amounts sufficient for immediate therapeutic requirements;

(C) Whenever access to such cabinet(s) shall have been gained, written ALI practitioner's orders and proofs of use, if applicable, are provided;

(D) A method of documenting responsibility for the key(s) at all times, and their transfer from one authorized person to another, is established;

(E) All drugs therein are monitored weekly, and discrepancies are reported in the PIC's report.

(F) A complete review of all activity concerning such cabinet(s) is conducted no less than once per month; and,

(G) Written policies and procedures are established to implement the requirements of this paragraph.

(c) **Access to drug room.** Whenever any drug is not available from floor supplies or night cabinets, and such drug is required to treat the immediate needs of a patient whose health would otherwise be jeopardized, such drug may be obtained from the drug room in accordance with the requirements of this paragraph.

(1) One supervisory registered professional nurse and only one in any given shift is responsible for removing drugs from the hospital drug room. The responsible nurse may, in time of emergency, delegate this duty to another nurse.

(2) The responsible nurse shall, prior to being permitted to obtain access to the drug room, be designated by position in writing by the appropriate committee of the hospital facility; and shall receive thorough education and training in the proper methods of access, removal of drugs, and records and

procedures required from the PIC.

(3) Such education and training shall be given by the PIC.

(4) The PIC shall require, at a minimum, the following records and procedures:

(A) The removal of any drug from the hospital drug room by an authorized licensed nurse must be recorded on a suitable record showing patient name, room number, name of drug, strength, amount, date, time and signature of nurse; and

(B) The drug room supervisor or the pharmacist shall properly and promptly check such record.

[Source: Added at 20 Ok Reg 2482, eff 1-1-04]

535:15-6-11. Administration of drugs to patients

(a) **General provisions**. Drugs shall be administered at a hospital facility in accordance with the policies and procedures of that facility.

(b) **Self-Administration**. Self-administration of drugs by patients shall be permitted per hospital policy only when specifically authorized by the prescribing ALI practitioner per hospital policy, provided the drugs to be self-administered have been identified by a licensed pharmacist or ALI practitioner.

(c) **Administration only.** The drugs supplied or provided from a drug room shall be for administration only to patients of the hospital. No drugs may be provided to employees nor to individuals who are not patients of the hospital.

[Source: Added at 20 Ok Reg 2482, eff 1-1-04; Amended at 26 Ok Reg 2274, eff 7-1-09]

535:15-6-12. Medication from other sources

(a) **Drugs from outside sources**. Whenever drugs or pharmaceutical services are obtained from outside of the hospital facility on a regular basis, arrangements shall be made to insure that such outside pharmacists provide their services in a manner that assures the safety of the patients and properly serves the need of the hospital drug room. Such arrangements shall be made in writing and shall at a minimum specify that:

(1) A pharmacist shall act in the capacity of a PIC, and therefore, shall be subject to these rules and regulations.

(2) A pharmacist shall provide on-call services at all times.

(3) The hospital drug room shall provide adequate storage facilities for such drugs.

(4) All drugs supplied shall be labeled so as to insure that recalls can be affected and that proper control and supervision of such drugs may be exercised. (Unit dose packaging is recommended.)

(b) **Emergency sources of medications**. Procedures shall be made, in writing, for the hospital facility to obtain emergency medications from a neighboring facility, retail pharmacy, or other source of drugs. (Unit dose packaging is recommended.)

(c) **Medications from home**. Whenever patients bring drugs into a hospital facility, such drugs shall not be administered unless they can be precisely identified and the licensed prescribing practitioner has specifically indicated on the patient chart that the patient is to receive their own medications.

[Source: Added at 20 Ok Reg 2479, eff 1-1-04]

535:15-6-13. Investigational drugs

(a) **Use within hospital.** Policies and procedures of the drug room shall reflect the use of investigational drugs within the hospital facility.

(b) **Approval for use.** The appropriate committee of the hospital shall approve all investigational drugs for use within a hospital.

(c) **Labeling and administration information.** All investigational drugs shall be labeled in accordance with this Subchapter with the drug's investigational status identified on the label. In addition, the individual responsible for the administration of the drug must be provided with complete information regarding its use.

(d) **Storage.** Investigational drugs shall be stored in an area separated from approved pharmaceuticals and shall be secured.

[Source: Added at 20 Ok Reg 2479, eff 1-1-04]

535:15-6-14. Drug storage stock inspections

(a) The PIC or his appropriate designee, shall conduct an inspection of all drug storage areas within the hospital on at least a monthly basis.

(b) This monthly drug storage area stock inspection shall verify at least the following (see 535:15-6-5 (a) for additional requirements):

(1) Drugs for internal use are stored separately from drugs and disinfectants for external use.

(2) Drugs requiring special storage conditions to insure their stability are properly stored.

(3) No outdated drugs are stocked in the facility and are removed from the facility not more than 6 months after the expiration date.

(4) Distribution and administration of controlled substances are properly and adequately documented and reported.

(5) Emergency drugs are adequate and in proper supply.

(6) All necessary and required security and storage standards are met.

(7) Metric-apothecaries' weight and measure conversion tables and charts are reasonably available to all medical personnel.

(8) Policies and procedures of the hospital drug room are followed.

[Source: Added at 20 Ok Reg 2479, eff 1-1-04]

535:15-6-15. Non-distributive roles of pharmacists

The policies and procedures of the hospital drug room shall reflect the scope of non-distributive roles carried out by the pharmacist of the hospital system.

[Source: Added at 20 Ok Reg 2479, eff 1-1-04]

535:15-6-16. Performance improvement

(a) **Purpose.** As a part of the hospital or health system's performance improvement program, the quality and appropriateness of patient care services provided by the drug room shall be monitored and evaluated through a planned and systematic approach to improving performance.

(b) **Responsibility.** The PIC is responsible for assuring that the process described in this section is implemented to assure safe use of drugs for good patient outcomes.

(1) The Board recommends the PIC serve as a voting member of the hospital wide Performance Improvement Committee.
(2) The Board recommends the PIC assume a leadership role within the hospital or health system for the medication-use process performance improvement (including dispensing, administration, monitoring, prescribing, and education) across the continuum of care.
(3) The PIC shall work in collaboration with patients, prescribing practitioners, nurses, and other health care providers in improving the medication use process.

(c) **Measurement.** The drug room shall have a systematic process in place to collect data and measure performance related to the medication-use process.
(d) **Assessment.** The drug room shall assess data to identify ways to improve the medication-use process.
(e) **Performance improvement.** The drug room shall achieve and sustain improved performance in the medication-use process.
(f) **Documentation.** The process described in (a) through (e) of this Section is recorded and documented in a manner consistent with the facility's overall performance improvement plan.
[Source: Added at 20 Ok Reg 2479 eff 1-1-04]

535:15-6-17. Board of Pharmacy inspections

(a) The Oklahoma State Board of Pharmacy's qualified designee shall inspect all aspects of the management and operation of all hospital drug rooms in the state of Oklahoma, to verify compliance with the law, the rules of this Title, and such other standards as may be appropriate to insure that the health, safety and welfare of patients of the facility serviced by the hospital drug room are protected.
(b) Any discrepancies or deficiencies noted at inspection shall be corrected.
[Source: Added at 20 Ok Reg 2479, eff 1-1-04]

535:15-6-18. Drug room training area

(a) A licensed hospital drug room may apply for a training area certificate after meeting the requirement in 535:10-5 and 535:25.
(b) If approved by the Board, such training area certificate enables the drug room to serve as a licensed training area so long as a qualified pharmacist preceptor is present and supervising each intern working in the drug room, as required in 535:10-5.
(c) Each drug room training area, pharmacist preceptor and intern shall meet requirements in 535:10-5.
[Source: Added at 20 Ok Reg 2479,eff 1-1-04]

535:15-6-19. Violations

(a) Unlawful acts are described in the Oklahoma Pharmacy Act.
(b) Hospital drug room rules of conduct, violations of rules of conduct, and rules for all applicants are found in 535:25.
(c) Rules of conduct and violations of rules of conduct for PIC are found in 535:10-3.
(d) Penalties for violations of this Title, the Oklahoma Pharmacy Act and federal and state laws and rules are listed in Title 59 O.S. Section 353.26.
[Source: Added at 20 Ok Reg 2479, eff 1-1-04]

535:15-6-20. Remote medication order processing

(a) Hospitals, the pharmacist manager and the director of pharmacy at the hospital that allow remote medication order processing shall establish and maintain policies and procedures related to remote medication order processing. Such registrants remain responsible to assure the hospital drug room meets requirements under Oklahoma laws and rules.

(1) Such registrants remain responsible to assure the hospital drug room meets requirements under Oklahoma laws and rules.

(2) Such registrants shall be responsible to assure RMOP, if used, is reviewed at least annually and that proper credentialing, review and that oversight is established, maintained and exercised.

(b) Prior to implementation of RMOP services, training shall be provided by the hospital drug room and the relevant portions of the hospital drug room's policy and procedure manual on RMOP entry shall be established and maintained; and reviewed by the Pharmacist providing RMOP entry services at least annually.

(c) All pharmacists involved in RMOP entry services are responsible for ensuring the confidentiality, privacy and security of patient health care information. At a minimum, the following conditions must be met:

(1) Pharmacists performing RMOP entry must be licensed by the Board.

(2) Pharmacists performing RMOP entry must adhere to the hospital's confidentiality policy and are responsible for ensuring the confidentiality of patient information as described in 535:10-3-1-1(6) and 535:10-3-1-2.(14).

(3) The hospital shall ensure the pharmacist performing remote medication order processing has individual, pharmacist-specific access to the hospital drug room's patient information system and to other electronic systems that on-site pharmacists have access to during the hours of operation of the hospital drug room.

(d) The hospital will make available to the pharmacist(s) performing RMOP entry, access to either hard-copy or online references as described in 535:15-5-9(1)(B) and 535:15-5-9(1)(C).

(e) The hospital's computer system shall have the ability to audit the activities of the pharmacist(s) remotely processing RMOP orders.

(f) A hospital drug room may allow RMOP for the patient population served under the hospital's drug room license by a pharmacist employed by the same licensed hospital drug room. Remote medication order processing performed for patients served under a different hospital drug room licensure requires a contractual arrangement fulfilling the responsibilities as outlined in 535:15-4-5.

(g) All Pharmacists who engage in RMOP shall ensure the following minimum information technology standards and specifications are met and maintained at the remote site:

(1) Availability of internet, phone, and scan or fax access to the hospital.

(2) Ability to access the hospital facility via the hospital's information system.

(3) To the extent possible, have redundant systems in place to ensure remote medication order processing service availability (e.g. internet connectivity, other information systems used to facilitate remote medication order processing).

(4) Have secure electronic access to the hospital's patient information system and to all other electronic systems that the on-site pharmacist has access to when the pharmacy is open.

(5) Use of a computer workstation e.g. with passwords, firewalls, and encryption.

(h) The record of each patient-specific RMOP drug or device order processed pursuant to this rule shall identify, by name or other unique identifier, each pharmacist involved in the review and verification of the order.

(i) Remote medication order processing by a pharmacist shall not relieve the hospital drug room from employing or contracting with pharmacist(s) to provide routine pharmacy services within the facility. The activities authorized by this rule are intended to supplement hospital drug room services when the pharmacy is closed or additional pharmacist assistance is needed and are not intended to eliminate the need for an on-site hospital drug room or pharmacist(s).

(j) Pharmacists performing remote medication order processing shall not be included in the ratio of the pharmacist and technician as outlined in 535:15-5-7.2.(e).

(k) A pharmacist employed by or contracting with a hospital drug room for on-site services from also providing remote medication order processing services when the hospital drug room is closed or additional pharmacist assistance is needed through a remote medication order processing pharmacy.

[**Source:** Added at 27 Ok Reg 2256, eff 7-11-10]

SUBCHAPTER 7. DRUG SUPPLIER PERMITS

Section
535:15-7-1. Definitions
535:15-7-2. Drug supplier requirements

535:15-7-1. Definitions

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

"Drug supplier" means a licensed retail pharmacy which supplies legend drugs to licensed practitioners for their office administration and/or which supplies legend drugs to hospitals and other licensed pharmacies for their dispensing.

"Legend drugs" means including, but not limited to, drugs, medicines, poisons, and/or chemicals (as defined in Title 59 O.S., Section 353 et seq.) which bear the legend "Caution: Federal Law Prohibits Dispensing Without Prescription" or "RX Only", or any other label FDA may require which restricts drugs to dispensing with a practitioner's prescription.

"Licensed practitioner" means a physician, dentist, podiatrist, osteopathic physician, veterinarian, or optometrist licensed by law to prescribe and administer within the scope of their practice.

[**Source:** Amended at 11 Ok Reg 3431, eff 6-27-94; Amended at 17 Ok Reg 2626, eff 7-1-00]

535:15-7-2. Drug supplier requirements

(a) **Permit eligibility.** In order to obtain and maintain a drug supplier permit, the applicant must have a valid retail pharmacy license

(b) **Total annual sales.** The total annual sales of the drug supplier shall not exceed

Chapter 689 — Pharmacists; Drug Outlets; Drug Sales

ORS sections in this chapter were amended or repealed by the Legislative Assembly during its 2012 regular session. See the table of ORS sections amended or repealed during the 2012 regular session: 2012 A&R Tables

New sections of law were adopted by the Legislative Assembly during its 2012 regular session and are likely to be compiled in this ORS chapter. See sections in the following 2012 Oregon Laws chapters: 2012 Session Laws 0043

2011 EDITION

PHARMACISTS; DRUG OUTLETS; DRUG SALES

OCCUPATIONS AND PROFESSIONS

STATE BOARD OF PHARMACY

689.151 Board control over licensing, standards and discipline. The State Board of Pharmacy shall be responsible for the control and regulation of the practice of pharmacy in this state including, but not limited to, the following:

(1) The licensing by examination or by reciprocity of applicants who are qualified to engage in the practice of pharmacy under the provisions of this chapter;

(2) The renewal of licenses to engage in the practice of pharmacy;

(3) The determination and issuance of standards based on nationally recognized standards of practice and accreditation criteria for recognition and approval of schools and colleges of pharmacy whose graduates shall be eligible for licensure in this state, and the specification and enforcement of requirements for practical training, including internship;

(4) The enforcement of those provisions of this chapter relating to the conduct or competence of pharmacists practicing in this state, and the suspension, revocation or restriction of licenses to engage in the practice of pharmacy;

(5) The training, qualifications and employment of pharmacy interns; and

(6) The licensing of pharmacy technicians. [Formerly 689.245; 2001 c.595 §1; 2005 c.313 §10]

MISCELLANEOUS

689.605 Power to dispense drugs from hospital pharmacies, drug rooms and penal institutions; rules. (1) In a hospital or long term care facility having a pharmacy and employing a pharmacist, the pharmacy and pharmacist are subject to the requirements of this chapter, except that in a hospital when a pharmacist is not in attendance, pursuant to standing orders of the pharmacist, a registered nurse supervisor on the written order of a person authorized to prescribe a drug may withdraw such drug in such volume or amount as needed for administration to or treatment of an inpatient or outpatient until regular pharmacy services are available in accordance with the rules adopted by the board. However, the State Board of Pharmacy may grant an exception to the requirement for a written order by issuing a special permit authorizing

the registered nurse supervisor in a hospital to dispense medication on the oral order of a person authorized to prescribe a drug. An inpatient care facility which does not have a pharmacy must have a drug room. In an inpatient care facility having a drug room as may be authorized by rule of the Department of Human Services or the Oregon Health Authority, the drug room is not subject to the requirements of this chapter relating to pharmacies. However, a drug room must be supervised by a pharmacist and is subject to the rules of the State Board of Pharmacy. When a pharmacist is not in attendance, any person authorized by the prescriber or by the pharmacist on written order may withdraw such drug in such volume or amount as needed for administration to or treatment of a patient, entering such withdrawal in the record of the responsible pharmacist.

(2) In a hospital having a drug room, any drug may be withdrawn from storage in the drug room by a registered nurse supervisor on the written order of a licensed practitioner in such volume or amount as needed for administration to and treatment of an inpatient or outpatient in the manner set forth in subsection (1) of this section and within the authorized scope of practice.

(3) A hospital having a drug room shall cause accurate and complete records to be kept of the receipt, withdrawal from stock and use or other disposal of all legend drugs stored in the drug room. Such record shall be open to inspection by agents of the board and other qualified authorities.

(4) In an inpatient care facility other than a hospital, the drug room shall contain only prescribed drugs already prepared for patients therein and such emergency drug supply as may be authorized by rule by the Department of Human Services.

(5) The requirements of this section shall not apply to facilities described in ORS 441.065.

(6) A registered nurse who is an employee of a local health department established under the authority of a county or district board of health and registered by the board under ORS 689.305 may, pursuant to the order of a person authorized to prescribe a drug or device, dispense a drug or device to a client of the local health department for purposes of caries prevention, birth control or prevention or treatment of a communicable disease. Such dispensing shall be subject to rules jointly adopted by the board and the Oregon Health Authority.

(7) The board shall adopt rules authorizing a pharmacist to delegate to a registered nurse the authority to withdraw prescription drugs from a manufacturer’s labeled container for administration to persons confined in penal institutions including, but not limited to, adult and juvenile correctional facilities. A penal institution, in consultation with a pharmacist, shall develop policies and procedures regarding medication management, procurement and distribution. A pharmacist shall monitor a penal institution for compliance with the policies and procedures and shall perform drug utilization reviews. The penal institution shall submit to the board for approval a written agreement between the pharmacist and the penal institution regarding medication policies and procedures. [1979 c.777 §38; 1979 c.785 §9d; 1985 c.565 §113; 1989 c.526 §1; 1993 c.272 §2; 1993 c.571 §16; 1995 c.523 §3; 2003 c.617 §2; 2009 c.595 §1103]

The Oregon Administrative Rules contain OARs filed through April 13, 2012

BOARD OF PHARMACY

DIVISION 41

OPERATION OF PHARMACIES (RETAIL AND INSTITUTIONAL DRUG OUTLETS) CONSULTING PHARMACISTS AND OPERATION OF DRUG ROOMS

855-041-0005

Pharmacy Registration (Both Retail and Institutional Drug Outlets)

(1) Pharmacies shall be registered as either retail drug outlets or institutional drug outlets or both.

(2) An application for registration of a new pharmacy shall be accompanied by a floor plan drawn to scale and shall be approved by the Board prior to opening.

(3) The application shall specify the location of the pharmacy and shall indicate the owner, trustee, receiver, or other person applying for the registration. When an applicant is not the owner of the pharmacy, the application shall indicate the owner and the applicant's affiliation with the owner:

(a) If the owner is a partnership or other multiple owner, the names of the partners or persons holding the five largest interests shall be indicated on the application;

(b) If the owner is a corporation, the name filed shall be the same as filed with the Corporation Commissioner. The name of the corporation, the names of the corporation officers and the names of the stockholders who own the five largest interests shall be indicated on the application.

(4) Upon request by the Board, the applicant shall furnish such information as required by the Board regarding the partners, stockholders, or other persons not named in the application.

(5) The application shall also identify any person who has incidents of ownership in the pharmacy who also has financial interest in any long-term care facility as defined in ORS 442.015.

(6) A certificate of registration will be issued upon Board approval of the application.

(7) All registration renewal applications shall be accompanied by the annual fee and shall contain the same information required in sections (3) and (4) of this rule.

(8) The initial and annual registration fee for pharmacies is set out in division 110 of this chapter.

(9) Pharmacy registration expires March 31, annually. If the annual registration fee referred to in section (7) of this rule is not paid by March 31 of the current year, a delinquent fee as set out in division 110 of this chapter shall be included with the application for registration renewal.

(10) The registration is not transferable and the registration fee cannot be prorated.

(11) A change of ownership requires the approval of the Board and new certificate of registration. Application shall be on a form supplied by the Board.

(12) A change of ownership includes any change in the legal form of the business including additions or deletions of partners.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.151, 689.155, 689.508
Hist.: 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; BP 2-2008, f. & cert. ef. 2-20-08

855-041-0095

Pharmacy Depots

(1) Except when delivering directly to a patient, licensed pharmacists may not participate in the transfer of completed prescription medication containers to or from any location that is not a licensed pharmacy, unless the transfer occurs to:

(a) The home or office of the patient's health care practitioner;

(b) The location of the patient; or location designated by the patient; or

(c) At the hospital or medical care facility in which a patient is receiving care.

(2) Upon written request, the Board may waive any of the requirements of this rule if a waiver will further public health or safety or the health and safety of a patient. A waiver granted under this section shall only be effective when it is issued by the Board in writing.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; BP 9-2011, f. 12-30-11, cert. ef. 1-1-12

855-041-0103

Confidentiality

(1) No licensee or registrant of the Board who obtains any patient information shall disclose that information to a third party without the consent of the patient.

(2) Section (1) of this rule does not apply to:

(a) Any disclosure made to the Board;

(b) Any disclosure made to a practitioner or to another pharmacist when the pharmacist reasonably believes that disclosing such information is necessary to protect the patient's health or well being; or

(c) To a third party when disclosure is otherwise authorized or required by law.

Stat. Auth.: ORS 689.155 & 689.205
Stats. Implemented:
Hist.: PB 5-1992, f. & cert. ef. 10-23-92

Institutional Drug Outlets

855-041-0105

Definitions

For purposes of these rules, OAR 855-041-0105 through 855-041-0160, the following definitions apply:

(1) "Institutional Facility" means a hospital or other health care facility which is an inpatient care facility referred to in ORS 442.015, which includes long-term care facilities and special inpatient care facilities, and such facility is licensed by the appropriate state agency.

(2) "Institutional Pharmacy" means a pharmacy where medications are dispensed to other health care professionals for administration to institutionalized patients served by an institutional facility, and which is:

(a) Located within the institutional facility;

(b) Located outside the facility but provides pharmaceutical services to institutionalized patients.

(3) "Drug Room" means a secure and lockable location within an inpatient care facility that does not have a pharmacy.

(4) "Pharmaceutical Service" means the control of the utilization of drugs, biologicals and chemicals including procuring, manufacturing, compounding, dispensing, distribution and storing of drugs, biologicals and chemicals under the conditions prescribed by this rule. The provision of drug information to patients and to other health professionals is included within the meaning of pharmaceutical services.

(5) "Supervision" means stationed within the same work area, coupled with the ability to control and be responsible for an action.

Stat. Auth.: ORS 689
Stats. Implemented:
Hist.: 1PB 2-1980, f. & ef. 4-3-80; PB 8-1990, f. & cert. ef. 12-5-90

855-041-0110

Applicability of Rules

The provisions of OAR 855-041-0005 through 855-041-0100 are applicable to all retail drug outlets and are applicable to all institutional drug outlets except where OAR 855-041-0105 through 855-041-0160 provide specific exemptions or exceptions or where OAR 855-041-0105 through 855-041-0160 are in direct conflict, in which case OAR 855-041-0105 through 855-041-0160 shall apply.

Stat. Auth.: ORS 689
Stats. Implemented:
Hist.: 1PB 2-1980, f. & ef. 4-3-80; PB 1-1989, f. & cert. ef. 1-3-89

855-041-0115

Registration

All institutional drug outlets shall register annually with the Board of Pharmacy. Institutional drug outlets which also provide outpatient pharmacy services shall also register as retail drug outlets.

Stat. Auth.: ORS 689
Stats. Implemented:
Hist.: 1PB 2-1980, f. & ef. 4-3-80

Hospitals with Drug Rooms

855-041-0135

Supervision of Consulting Pharmacist

(1) In a hospital having a drug room and no pharmacy, the drug room must be supervised by a licensed pharmacist who provides his or her services with sufficient professionalism, quality and availability to adequately protect the safety of the patients and to properly serve the needs of the facility. The arrangements for a consulting pharmacist shall be in writing, and shall, at a minimum, provide that:

(a) The pharmacist is to act in the capacity of a part-time director;

(b) The pharmacist shall provide on-call service at all times;

(c) Adequate storage facilities for drugs will be provided; and

(d) All drugs supplies shall be labeled so as to insure that recalls can be effected and that proper control and supervision of such drugs may be exercised.

(2) One registered nurse supervisor and only one in any given shift may have access to the drug room and may remove drugs therefrom, except in an emergency situation. In that case, such nurse may designate another licensed nurse to obtain the required drug(s). Any access to the drug room deviating from the requirements of this section must be approved by the Board prior to implementation. The registered nurse supervisor shall be designated in writing by the appropriate committee of the hospital and shall, prior to being permitted to obtain access to the drug room, receive thorough education and training in the proper methods of access, removal of drugs, and records and procedures required. Such education and training shall be given by the director of pharmacy, who shall require, at a minimum, the following records and procedures:

(a) Drugs can only be removed from the drug room on a practitioner's written order, or verbal order which has been reduced to writing;

(b) A log of drugs withdrawn from a drug room shall be maintained and initialed by the registered nurse;

(c) Drugs shall be removed for outpatients only in compliance with section (3) of this rule.

(3) The consultant pharmacist who is the part-time director of pharmaceutical services shall in concert with the appropriate committee of the hospital medical staff, develop policies and procedures which shall be implemented to provide emergency pharmaceuticals to outpatients during the hours when normal community or hospital pharmacy services are not available. Such policies shall allow the designated registered nurse supervisor to issue medications pursuant to the pharmacist's standing orders, which shall provide:

(a) A written order of a practitioner authorized to prescribe a drug is presented;

(b) The medication is prepackaged by a pharmacist and contains:

(A) Name, address and telephone number of the

hospital;

(B) Name of drug, strength, and number of units; when a generic name is used, the label shall also contain the name of the manufacturer or distributor;

(C) Required precautionary information regarding controlled substances;

(D) Such other and further accessory cautionary information as required for patient safety;

(E) An expiration date after which the patient should not use the medication.

(c) No more than a 24-hour supply is provided to the patient, except when the pharmacist has informed the nurse supervisor that normal services will not be available within 24 hours;

(d) The container is labeled by the nurse supervisor before presenting to the patient, and shows the following:

(A) Name of patient;

(B) Directions for use to the patient;

(C) Date;

(D) Identifying number;

(E) Name of prescribing practitioner;

(F) Initials of the supervisor.

(e) The original written order by the prescriber is retained for verification by the pharmacist after completion by the nurse supervisor and shall bear:

(A) Name and address of patient;

(B) Date of issuance;

(C) Units issued;

(D) Initials of supervisor issuing medication.

(f) The original written order is verified by the pharmacist, initialed, dated, and filed in a separate location for a period of three years for Board inspection;

(g) The withdrawal of a single dose for immediate administration to the patient need not follow the requirements of subsection (d) of this section.

(4) Emergency Kits:

(a) Emergency Kit Drugs Defined. Emergency kit drugs are those drugs which may be required to meet the immediate therapeutic needs of in-patients, and which are not available from any other authorized source in sufficient time to prevent risk of harm to patients by delay resulting from obtaining such drugs from such other source;

(b) Supplying Pharmacist. All emergency kit drugs shall be prepared by a licensed pharmacist;

(c) Drugs Included. The director of pharmacy and the medical staff of the hospital shall jointly determine and prepare a list of drugs, by identity and quantity, in amounts sufficient for immediate therapeutic requirements, to be included in emergency kits. Such list of drugs shall be reviewed annually by the appropriate medical staff committee;

(d) Storage. Emergency kits shall be stored in areas to prevent unauthorized access and to insure a proper environment for preservation of the drugs within them, as required in official compendia;

(e) Labeling -- Interior. All drugs contained in emergency kits shall be labeled in accordance with OAR 855-041-0130(7);

(f) Labeling -- Exterior. The exterior of emergency kits shall be labeled to clearly and unmistakable indicate that is is an emergency drug kit and it is for use in emergencies only; such label shall also contain a listing of the name, strength and quantity of the drugs contained therein and an expiration date;

(g) Expiration Date. The expiration date of an emergency kit shall be the earliest expiration date on any drug supplied in the kit. Upon the occurrence of the expiration date, the supplying pharmacist shall open the kit and replace expired drugs;

(h) Removal of Drugs. Drugs shall be removed from emergency kits by authorized personnel only pursuant to a valid order or by the supplying pharmacist;

(i) Notifications. Whenever an emergency kit is opened or has expired, the supplying pharmacist shall be notified and the pharmacist shall restock and reseal the kit within a reasonable time so as to prevent risk of harm to patients.

Stat. Auth.: ORS 689
Stats. Implemented:
Hist.: 1PB 3-1979(Temp), f. & ef. 10-31-79; 1PB 2-1980, f. & ef. 4-3-80; PB 12-1989, f. & cert. ef. 8-11-89

855-041-0140

Drug Distribution and Control from a Drug Room in a Hospital

(1) General. The director of pharmacy shall establish and implement written procedures for the safe and efficient distribution of pharmaceutical products. An annually updated copy of such procedures shall be available for inspection by the Board.

(2) Availability. A pharmacist providing pharmaceutical services to a hospital maintaining a drug room shall be engaged by the hospital and shall schedule on-premises visits on at least a weekly basis.

(3) Span of Control. The pharmacist's span of supervision shall extend to all areas of the hospital where drugs are stored. No less than every two months inspections of these areas shall be conducted and substantiated by records so as to verify at least proper drug storage, documentation of distribution and administration of controlled substances, absence of outdated drugs, and the integrity of the required emergency drug supply.

(4) Director's Absence. In the absence of the director of the pharmaceutical service, pharmaceutical services shall be directed by a designated pharmacist.

(5) Responsibility. The director of pharmacy shall be responsible for procedures for the safe and efficient distribution of, control of and accountability for drugs. Accordingly, the director shall be responsible for, at a minimum, the following:

(a) Procedures for preparation and sterilization of parenteral medications manufactured within the hospital;

(b) Procedures for admixture of parenteral products, including education and training of nursing personnel concerning incompatibility and provision of proper incompatibility information. When the admixture of parenteral products is not accomplished under the direct supervision of a pharmacist, such preparation shall be limited to a practitioner or registered nurse;

(c) Manufacture and compounding of drugs;

(d) Procedures for establishment of specifications for procurement of all pharmaceutical materials, including drugs, chemicals and biologicals, subject to approval of the appropriate committee of the hospital;

(e) Procedures for participation in the development and revisions of a hospital formulary system;

(f) Procedures for filling and labeling all stock containers from which drugs are to be administered;

(g) Maintaining and making available a sufficient inventory of antidotes and other emergency drugs, as well as current antidote information, telephone numbers of poison control center(s) and other emergency assistance organizations, and such other materials and information as may be deemed necessary by the appropriate committee of the hospital;

(h) Records of all transactions of the hospital relating to pharmaceutical services as may be required by state or federal law, and maintenance of accurate control over and accountability for all pharmaceutical materials. The procedures shall include the keeping of accurate and complete records of the receipt, withdrawal from stock and use or other disposal of all legend drugs stored in the drug room and all other locations in the hospital;

(i) Participation in those aspects of the hospital's patient care evaluation program which relate to pharmaceutical material utilization and effectiveness;

(j) Meeting all inspection and other requirements of the pharmacy and drug laws of this state and rules thereunder.

Stat. Auth.: ORS 689
Stats. Implemented:
Hist.: 1PB 3-1979(Temp), f. & ef. 10-31-79; 1PB 2-1980, f. & ef. 4-3-80

Pharmacists Serving Long Term Care Facilities and Community Based Care Facilities

855-041-0145

Definitions

As used in OAR 855-041-0145 through 855-041-0164:

(1)(a) "Long term care facility" means a facility with permanent facilities that include inpatient beds, providing medical services, including nursing services but excluding surgical procedures except as may be permitted by the rules of the director, to provide treatment for two or more unrelated patients. "Long Term Care facility" includes skilled nursing facilities and intermediate care facilities but may not be construed to include facilities licensed and operated pursuant to ORS 443.400 to 443.455.

(b) For the purposes of Schedule II prescriptions in 21 CFR 1306.11-1306.13, the DEA definition of "long term care facility" as defined in 21 CFR 1300.01(25) includes "community based care facilities."

(2) "Community Based Care Facility" means a home, facility or supervised living environment licensed or certified or otherwise recognized by an agency of the state of Oregon which provides 24-hour care, supervision, and assistance with medication administration. These include but are not limited to Adult Foster Homes, Residential Care Facilities (RCF), Assisted Living Facilities (ALF), Group Homes for the Developmentally Disabled and Mentally Retarded and Inpatient Hospice.

(3) "Pharmaceutical Care" means the responsible provision of any or all of the following services by the pharmacist:

(a) Develop and maintain policies and procedures for pharmaceutical services;

(b) Provide direction and oversight regarding all aspects of the acquisition, disposition, handling, storage, and administration of drugs including but not limited to the following:

(A) Receipt and interpretation of physician's orders;

(B) Ordering and receiving of medications;

(C) Handling of emergency drugs and supplies;

(D) Labeling of all drugs;

(E) Selection of drug delivery systems;

(F) Development of systems to provide timely delivery of drugs and supplies;

(G) Monitoring of drug storage conditions and expiration dates;

(7) The pharmacist must assign a separate and unique identifier to each prescription and clearly identity this number on each corresponding prescription label.

Counseling

(8) The pharmacist is not required to obtain an EPT patient's or partner's name, address, or demographics; however, the pharmacist must:

(a) Provide counseling in the form of written patient information to accompany each prescription for each partner and ask the patient about any known allergies or other drugs being taken by each partner. The pharmacist should advise the patient to encourage each partner to call the pharmacist before taking the drug if they have experienced any adverse effect from a drug in the past or if they are taking other drugs;

(b) Document counseling.

Records

(9) All documentation required by this rule must be attached to the prescription and must be referenced to each partner's prescription. Such documentation must be retained in accordance with the other rules in this division and must be made available to the Board upon request.

Stat. Auth.: ORS 689.205
Stats. Implemented: 2009 OL Ch 522
Hist.: BP 1-2010, f. & cert. ef. 2-8-10

Hospitals with Pharmacies

855-041-6050

Definitions

(1) In these rules, OAR 855-041-6000 through 855-041-6999, the terms below have these meanings:

(a) "Automated Distribution Cabinet" (ADC) means a computerized drug storage device or cabinet that allows a drug to be stored and dispensed near the point-of-care, while controlling and tracking drug distribution;

(b) "Drug" means a drug, a prescription device, a biological medication, a chemical or any combination of these terms;

(c) "Central pharmacy" means a pharmacy within a licensed hospital with a single location and inventory, which prepares and distributes drugs to secondary storage areas in the facility, and remote locations;

(d) "Chief Pharmacy Officer" (CPO) means an Oregon licensed pharmacist who supervises the pharmacy operations in a hospital. The CPO may hold the title of Pharmacy Manager, Pharmacy Director, Director of Pharmacy, Pharmacy Administrator or other pharmacy supervisory management title within the organization. The PIC may also be the CPO if there is only one pharmacy in the hospital;

(e) "Drug profile" means a complete and comprehensive summary of a patient's current drugs and details of each drug including information such as active ingredient, strength and form, dose and directions for use, and other supplementary information;

(f) "Licensed Independent Practitioner" (LIP) means an individual permitted by law and by the organization to provide care and services, without direction or supervision, within the scope of the individual's license;

(g) "Out-patient" means a person who is not residing in the facility but who is registered with the facility and is using the facility for treatment or diagnostic services;

(h) "Remote storage area" means a patient care area which is part of the hospital that is under the supervision and control of the hospital's central pharmacy but is not located in the same building as the central pharmacy;

(i) "Secondary drug storage area" means an area in a hospital or licensed residential facility, which is supplied by a central pharmacy and may include facilities such as a drug room, a distribution cabinet or a hospital department;

(j) "Unit-dose" means a quantity of a drug designed to be administered to a patient, such as:

(A) An oral solid individually packaged or re-packaged;

(B) An oral liquid drawn up in a labeled oral syringe;

(C) An injectable product; or

(D) A pre-mixed IV product.

(2) Not withstanding 855-006-0005 and 855-019-0200(2) and (3), for the purpose of these rules, OAR 855-041-6000 through 855-041-6999, verification or final verification means the confirmation by a pharmacist of the correctness, exactness and accuracy of the act, tasks, or function as specified elsewhere in this Division of rules.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 3-2010, f. 4-29-10, cert. ef. 4-30-10

855-041-6100

Registration

(1) Each central pharmacy must be registered with the Board. In a hospital with multiple central pharmacies, each pharmacy location must be registered with the Board.

(2) A secondary drug storage area within the hospital or in a structure physically attached to the hospital does not require a separate registration.

(3) A registered pharmacy in a hospital may use additional locations within the hospital, supervised by a pharmacist, without acquiring separate registrations for each additional location.

(4) A secondary drug storage area in a separate location must be registered as a drug room and must follow all rules that apply to secondary storage areas in the hospital.

(5) A residential healthcare facility that is licensed by DHS and that has a central pharmacy must register the pharmacy with the Board.

(6) Upon written request, the Board may waive any of the requirements of this rule if a waiver will further public heath or safety or the health and safety of a patient. A waiver granted under this section shall only be effective when it is issued by the Board in writing. A waiver is not valid for more than five years.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155 & 689.305
Hist.: BP 3-2010, f. 4-29-10, cert. ef. 4-30-10

855-041-6150

General Pharmacy Requirements

(1) Each hospital pharmacy must have an Oregon licensed pharmacist designated as Pharmacist-in-Charge (PIC).

(2) A hospital that has more than one pharmacy must designate an Oregon licensed pharmacist as CPO or an equivalent position who has responsibility for directing pharmacy services in the hospital. The CPO may also be the PIC of one of the pharmacies.

(3) A hospital pharmacy may only be operated when under the direct supervision of an Oregon licensed pharmacist. The pharmacist shall be responsible for all areas of the hospital where drugs are stored, including remote storage areas

(4) The pharmacy must be operated at least part-time, five days a week.

(5) The hospital pharmacy must have adequate space so that drugs can be prepared in sanitary, well-lit, enclosed places. Space and equipment must be adequate for the pharmaceutical services provided including compounding, distributing, and storage of drugs and parenteral preparations.

(6) As a minimum, the pharmacy must have the following:

(a) Equipment listed in OAR 855-041-0040, except that a pharmacy that is only registered as an institutional drug outlet does not need to have an Official Poison and Exempt Narcotic Register;

(b) A drug formulary approved by the appropriate hospital committee;

(c) Pharmacy policy and procedures.

(7) All areas occupied by a hospital pharmacy must be secured to prevent access by unauthorized personnel.

(a) Whenever any area of a hospital pharmacy is not under direct supervision of a pharmacist, the area must be secured;

(b) The CPO shall designate in writing, by title and specific area, those persons who may have access to specific areas within the pharmacy;

(c) Unless otherwise permitted by these rules, a non-pharmacist may not have access to the pharmacy unless a pharmacist is on duty and present in the hospital.

(8) A residential healthcare facility that has a central pharmacy must comply with these rules.

(9) Upon written request, the Board may waive any of the requirements of this rule if a waiver will further public health or safety or the health and safety of a patient. A waiver granted under this section shall only be effective when it is in writing. A waiver is not valid for more than five years.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 3-2010, f. 4-29-10, cert. ef. 4-30-10

Drug Distribution and Control

855-041-6200

Chief Pharmacy Officer and Pharmacist in Charge

(1) The CPO must specify the respective responsibilities of the CPO and the PIC if separate individuals hold these positions.

(2) In addition to the duties listed in this rule, the PIC has the responsibilities listed in OAR 855-019-0300.

(3) The CPO must establish policies and procedures that include:

(a) Procedures for general distribution of drugs throughout the hospital;

(b) A procedure for review and revision of the policies and procedures not less than every three years;

(c) Procedures for the supervision of pharmacy services including storage, distribution, control and accountability for drugs including controlled drugs;

(d) Procedures to ensure that all areas of the hospital where drugs are stored are inspected not less than every two months to verify proper drug storage, documentation of distribution and administration of controlled substances, absence of outdated drugs, and the integrity of the emergency drug supplies;

(e) Policies and procedures that govern the preparation, verification and sterilization of parenteral drugs compounded within the hospital. Procedures must comply with OARs 855-045-0200 through 855-045-0270 and these rules;

(f) Procedures for administration of drugs, including self-administration;

(g) Procedures for labeling drugs;

(h) Policies and procedures that govern the filling and labeling of containers from which drugs are to be administered;

(i) Procedures for a Quality Assurance program to ensure that there is a planned, ongoing and systematic process for the monitoring and evaluation of the quality and appropriateness of pharmacy services, and for identifying and resolving problems. Such monitoring and evaluation must be accomplished through ongoing collection of information and periodic assessment of the collected information;

(j) Emergency drug distribution;

(k) Procedures for procurement of all drugs subject to approval of the appropriate committee of the hospital;

(l) Procedures to ensure that discontinued, outdated, adulterated or misbranded drugs are returned to the pharmacy for proper disposition, or that the PIC makes proper disposition or disposal of such drugs at the storage site;

for the provision of pharmacy services or prescription drug orders; the delivery, dispensing or distribution of prescription drugs; participation in drug and device selection; drug administration; drug regimen review; drug therapy management, including such services provided under the Medicare Prescription Drug, Improvements, and Modernization Act of 2003 (Public Law 108-173, 117 Stat. 2066); drug or drug-related research; compounding; proper and safe storage of drugs and devices; management of drug therapy pursuant to section 9.3 or, if in an institutional setting, consistent with the institution's assignment of clinical duties pursuant to a written agreement or protocol as set forth in section 9.1; maintaining proper records; patient counseling; and such acts, services, operations or transactions necessary or incident to the provision of these health care services. The "practice of pharmacy" shall not include the operations of a manufacturer or distributor as defined in "The Controlled Substance, Drug, Device and Cosmetic Act." ((11) amended June 1, 2010, P.L.201, No.29)

(12) "Pharmacy" means every place properly issued a permit by the Board of Pharmacy where drugs, devices and diagnostic agents for human or animal consumption are stored, dispensed or compounded, excluding offices or facilities of veterinarians licensed by the State Board of Veterinary Medical Examiners. The term "pharmacy" shall not include the operations of a manufacturer or distributor as defined in "The Controlled Substance, Drug, Device and Cosmetic Act." In an institution, "pharmacy" refers to the organized pharmacy service in the institution under the direct supervision of a licensed pharmacist.

(13) The words "drug" and "devices" shall not include surgical or dental instruments or laboratory materials, gas and oxygen, therapy equipment, X-ray apparatus or therapeutic equipment, their component parts or accessories, or equipment, instruments, apparatus or contrivances used to render such articles effective in medical, surgical or dental treatment, or for use or consumption in or for mechanical, industrial, manufacturing or scientific applications or purposes, nor shall the word "drug" include any article or mixture covered by the Pesticide Act of 1957, nor medicated feed intended for and used exclusively as a feed for animals other than man.

(14) "Management of drug therapy" means any of the following processes which shall be performed pursuant to a written agreement or protocol as set forth in section 9.1 or pursuant to section 9.3: adjusting a drug regimen; adjusting drug strength, frequency of administration or route; administration of drugs; ordering laboratory tests and ordering and performing other diagnostic tests necessary in the management of drug therapy; monitoring the patient's vital signs; and providing education and training to the patient which is related to the management of drug therapy. The management of drug therapy under section 9.1 shall be performed consistent with the institution's assignment of clinical duties, and ordering of laboratory tests and ordering or performing other diagnostic tests necessary in the management of drug therapy shall be consistent with the testing standards of the institution. ((14) amended June 1, 2010, P.L.201, No.29)

CHAPTER 27. STATE BOARD OF PHARMACY

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PHARMACISTS

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INSTITUTIONS

§ 27.41. Qualified institutions.

Only institutions accredited by the Joint Commission on Accreditation of Hospitals or the Commission on Hospital Accreditation of the American Osteopathic Association or meeting the requirements of the ''Conditions of Participation for Extended Care Facilities,'' Federal Health Insurance for the Aged, or licensed by the Department of Welfare or Department of Health, will be considered for an application for a permit to operate a pharmacy. An institution may not be consid-ered for a pharmacy permit unless the pharmacy in that institution is open a minimum of 20 hours per week under the supervision of a registered pharmacist manager.

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§ 27.42. Institutional regulation.

Pharmaceutical services in institutions shall always be conducted in accordance with rules and regulations affecting the services which have been or may hereafter be promulgated by the Department of Public Welfare or Department of Health, and the rules and regulations are hereby incorporated automatically. Violation of the rules and regulations constitute a violation of this chapter.

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TITLE 5
Businesses and Professions

CHAPTER 5-19.1
Pharmacies

SECTION 5-19.1-5

§ 5-19.1-5 State board of pharmacy – Powers and duties. – The board, subject to the approval of the director, shall:

(1) Regulate the practice of pharmacy and enforce all laws relating to pharmacy;

(2) Approve examinations for applicants for pharmacists' licenses;

(3) Establish the qualifications for licensure of pharmacists, pharmacy interns, pharmacy technicians, other classes of pharmacy personnel and wholesalers, or manufacturers;

(4) Conduct hearings for the revocation or suspension of licenses, permits, registrations, certificates, or any other authority to practice granted by the board, these which hearings may, at the board's discretion, also be conducted by an administrative hearing officer;

(5) Issue subpoenas and administers oaths in connection with any hearing, or disciplinary proceeding held under this chapter or any other chapter assigned to the board; provided, however, that no deceased pharmacist shall have his/her name kept on the health department list of pharmacists that have had a disciplinary action taken against his/her license;

(6) Be authorized to promulgate rules and regulations necessary to carry out the purposes of this chapter.

(7) Adopt rules establishing and governing continuing education requirements for pharmacists and other licensees applying for renewal of licenses under this chapter;

(8) Assess an administrative penalty on any person who fails to comply with any provision of this chapter or any rule, regulation, order, license or approval issued by the board relating to pharmacy;

(9) Adopt any other rules and regulations as necessary to carry out provisions of this chapter.

History of Section.
(P.L. 2001, ch. 60, § 2; P.L. 2007, ch. 316, § 1.)

RULES AND REGULATIONS PERTAINING TO PHARMACISTS, PHARMACIES AND MANUFACTURERS, WHOLESALERS AND DISTRIBUTORS

[R5-19.1-PHAR]

STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS

DEPARTMENT OF HEALTH

March 1985

As Amended:

May 1986
August 1986
April 1987
April 1988
October 1988 (E)
January 1989
September 1989 (E)
December 1989
May 1990
October 1990 (T)
September 1992 (E)
February 1993 (E)
April 1993
November 1993
February 1994
July 1996
July 1997
February 2000
July 2000 (E)
November 2000 (E)
December 2000
April 2001
August 2001 (E)
December 2001 (E)
December 2001 (E)
January 2002 (re-filing in accordance with the provisions of section 42-35-4.1 of the Rhode Island General Laws, as amended)
January 2002
July 2002
December 2002
May 2003
June 2003 (E)
October 2003 (E)
December 2003
February 2004
December 2004
July 2005
October 2005
June 2006
January 2007 (re-filing in accordance with the provisions of section 42-35-4.1 of the Rhode Island General Laws, as amended)
April 2007
July 2007
January 2008
April 2009
July 2009 (E)
November 2009 (E)
January 2010
January 2012 (re-filing in accordance with the provisions of section 42-35-4.1 of the Rhode Island General Laws, as amended)
April 2012

retail purchaser to the pharmacy for any prescription drug listed at the usual strength and amount listed.

14.4 The requirements of this section do not apply to an order to dispense a drug for immediate administration to a hospital patient.

Section 15.0 *General Requirements: Institutional Pharmacies*

Physical Requirements

15.1 An institutional pharmacy shall have sufficient floor space allocated to it to ensure that drugs are prepared in sanitary, well-lighted and enclosed places. It shall have sufficient equipment, supplies and physical facilities for proper compounding, dispensing and storage of drugs, including parenteral preparations and for the provision of pharmaceutical care. All work surfaces shall be free of equipment, supplies, records and labels unrelated to the preparation of medications. The equipment and physical facilities shall include, but are not limited to, the following:

(a) Compounding and dispensing areas;

(b) Physically separate parenteral solution additive area when solutions are compound in the pharmacy as described in §19.0 of these Regulations;

(c) Receiving and storage areas;

(d) Packaging and repackaging areas;

(e) Office space sufficient to allow for administrative functions without interference with the safe compounding and dispensing of medications and security of the pharmacy.

After-hours Pharmacy Services

15.2 The pharmacist-in-charge shall establish policies and procedures for the provision of a limited supply of medications for filling of urgent orders to patients of the medical institution after the scheduled hours of operation of the pharmacy. The pharmacist in charge shall provide for the provision of pharmaceutical care after normal working hours by use of an "on call" pharmacist accessible to the medical institution after hours. The institutional pharmacy may enter into a contractual arrangement with another pharmacy or pharmacist for the provision of such services. Medications may be accessed from a pharmacy-designated area. The policies and procedures shall address:

(a) A list of those individuals authorized by the pharmacist-in-charge to remove medications from the pharmacy-designated area.

(b) A list of medications authorized for removal from the pharmacy-designated area determined by the pharmacist-in-charge or designee, and the medical staff of the medical institution. The pharmacist in charge shall limit the number of medications, quantity and dosage forms to maximize patient safety. Medications shall be removed from the designated area in unit-of-use packaging, whenever possible. If a non-unit-dosed medication is needed when the pharmacy is closed, the bulk medication container shall

be signed out. When the pharmacy re-opens, the pharmacist shall retrieve the bottle and dispense the necessary amount of medication. The bottle shall be returned to the pharmacy within twenty-four (24) hours after the pharmacy re-opens.

(c) Documentation of medications removed from the pharmacy-designated area, which shall include, but not be limited to, medication name, strength, signature of authorized person removing medications, quantity and name of patient.

(D) methods for performing a periodic review of those policies and procedures.

Medication Distribution and Control

15.3 The pharmacist-in-charge shall establish policies and procedures relating to the procurement, distribution and control of all drug products used in the medical institution.

Medication Orders

15.3.1 Medications are to be prescribed, dispensed and administered only upon orders of authorized practitioners and medication orders transmitted to the pharmacy in an appropriate manner.

15.3.2 A licensed pharmacist in the institutional pharmacy shall review all medication orders for appropriateness upon receipt in the pharmacy prior to dispensing, except orders initiated in the operating room, emergency room, procedural rooms, and ambulatory care centers. Medication orders written when the pharmacy is closed shall be reviewed within twenty-four (24) hours after the pharmacy re-opens.

15.3.3 All patient medication orders shall be contained in the patient's medical record.

Medication Storage and Security

15.3.4 All areas designated for medication storage shall have and shall maintain proper security to limit accessibility of unauthorized personnel on the premises and to safeguard against diversion of drugs, biologicals and medications.

15.3.5 All medications shall be stored in designated areas under proper conditions of sanitation, temperature, light, moisture, ventilation, and segregation to ensure medication integrity. Medications shall be stored in accordance with medication labeling pursuant to the federal and state Food Drug and Cosmetic Acts.

15.3.6 Each pharmacy shall adhere to written policies and procedures that require all stocks of medications to be inspected routinely for outdated, unusable or mislabeled products.

15.3.7 Floor stock of medications shall be limited to medications for emergency use, non-legend medications that are routinely used, and limited medications as designated by the facility.

15.3.8 All medication areas including auxiliary drug supplies, unit dose carts and emergency kits, shall remain secured at all times. All medications must be adequately secured to restrict access by unauthorized personnel.

15.3.9 Sample medications shall be procured, stored, dispensed and/or donated to charitable institutions in accordance with the federal Food Drug and Cosmetic Act.

Labeling

15.3.10 All drugs dispensed within a medical institution shall be labeled and identified up to the point of administration.

15.3.11 Whenever a drug is added to a parenteral admixture, it shall be labeled with a supplementary label indicating the name and amount of the drug added, expiration date and expiration time, if applicable. For admixtures prepared outside the pharmacy, the pharmacist-in-charge shall develop policies and procedures for preparation and labeling.

15.3.12 Labels for outpatient medications shall comply with RIGL §21-31-15(l)(l).

Records

15.3.13 The pharmacist-in-charge shall develop a system of daily accountability for medication compounding and dispensing that shall permit the identification of the responsible pharmacist. Readily retrievable records of accountability shall be maintained for at least two (2) years. At a minimum, this system shall identify all personnel who perform these activities and the pharmacist responsible for:

(a) Interpretation and appropriateness of new medication orders;

(b) Profile entry of new medication orders;

(c) Dispensing of new medication orders including "stat" doses;

(d) Daily cart fills;

(e) Compounding medications; and

(f) Periodically assessing the quality of pharmacy procedures for preparation and release of drugs for replenishment of floor stock, ancillary drug supplies, emergency kits and automated dispensing devices in locations outside the pharmacy.

Patient's Personal Medications

15.3.14 Medications brought into the hospital by patients may only be administered pursuant to a written order. Prior to administration, medications shall be identified by a prescribing practitioner or a pharmacist.

15.3.15 In the case that the medications are not to be used during the patient's hospitalization, every attempt shall be made to give the medications to the patient's family or caregiver. If this is not possible, the pharmacy shall package and seal the medications and store the medications in a secure location until such time that the patient is discharged. No medication shall be retained by the medical institution for longer than thirty (30) days after the patient's discharge and shall be disposed of in accordance with the policy of the medical institution.

Emergency Outpatient Medications

15.3.16 The pharmacist-in-charge and medical staff shall establish policies and procedures for the dispensing of medications from the emergency room.

15.3.16.1 Only a licensed prescriber shall be authorized to dispense medications to patients in an emergency situation.

15.3.16.2 Emergency medications shall be labeled in accordance with RIGL §21-31-15(l)(l).

Monitoring Drug Therapy

15.4 The pharmacist shall review the appropriateness of the choice of medications for the patient and the patient's therapeutic regimen, pursuant to §13.13 of these Regulations.

15.4.1 Pharmacists shall have access to the following information:

(1) Admission diagnosis;

(2) Age, weight, height and sex;

(3) History of allergies and/or previous adverse drug reactions;

(4) Current and discontinued medications;

(5) Co-morbid disease states;

(6) Pertinent laboratory information.

15.4.2 The pharmacist shall review each medication order and, in the case of an identified, significant problem or opportunity for improvement, the pharmacist shall contact the prescribing practitioner. All such communications shall be documented electronically or in writing. Pharmacy interventions shall be reviewed with appropriate staff committees on a routine basis.

15.4.3 ***Medication Use Evaluation Program*:** The pharmacist-in-charge and medical staff shall establish policies and procedures to increase the effectiveness and minimize the risk of drug use. Policies and procedures shall include defining, monitoring, detecting, reporting and reviewing the following:

15.4.3.1 ***Adverse Drug Reactions (ADR)*:**. ADRs that the pharmacist deems to be significant shall be reported to the FDA's MedWatch Program. Vaccine-related adverse events shall be reported to the CDC.

15.4.3.2 **Medication Errors:** Special consideration shall be given to measures to prevent medication administration errors associated with preparing parenteral and sterile products.

15.4.3.3 ***Medication Use Evaluation*:** The system shall identify, and resolve actual and potential medication-related problems, and prevent potential medication problems that could interfere with optimum patient outcomes from medication therapy.

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(d) fulfilled continuing education requirements as provided for in Section 40-43-130(G).

(2) The pharmacist-in-charge shall verify compliance with the requirements of item (a) of subsection (B)(1) and maintained a record of this requirement in a readily retrievable manner for inspection.

(C) Notwithstanding any other provision of this chapter, a supervising pharmacist may authorize a certified pharmacy technician to:

(1) receive and initiate verbal telephone orders;

(2) conduct one time prescription transfers;

(3) check a technician's refill of medications if the medication is to be administered by a licensed health care professional in an institutional setting;

(4) check a technician's repackaging of medications from bulk to unit dose in an institutional setting.

(D) A formal academic pharmacy technician training program that leads to a certificate, diploma, or higher degree may be approved by the board if it includes at a minimum:

(1) introduction to pharmacy and health care systems;

(2) pharmacy law and ethics;

(3) pharmacy calculations;

(4) pharmacology;

(a) anatomy and physiology;

(b) therapeutic agents;

(c) prescription drugs;

(d) nonprescription drugs;

(5) pharmacy operations;

(a) drug distribution systems;

(b) records management and inventory control;

(c) ambulatory and institutional practice;

(6) compounding;

(a) aseptic technique;

(b) nonsterile compounding;

(7) general education;

(a) medical terminology;

(b) interpersonal relations;

(c) communications;

(d) computers/keyboarding;

(8) problem solving/critical thinking;

(9) experiential training (practical experience).

(E) A pharmacist whose license has been denied, revoked, suspended, or restricted for disciplinary purposes is not eligible to be registered as a pharmacy technician.

(F) Notwithstanding the requirements of this section or any other provision of law or regulation, an individual who works as an unpaid volunteer under the personal supervision of a licensed pharmacist or who handles legend drugs in a pharmacy department of a free medical clinic staffed by a licensed pharmacist may be registered as a pharmacy technician and may perform pharmacy functions as a pharmacy technician without payment of a registration fee or filing with the board; provided, that a register is maintained in the pharmacy department of the free medical clinic bearing the name of every such volunteer performing pharmacy functions as a pharmacy technician and documenting each volunteer's period of service. This special registration is valid only in the free medical clinic. The register must be kept for a period of three years. For the purposes of this section, "free medical clinic" means a permitted facility that provides medical services, including the dispensing of legend drugs and other medications, free of any charge to members of the public.

HISTORY: 1998 Act No. 366, Section 1; 2000 Act No. 297, Section 1; 2002 Act No. 314, Section 4.

SECTION 40-43-83. In-state facilities dealing with prescription drugs; out-of-state facilities in mail order pharmacy service; permits; registered agents; required pharmacist-in-charge; display of permit; penalty; refusal of permit if not in public interest.

(A) All facilities located within this State engaging in the manufacture, production, sale, distribution, possession, or dispensing of prescription drugs or devices and all facilities located outside of this State whose primary business is mail order pharmacy service engaging in the sale, distribution, or dispensing of prescription drugs or devices in this State must be permitted by the Board of Pharmacy, and annually shall renew the permit by June first. Where operations are conducted at more than one location, each location must be permitted by the Board of Pharmacy.

This subsection does not apply to a college or university athletic department that dispenses prescription drugs or devices.

(B) Each permittee located outside of this State who ships, mails, distributes, or delivers prescription drugs or devices in this State and every pharmacy located outside of this State who ships, mails, distributes, or delivers prescription drugs or devices in this State shall designate a registered agent in this State for service of process. Any such permittee or pharmacy who does not so designate a registered agent is deemed to have designated the Secretary of State of this State to be its true and lawful attorney, upon whom may be served all legal process in any action or proceeding against such permittee growing out of or arising from such delivery. A copy of any such service of process shall be mailed to such permittee or pharmacy by the board by certified mail, return receipt requested, postage prepaid, at the address such permittee has designated on its application for licensure in this State. If any such person is not permitted in this State, service on the Secretary of State only is sufficient service.

(C) The board shall determine and promulgate the permit classifications of all permits by regulation under this chapter and establish minimum standards for such permits.

(D) Each pharmacy shall have a pharmacist-in-charge; however, a college or university athletic department pharmacy is not required to have a pharmacist-in-charge. Whenever an applicable rule requires or prohibits action by a pharmacy, responsibility is that of the permit holder and the pharmacist-in-charge of the pharmacy, whether the ownership is a sole proprietor, partnership, association, corporation, or otherwise.

(E) The board may enter into agreements with other states or with third parties for the purpose of exchanging information concerning the permitting and inspection of entities located in this jurisdiction and those located outside this State.

(F) Permits issued under this section must be displayed in a conspicuous place in the permitted facility for which it was issued in such a manner that will enable an interested person to determine the name of the permittee, permit number, and permit expiration date. The permits are not transferable.

(G) This section must not be construed as precluding any person from owning or being a permit holder if all of the dispensing, compounding, and retailing of prescription drugs in it are under the supervision and direction of a licensed pharmacist.

(H) The Board of Pharmacy may deny or refuse to renew a permit if it determines that the granting or renewing of such permit would not be in the public interest. If an application is refused, the board shall notify the applicant in writing of its decision and the reasons for its decision.

(I) A permit is required for the sale, distribution, possession, or dispensing of drugs bearing the legend "Caution: Federal law prohibits dispensing without a prescription" including, but not limited to, pharmacies (institutional or community, public or private), nursing homes, hospitals, convalescent homes, extended care facilities, family planning clinics, public or private health clinics, infirmaries, wholesalers, correctional institutions, industrial health clinics, mail order vendors, and manufacturers within or outside this State.

(J) The board shall assess a civil penalty in the amount of fifty dollars for failure to display a permit as required by this section.

(K) The Department of Health and Environmental Control is exempt from the provisions of this section that require facilities distributing or dispensing prescription drugs to be permitted by the Board of Pharmacy and from the provisions of this section that require each pharmacy to have a pharmacist-in-charge; however, each health district in this State must have a permit to distribute or dispense prescription drugs.

HISTORY: 1998 Act No. 366, Section 1; 2000 Act No. 340, Section 8; 2002 Act No. 356, Section 1, Part II.H(1),(2); 2007 Act No. 49, Section 3.A.

SECTION 40-43-84. Internship and externship certificates; program requirements; intern and extern restrictions; requirements for supervisory site and pharmacist.

(A) All applicants for licensure by examination shall obtain one thousand five hundred hours of practical experience in the practice of pharmacy. The board shall establish certificate requirements for interns/externs and standards for internship, or any other experiential program necessary to qualify an applicant for licensure. The board shall issue an intern certificate to a qualified applicant. No intern/extern may receive credit for practical experience unless he has been issued a certificate by the board. Such certificate must be granted only to individuals who have been accepted by or graduated from an approved college of pharmacy, but no sooner than three months before beginning pharmacy school. No credit shall be given for internships worked more than three months before beginning pharmacy school or if the student does not matriculate. A foreign pharmacy graduate may secure a certificate of registration as a pharmacy intern upon presenting to the board proof of graduation from a pharmacy school located in a foreign country and a statement of his intent to complete the requirements of the Foreign Pharmacy Graduate Equivalency Examination (FPGEE).

(B) An intern/extern may not represent himself as a pharmacist. The board shall issue to an intern/extern a certificate for purposes of identification and verification of his role as an intern/extern. The internship certificate must be displayed in the pharmacy or site in which the experience is being gained. No individual who has not been issued a certificate by the board as an intern/extern shall take, use, or exhibit the title of intern/extern, or any other term of similar like or import.

(C) An intern/extern may engage in the practice of pharmacy if such activities are under the direct supervision of a licensed pharmacist. A pharmacist must be in continuous personal eye and voice contact with, and actually giving instructions to, the intern/extern during all professional activities throughout the entire period of the internship/externship. The pharmacist shall physically review the prescription drug order and the dispensed product before the product is delivered to the patient or the patient's agent. The pharmacist is responsible for the work of the intern/extern. A pharmacist may not supervise more than one intern at any one time.

Pharmacy interns/externs shall not be left in sole charge of a prescription department or other approved site at any time. Violation of this may result in cancellation of any and all internship/externship hours toward licensure that may have been accrued by the intern/extern, and may, in the discretion of the board, cause the board after sufficient notice to the pharmacy intern/extern, to revoke or suspend the internship certificate as provided above. The supervising pharmacist or designated pharmacist may also be subject to disciplinary action by the board.

An applicant for licensure, who is guilty of compounding or dispensing a prescription of a practitioner or selling legend drugs or medicines while not under the supervision of a licensed pharmacist may be refused licensure.

(D) All interns shall notify the board of any change of employment or residence address within ten days.

(E) Credit for claims of practical experience required under the pharmacy laws will not be recognized by the board unless such claims are corroborated by records on file in the board office, showing the beginning and ending of the practical experience claimed as supplied by the applicant during the training period and by the pharmacist who supervised the practical experience during the training period.

(F) The pharmacy, site, or program in which practical experience is being obtained shall have a current, valid pharmacy permit, as required by this chapter, and the designated pharmacist shall hold a current, valid license to practice pharmacy.

HISTORY: 1998 Act No. 366, Section 1; 1999 Act No. 76, Section 4.

SECTION 40-43-85. Notification form regarding internship; practical experience; experience gained outside State; credit for externship programs; requirements for site and supervising pharmacists.

(A) An intern shall notify the Board of Pharmacy within ten days after the beginning and again within ten days after the ending of each and every calendar year, if the intern is employed, and within ten days after the beginning of each new employment and within ten days after the ending of each employment, on forms provided by the board, of the identity of the internship site and of the designated pharmacist. This form must be certified by the designated pharmacist. The pharmacy intern is responsible for the submission of the appropriate forms within the time limits as set.

(B) An intern may gain practical experience toward licensure as a pharmacist in accordance with this section and as may otherwise be required by this chapter.

(C) Where practical experience is gained in a pharmacy, other site, or program located outside of the State, the board has the discretion to determine whether such experience meets the requirements of the board. The applicant shall submit from the secretary of the Board of Pharmacy of the state in which practical experience was gained certification of the validity of the supervising pharmacist's license and the pharmacy permit.

(D) A minimum of five hundred hours of practical experience must be obtained in a retail or institutional pharmacy. Approval of all experience gained is left to the discretion of the board after receiving a description of the experience by the intern and the designated pharmacist.

(E) Students enrolled in an approved program leading to a bachelor of science degree in pharmacy may receive practical experience credit for up to five hundred hours for participation in an externship program upon completion of the program. Hours earned must be certified by the college of pharmacy, none of which may be used to fulfill the requirement in subsection (D).

(F) Students enrolled in an approved doctor of pharmacy program consisting of six or more years of collegiate studies may receive practical experience credit for up to one thousand hours for practice related experiences upon completion of such program, the number of hours certified by the college of pharmacy, none of which shall be used to fulfill the requirements in subsection (D).

(G) A pharmacy, site, or program offering interns/externs practical experience toward licensure as a pharmacist shall conform to the best traditions of pharmacy, shall have available all necessary reference books, in addition to the official standards and current professional journals and periodicals, and must be operated at all times under the supervision of a licensed pharmacist as required by law. The designated pharmacist must signify willingness to train interns/externs desiring to obtain practical experience in accordance with this chapter. The pharmacy at which an intern/extern is being trained shall provide an environment that is conducive to the learning of the practice of pharmacy by an intern/extern. It is expected that the intern/extern will be exposed to all facets of the practice of pharmacy in that setting including, but not limited to:

(1) evaluation of prescription drug orders;

(2) preparation and labeling of drugs;

(3) dispensing of drugs;

(4) patient profile update and review;

(5) drug use review;

Policies & Procedures

Revised June 2010

South Carolina Department of
Labor, Licensing, & Regulation

Board of Pharmacy
Synergy Office Park, Kingstree Building
110 Centerview Drive, Suite 306
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Columbia, South Carolina 29211-1927
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www.llr.state.sc.us/pol/pharmacy

Revised at the March 2008 Board Meeting

Policy and Procedure #115

Emergency room physicians or supervisors may not delegate a nurse or other person their personal authority under S.C. Code Ann.§40-43-86(X) to dispense legend drugs to meet the immediate needs of patients.

Revised at the March 2008 Board Meeting

36-11-11. Promulgation of rules. The Board of Pharmacy may promulgate rules pursuant to chapter 1-26 as follows:

(1) Pertaining to the practice of pharmacy;

(2) Relating to the sanitation of persons and establishments licensed under the provisions of this chapter;

(3) Pertaining to establishments licensed under the provisions of this chapter wherein any drug is compounded, prepared, dispensed or sold;

(4) Providing for minimum equipment and standards of establishments licensed under the provisions of this chapter;

(5) Pertaining to the sale of drugs by or through any mechanical device;

(6) In cooperation with other governmental agencies where there exists a joint responsibility for protecting the public health and welfare;

(7) Pertaining to the sale of nonprescription drugs;

(8) To adopt such publications or supplements thereto as shall from time to time be deemed necessary to describe the drugs, medicines, prescription drugs, dispensing physician or other terms used in § 36-11-2;

(9) Pertaining to the posting of prescription prices on the premises of a pharmacy department to provide consumers with comparative pricing information;

(10) Pertaining to registration of drug wholesalers and manufacturers;

(11) Pertaining to home health care and service;

(12) Pertaining to computerized pharmacy;

(13) Pertaining to the registration of registered pharmacy technicians and the suspension or revocation of registration; an annual registration fee not to exceed thirty dollars; and tasks that may not be delegated by a licensed pharmacist to a registered technician;

(14) Redispensing of pharmaceuticals.

Source: SDC 1939, § 27.1006; SL 1967, ch 102, § 7; SL 1973, ch 244, § 2; SL 1986, ch 302, § 111; SL 1990, ch 325, § 1; SL 1997, ch 216, § 2; SL 2004, ch 248, § 2; SL 2004, ch 249, § 1; SL 2012, ch 194, § 10.

36-11-33. Institutional pharmacy permits--Scope of services provided--Minimum standards. The Board of Pharmacy may issue to pharmacists in good standing a permit to conduct a part-time, limited, or conditional pharmacy in hospitals, nursing homes or related facilities provided that the pharmacy services are limited to patients. A permit to conduct a pharmacy, the merchandise and fixtures of which are owned by a person, firm, or corporation other than a registered pharmacist, upon said registered pharmacist making application for a permit hereunder, may be issued and granted to the said registered pharmacist, on compliance with the provisions of this chapter, and with minimum standards as established by the board.

Source: SL 1967, ch 121, § 15.

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ARTICLE 20:51

PHARMACISTS

Chapter	
20:51:01	Registration by examination.
20:51:02	Internship requirements.
20:51:03	Interns in clinical projects, Repealed.
20:51:04	Registration by reciprocity.
20:51:05	Restricted professional practices.
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20:51:15	Pharmacies in hospitals, nursing facilities, or related facilities.
20:51:16	Rules of professional conduct.
20:51:17	Automated mechanical distribution devices.
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20:51:15:02. Pharmaceutical services supervised by pharmacist. All pharmaceutical services shall be performed either by, or under the personal supervision of a registered pharmacist.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986.

General Authority:SDCL 36-11-11.

Law Implemented:SDCL 36-11-33.

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20:51:15:03. Central area to be licensed as a pharmacy. The central area in a hospital, nursing facility, and related facilities where drugs are procured, stored, and issued, and where pharmaceutical services are performed shall be licensed as a pharmacy and by appropriate sign must be designated by that name and no other. The pharmacy must meet all requirements of South Dakota and federal law and the rules of the South Dakota Board of Pharmacy and shall have a registered pharmacist in charge of the pharmacy.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986.

General Authority:SDCL 36-11-11.

Law Implemented:SDCL 36-11-33.

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20:51:15:04. Dispensing limited to pharmacist. The act of dispensing is limited to a registered pharmacist and may not be performed by any other person except under the personal supervision of a registered pharmacist.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986.

General Authority:SDCL 36-11-11.

Law Implemented:SDCL 36-11-33.

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20:51:15:05. Transferring drugs from original containers limited to pharmacists. The act of transferring a drug or preparation from an original container to a new container is an act of dispensing which is restricted to a registered pharmacist.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986.

General Authority:SDCL 36-11-11.

Law Implemented:SDCL 36-11-33.

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20:51:15:06. Removing a single dose from prescription container. Removing a single dose of medication from a prescription container which has been dispensed by a pharmacist to a medicine cup and placing this medicine cup on a tray with appropriate identification constitutes a step in administration of medication.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986.

General Authority:SDCL 36-11-11.

Law Implemented:SDCL 36-11-33.

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20:51:15:07. Preparing a solution. The preparation of a solution by a licensed nurse for injection by a licensed nurse is considered a step in administration of medication.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986.

General Authority:SDCL 36-11-11.

Law Implemented:SDCL 36-11-33.

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20:51:15:08. Medication floor stocks. Licensed hospitals and intensive care units having an organized medical staff, may maintain necessary floor stocks of medications at the nurses' station.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986.

General Authority:SDCL 36-11-11.

Law Implemented:SDCL 36-11-33.

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20:51:15:09. Filling or refilling of nursing station containers limited to pharmacists. The filling or refilling of a nursing station medication container, or container from other service areas where medications are stocked, with the drug called for, or the furnishing of a medication to such area, is dispensing and can be engaged in legally only by a licensed pharmacist under South Dakota pharmacy law.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986.

General Authority:SDCL 36-11-11.

Law Implemented:SDCL 36-11-33.

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20:51:15:10. Registration and renewal. The board may issue to a pharmacist in good standing a permit to conduct a part-time, limited, or conditional pharmacy in a hospital, nursing facility, or related facility for the fiscal year ending June thirtieth if the pharmacist applies yearly on a form supplied by the board and pays a fee of $160.

Source: SL 1975, ch 16, § 1; 2 SDR 56, effective February 11, 1976; 4 SDR 85, effective June 19, 1978; 11 SDR 151, effective May 15, 1985; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 24 SDR 160, effective May 26, 1998.

General Authority:SDCL 36-11-11(4), 36-11-32.

Law Implemented:SDCL 36-11-33.

Cross-Reference: Pharmacy registration, ch 20:51:06; Minimum equipment requirements, ch 20:51:07.

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20:51:15:11. Schedule of attendance by pharmacist. A registered pharmacist employed or otherwise engaged to supply pharmaceutical services may have a flexible schedule of attendance, but the pharmacist must be present for a sufficient number of hours weekly to maintain an adequate supply of medications at the several service areas from which medications are administered, to maintain all required records, to perform other services permitted or required by law, and to provide adequate control over all pharmaceutical services rendered by the hospital, nursing facility, or related facilities.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986.

General Authority:SDCL 36-11-11.

Law Implemented:SDCL 36-11-33.

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20:51:15:12. Supervision of drugs located in areas other than pharmacy. Drugs, medications and poisons located in areas of the facility other than in the pharmacy shall be under the general supervision of the registered pharmacist employed or otherwise engaged.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986.

General Authority:SDCL 36-11-11.

Law Implemented:SDCL 36-11-33.

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20:51:15:13. Access to pharmacy -- Records. Only a registered pharmacist may have access to the pharmacy stock of drugs in the hospital, nursing facility, or related facilities. However, when the pharmacist is absent from the hospital or other like facility, a registered nurse designated by the hospital may obtain from a hospital pharmacy stock of drugs a unit dose of a drug or medication necessary to administer to a bona fide patient in carrying out treatment and medication orders as prescribed by a licensed physician when the drug is not available in floor supplies or the emergency drug kit, to meet the immediate need in an emergency. This nurse shall leave in the pharmacy, on a suitable form, a record of any drugs removed, showing the name of the patient, the name of the drug, dosage size, amount taken, the date and the time, and signed by the nurse. Further, the nurse shall leave with the record the container from which the emergency dose was taken for drug administration purposes in order that it may be properly checked by the pharmacist. Such records shall be kept for three years.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986.

General Authority:SDCL 36-11-11.

Law Implemented:SDCL 36-11-33.

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20:51:15:14. Pharmacy must be in a separate room. The pharmacy must be in a separate room and locked at all times when the registered pharmacist is not on duty.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986.

General Authority:SDCL 36-11-11.

Law Implemented:SDCL 36-11-33.

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20:51:15:15. Pharmacist controls emergency drugs in health care facilities. A pharmacist of a registered pharmacy in a health care facility may provide, upon written request of the health care facility's physicians, a defined supply of legend drugs in an emergency drug kit or crash cart. The emergency drugs shall meet the immediate therapeutic needs of a patient to prevent harm to the patient due to a delay in obtaining such drugs from the pharmacy. The emergency drugs shall remain the property of the registered pharmacy and shall be stored on-site in a suitable controlled location in the health care facility. The emergency drug supplies shall comply with the following requirements:

(1) The facility's registered pharmacist controls the emergency drugs contained in an emergency kit or crash cart;

(2) Drug quantities are limited, properly labeled, and supplied in single dose packaging, if possible;

(3) All legend drugs used for an emergency shall be identified for replacement by a pharmacist;

(4) The pharmacist or the pharmacist's employee shall inventory the contents of the emergency drug supply after each reported use or at least monthly.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 26 SDR 92, effective January 6, 2000.

General Authority:SDCL 36-11-11(1)(4).

Law Implemented:SDCL 36-11-33.

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20:51:15:15.01. Pharmacist controls emergency kit in nursing facility. A registered pharmacist may provide to a nursing facility a limited quantity of controlled legend drugs pursuant to § 44:04:08:07.01 and a limited amount of noncontrolled legend drugs and nonprescription drugs, for emergency and supportive treatment, when requested in writing by the medical director The pharmacist shall retain control of all medications provided in emergency kits.

The provider pharmacist shall comply with the following requirements:

(1) The provider pharmacy shall provide to the Board of Pharmacy yearly the name of each nursing facility where emergency drugs are kept and stored;

(2) The medical director and provider pharmacist shall jointly determine and prepare a limited list of emergency drugs by identity and quantity;

(3) Noncontrolled legend drugs in the emergency kit shall be limited to the extent possible with the following requirements:

(a) No more than 30 different noncontrolled legend drugs, up to a 24-hour supply shall be stocked, not counting oral antibiotics; and

(b) An unlimited number of oral antibiotics may be stocked;

(4) The provider pharmacist shall review all first dose antibiotic drug orders prior to administration to the patient from the emergency kit;

(5) The provider pharmacist shall be notified of any drug taken from the emergency kit;

(6) The provider pharmacist or the pharmacist's employee shall inventory the contents of the emergency kit after reported use or at least monthly;

(7) The emergency kit shall be stored in a suitable, controlled location in the nursing facility to prevent the unauthorized access and preservation of the drugs within it. The emergency kit exterior shall be labeled clearly, and unmistakably, that it is an emergency kit and is for emergency use only. The emergency kit shall contain the name, strength, quantity, and expiration date of drugs contained therein.

All other controlled and noncontrolled legend medications shall be obtained from a pharmacy licensed to distribute to patients pursuant to SDCL 34-12B-1 and 34-12B-2.

Source: 26 SDR 92, effective January 6, 2000.

General Authority:SDCL 36-11-11(1)(4).

Law Implemented:SDCL 36-11-33.

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20:51:15:16. Minimum standards for pharmacy service. Pharmacy service pursuant to pharmacy permits issued under this section, shall be rendered in accordance with pages 119 to 128, inclusive, pharmaceutical services, of Accreditation Manual for Hospitals, 1985 edition, Joint Commission on Accreditation of Hospitals.

Source: SL 1975, ch 16, § 1; 12 SDR 86, effective November 27, 1985; 12 SDR 151, 12 SDR 155, effective July 1, 1986.

General Authority:SDCL 36-11-11.

Law Implemented:SDCL 36-11-33.

Reference: Accreditation Manual for Hospitals, 1985 edition, 237 pages, is published by the Joint Commission on Accreditation of Hospitals, 875 North Michigan Avenue, Chicago, Illinois 60611. Current cost is $40.

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20:51:15:17. Federal and state statutes control. Repealed.

Source: SL 1975, ch 16, § 1; repealed, 12 SDR 86, effective November 27, 1985.

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Tenn. Code Ann. § 63-10-204 (Copy w/ Cite) Pages: **8**

Tenn. Code Ann. § 63-10-204

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*** CURRENT THROUGH THE 2011 REGULAR SESSION ***

Title 63 Professions Of The Healing Arts
Chapter 10 Pharmacy
Part 2 Pharmacy Practice

Tenn. Code Ann. § 63-10-204 (2012)

63-10-204. Definitions.

As used in parts 2-5 of this chapter, unless the context otherwise requires:

(1) "Administer" means the direct application of a drug to a patient or research subject by injection, inhalation, ingestion, topical application or by any other means;

(2) "Board" means the Tennessee board of pharmacy;

(3) "Certification" means a voluntary process by which a practitioner's training, experience and knowledge are identified as meeting or surpassing a standard, defined or approved by the board beyond that required for licensure or registration;

(4) "Compounding" means the preparation, mixing, assembling, packaging or labeling of a drug or device:

(A) As the result of a prescription order or initiative based on the prescriber-patient-pharmacist relationship in the course of professional practice;

(B) In anticipation of prescription orders based on routine, regularly observed prescribing patterns; or

(C) For the purpose of, or as an incident to, research, teaching or chemical analysis and not for sale or dispensing;

(5) "Continuing education" means planned, organized learning experiences and activities beyond the basic educational or preparatory program. These learning experiences and activities are designed to promote the continuous development of skills, attitudes and knowledge necessary to maintain proficiency, provide quality service or products, be responsive to needs and keep abreast of significant change;

(6) "Continuous quality improvement program" means a system of standards and procedures to identify and evaluate quality-related events and to improve patient care;

(7) "Controlled substance" means a drug, substance or immediate precursor identified, defined or listed in title 39, chapter 17, part 4 and title 53, chapter 11;

(8) "Deliver" or "delivery" means the actual, constructive or attempted transfer from one person to another whether or not there is an agency relationship;

(9) "Device" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article, including any component part or accessory, that is required under federal or state law to be ordered or prescribed by a person duly authorized;

(10) "Dietary supplement" means a product, other than tobacco, intended to supplement the diet that bears or contains one (1) or more of the following ingredients: a vitamin, mineral, herb or other botanical, amino acid, dietary substance for use by humans to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract or combination of any of these ingredients and any other products designated as dietary supplements by federal or state law;

(11) "Director" means the director of the health related boards;

(12) "Dispense" means preparing, packaging, compounding or labeling for delivery and actual delivery of a prescription drug, nonprescription drug or device in the course of professional practice to a patient or the patient's agent by or pursuant to the lawful order of a prescriber;

(13) "Distribute" means the delivery of a drug or device, other than by administering or dispensing, to persons other than the patient or the patient's agent;

(14) "Division" means the division of health related boards;

(15) "Doctor of pharmacy" means a person duly licensed by the board to engage in the practice of pharmacy. "Doctor of pharmacy" and "pharmacist" shall be used interchangeably within parts 4-6 of this chapter and, any other provision of Tennessee Code Annotated and in any rule or regulation promulgated by the state of Tennessee and its agencies;

(16) "Drug" means any of the following:

(A) Articles recognized as drugs or drug products in any official compendium or supplement thereto;

(B) Articles, other than food, intended to affect the structure or function of the body of humans or other animals;

(C) Articles, including radioactive substances, intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans or other animals; or

(D) Articles intended for use as a component of any articles specified in this subdivision (16);

(17) "Executive director" means the executive director of the Tennessee board of pharmacy;

(18) "Label" means any written, printed or graphic matter on the immediate container of a drug or device;

(19) "Labeling" means the process of affixing all labels and other written, printed or graphic matter:

(A) Upon any article or any of its containers or wrappers; or

(B) Accompanying such article;

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*** CURRENT THROUGH THE 2011 REGULAR SESSION ***

Title 63 Professions Of The Healing Arts
Chapter 10 Pharmacy
Part 3 Board of Pharmacy

Tenn. Code Ann. § 63-10-304 (2012)

63-10-304. Enforcement of pharmaceutical laws -- Rules and regulations.

(a) It is the duty of the board to enforce all the laws of the state now or hereafter enacted that pertain to the practice of pharmacy, the manufacture, distribution or sale of drugs, and the medication use process, including, but not limited to compounding, selection, preparation/production, dispensing/distribution, patient administration, education and monitoring of drugs, devices, chemicals or poisons. The division shall employ for the board the necessary administrative and clerical staff and investigators who are pharmacists to carry out the board's duty to enforce the pharmaceutical laws. The pharmacist investigators shall be authorized to conduct inspections of pharmacies and any other site where drugs, medicines, chemicals, pharmaceuticals or poisons are manufactured, stored, sold, dispensed, distributed or administered and shall conduct investigations of any licensee of the board. The pharmacist investigators may also assist in inspections and investigations undertaken by other health related boards attached to the division, and investigators assigned to these other health related boards may assist pharmacist investigators as appropriate.

(b) (1) The board shall adopt, amend and repeal rules for the proper administration and enforcement of parts 2-5 of this chapter, consistent with such provisions. The rules shall be adopted, amended or repealed in accordance with the Tennessee Uniform Administrative Procedures Act, compiled in title 4, chapter 5.

(2) The board shall adopt rules establishing minimum standards and conditions for operation of a pharmacy.

(3) If the board determines it necessary in order to protect the health and welfare of the citizens of this state, it may adopt rules concerning the practice of pharmacy in this state also applicable to the practice of pharmacy located in another state.

(c) The board also has the power and authority to adopt, amend and repeal rules of professional conduct appropriate to the establishment and maintenance of a high standard of integrity and dignity in the profession of pharmacy.

(d) The board shall meet at least annually and at such other times as it deems necessary to perform its duties under this chapter.

(e) The board shall keep a record of all its proceedings. The board shall issue and maintain a register of all persons to whom licenses have been issued and all renewals and a register of

pharmacists having been designated as a pharmacist-in-charge. The board may maintain a register of pharmacy technicians as necessary to maintain public welfare.

(f) (1) The board is authorized to conduct hearings and issue orders concerning alleged violations of parts 2-5 of this chapter or rules promulgated pursuant to parts 2-5 of this chapter and shall retain jurisdiction over all of its orders to allow, when good cause is established, modification of those orders and the reinstatement or reactivation of any license or certificate that the board revoked or suspended pursuant to those orders.

(2) The board is authorized to petition any circuit or chancery court having jurisdiction of any person who is practicing pharmacy in Tennessee without a valid license or who has violated any of the provisions of parts 2-5 of this chapter or the rules of the board to enjoin that person from continuing to practice within this state.

(3) The director is granted authority to issue subpoenas for witnesses and records and to administer oaths to witnesses.

(g) (1) The board may join professional organizations and associations organized to promote the improvement of the standards of the practice of pharmacy for the protection of the health and welfare of the public.

(2) The board may authorize, subject to the approval of the commissioner, administrative and investigative personnel and board members to attend local, state, regional and national meetings and to perform other necessary functions. These personnel shall be reimbursed for all travel and other necessary expenses, which shall be claimed and paid in accordance with the prevailing travel regulations of state government.

(h) The board has the other duties, powers and authority necessary to enforce parts 2-5 of this chapter.

(i) The board shall adopt rules establishing minimum standards and conditions for receiving, preparing, maintaining, transferring and dispensing of prescription orders.

(j) (1) The board of pharmacy shall regularly notify each holder of a pharmacy or a pharmacist license of changes that are to be implemented or enforced by the board that affect the licensee. These changes shall include newly promulgated or amended statutes, rules, policies or guidelines.

(2) The board of pharmacy shall establish and maintain a link or links on the board of pharmacy web site to the statutes, rules, policies and guidelines that are implemented or enforced by the board and affect the licensee.

(3) The board of pharmacy shall mandate that the licensee maintain at the site of the licensee's practice a copy of the board of pharmacy statutes, rules, policies and guidelines.

HISTORY: Acts 1996, ch. 651, § 11; T.C.A. 63-10-504; Acts 2007, ch. 407, §§ 2, 10-14; 2008, ch. 1072, § 1; 2009, ch. 29, § 1.

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RULES
OF
THE TENNESSEE BOARD OF PHARMACY

CHAPTER 1140-4
INSTITUTIONAL AND ALTERNATE OR ALTERNATIVE INFUSION PHARMACY PRACTICE SITES

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1140-4-.01 APPLICABILITY.

A pharmacy providing products and services to any institutional facility, and alternate or alternative infusion pharmacy practice site, shall be subject to all rules of the board dependent upon services provided.

Authority: *T.C.A. §§63-10-404(2) and (28) and 63-10-504(b)(1) and (2).* ***Administrative History:*** *Original rule filed February 7, 1983; effective March 9, 1983.*

1140-4-.02 PERSONNEL.

(1) Pharmacist in charge. The practice of pharmacy and the performance of pharmacists and supportive pharmacy personnel associated with any institutional facility shall be under the direction, supervision and responsibility of the pharmacist in charge. The pharmacist in charge shall also be responsible for the dispensing, distribution, compounding, storage and the procurement of prescription and nonprescription drugs used throughout the institutional facility. Policies and procedures defining the scope of pharmacy practice and the responsibilities of the pharmacists and supportive personnel, and the safe use and management of drugs, devices and related materials shall be established by the pharmacist in charge. The pharmacist in charge or designee shall participate in the institution's drug policy committees which serve to ensure rational drug use, patient care evaluation processes relating to drug utilization and effectiveness, drug delivery device selection and evaluation systems, and educational activities for the safe and appropriate use of drugs which will assess the quality of services and products provided and document actions taken. Policies and procedures as indicated in this chapter shall be written and shall be made available to the board.

(2) Pharmacists. The pharmacist in charge shall be supported by a sufficient number of pharmacists to provide appropriate practice of pharmacy for the patients served by the institutional facility. Employment of pharmacists by the institutional facility shall be determined by the pharmacist in charge.

(3) Institutional consultant pharmacist. An institutional facility may utilize a consultant pharmacist who may or may not be independent of the pharmacy practice site, who shall provide patient care service which includes, but is not limited to:

(a) development, interpretation, and communication of drug, device and related materials orders and health information;

(Rule 1140-4-.02, continued)

(b) providing consultation on matters pertaining to efficient drug distribution systems, proper drug selection, rational and safe drug use, and drug therapy assessment;

(c) evaluation of a patient's drug therapy to maximize outcome(s), including effective communication with prescribing practitioners and other healthcare professionals;

(d) effective counseling of a patient or a patient's attorney for healthcare or other caregiver;

(e) service on committees or governing bodies; and

(f) providing in service educational programs for members of the healthcare team.

(4) Supportive personnel. The pharmacist in charge shall be assisted by a sufficient number of pharmacy technicians, as defined in 1140-2-.02 pharmacy interns, and other supportive personnel as may be required to operate the pharmacy competently, safely, and adequately to meet the needs of the patients served by the institution.

(5) Supervision. All of the activities associated with the practice of pharmacy and the operations of the pharmacy at a specific institutional pharmacy practice site shall be supervised by a sufficient number of pharmacists to ensure that all functions and activities are performed competently, safely and without risk of harm to patients.

Authority: *T.C.A. §§63-10-404(4), (8), (11), (14), (21), (26), (27), (28), and (30) and 63-10-504(b)(1) and (2).*
Administrative History: *Original rule filed February 7, 1983; effective March 9, 1983.*

1140-4-.03 PHYSICAL REQUIREMENTS.

(1) Area. An institutional or alternative infusion pharmacy practice site shall have sufficient floor space allocated to it to ensure that medical and prescription orders are prepared and dispensed in sanitary, well lighted, and enclosed spaces. The institutional pharmacy shall also have sufficient counter space or other suitable work module to ensure that medical and prescription orders are prepared and dispensed in an orderly manner.

(2) Equipment and Materials. The pharmacy practice site shall have sufficient equipment and physical facilities for the practice of pharmacy. This shall include but not be limited to:

(a) hot and cold running water;

(b) refrigerated storage space;

(c) frozen storage space as appropriate; and

(d) adequate information systems.

(3) Storage. All prescription drugs and devices and related materials shall be stored in designated areas within the pharmacy practice site which are sufficient to ensure proper sanitation, temperature, light, ventilation, moisture control, segregation, and security.

(4) Alcohol and Flammables. Alcohol and flammables shall be stored in an area that shall, at a minimum, meet basic local building code requirements for the storage of volatiles, and such other laws, ordinances, or regulations that may apply.

(5) Security. A pharmacy practice site shall be capable of being locked to prevent access by unauthorized personnel. A pharmacist must be accessible within the institutional facility where an institutional

(Rule 1140-4-.03, continued)

pharmacy practice site is located; and when no pharmacist is present at the institution, the pharmacy practice site must be kept closed and securely locked except as provided in 1140-4-.14.

Authority: *T.C.A. §§63-10-404(8), (14), and (28) and 63-10-504(b)(1) and (2).* ***Administrative History:*** *Original rule filed February 7, 1983; effective March 7, 1983.*

1140-4-.04 PRESCRIPTION ORDERS.

A pharmacist shall review all prescription orders before the drug is first dispensed. In the event that medications available in the institutional facility are ordered and administered before the pharmacist's review, the order shall be reviewed by a pharmacist in a timely manner. The pharmacist shall have access to the patient's medical record. The original order must be maintained in a readily retrievable manner according to the pharmacy practice site policy for at least two (2) years from the date of its issuance.

Authority: *T.C.A. §§63-10-404(1), (11), (14), (26), and (28) and 63-10-504(b)(1) and (2).* ***Administrative History:*** *Original rule filed February 7, 1983; effective March 9, 1983. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

1140-4-.05 DISTRIBUTION AND CONTROL OF DRUGS.

The pharmacist in charge or designee, in conjunction with appropriate committees of the facility, shall be responsible for approving policies for the distribution and control of drugs within the facility. The process shall be established to provide for the safe and efficient distribution of drugs and for the provision of pharmaceutical care, and shall include but not be limited to:

(1) A drug dispensed from the pharmacy for subsequent administration to a patient shall be appropriately identified with the name and location of the patient and the name and strength of the drug.

(2) The pharmacist in charge is responsible for the development and maintenance of an audit trail on drugs dispensed.

(3) The prescription order shall be recorded on a patient medication profile that will be maintained during the patient's treatment. This profile shall include the date of the prescription order, the name and dosage form of the drug and the dose and administration frequency.

(4) The facility distribution system may be based on a combination of processes that will ensure compliance with federal and state guidelines such as emergency kits/crash carts, floorstock systems, automated dispensing devices, medication carts, and/or after-hours procedures for pharmacy site access.

Authority: *T.C.A. §§63-10-404(11), (14), and (27) and 63-10-504(b)(1) and (2).* ***Administrative History:*** *Original rule filed February 7, 1983; effective March 9, 1983. Amendment to rule filed November 16, 1992; effective January 8, 1993. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

1140-4-.06 MEDICATION CARTS.

Drugs distributed from the pharmacy to other areas of the institutional facility may be stored in medicine cabinets or drug carts which shall be kept secured unless in use by the nursing staff or other authorized personnel. Access to the medication cart shall be defined by facility policies. It is recommended that drugs be dispensed in unit dose packaging and medications for each patient shall be distributed and stored in separate trays, drawers, compartments, or containers assigned to that resident and bearing the resident's name and location.

(Rule 1140-4-.06, continued)

Authority: *T.C.A. §§63-10-404(11), (14), and (28) and 63-10-504(b)(1) and (2).* ***Administrative History:*** *Original rule filed February 7, 1983; effective March 9, 1983. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

1140-4-.07 FLOORSTOCK DRUGS.

The pharmacist in charge or designee, in conjunction with appropriate committees, shall be responsible for approving policies and procedures for floorstock at the institutional facility. The policies shall include specific drugs, quantities, prescription order review, storage requirements, and replenishment of drugs, devices, or related materials which are supplied to the institutional facility as floorstock.

Authority: *T.C.A. §§63-10-404(8), (14), and (27) and 63-10-504(b)(1) and (2).* ***Administrative History:*** *Original rule filed February 7, 1983; effective March 9, 1983. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

1140-4-.08 CONTROLLED DRUGS.

(1) Controlled substances (and those drugs deemed by the pharmacist in charge to have a potential for abuse) which are issued as floorstock shall be accounted for by providing documentation of:

(a) the drug name, strength, and dosage form;

(b) the date and time of administration;

(c) the quantity/dose administered;

(d) identification of the patient;

(e) identification of the prescriber; and

(f) identification of the authorized personnel administering the controlled substance.

(2) A record of the destruction of controlled substances previously dispensed to or for patients shall be maintained so as to be readily retrievable for at least two (2) years, and such records shall include:

(a) the identification of patient;

(b) drug name, strength, dosage form, and quantity;

(c) the date and method of destruction; and

(d) the identification of authorized personnel witnessing the destruction and its record.

(3) Schedule II controlled substances which are kept within a pharmacy practice site shall be stored in a secured, substantially constructed cabinet, safe, or other structure which provides a double locked secured system.

(4) Nothing in this rule shall be interpreted to authorize the destruction of controlled substance floorstock or pharmacy stock. Such drugs shall upon request, be destroyed or returned to the pharmacy for destruction by a board approved agent or vendor.

Authority: *T.C.A. §§53-11-302, 63-10-404(11), (14), (27), and (28) and 63-10-504(b)(1) and (2)(j).* ***Administrative History:*** *Original rule filed February 7, 1983; effective March 9, 1983. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

1140-4-.09 EMERGENCY AND HOME CARE KITS.

Drugs and devices and related materials may be provided by emergency kits as defined by policies and procedures provided that such kits meet the following requirements:

(1) Emergency Kits.

(a) Drugs and devices and related materials may be provided by emergency kits as defined by policies and procedures, provided that such kits meet the following requirements:

1. Emergency kit drugs are those drugs which may be required to meet the immediate therapeutic needs of patients and which are not available from any other authorized source in sufficient time to prevent risk of harm to patients. Drugs in this kit are to be used only for emergency orders.

2. The policies and procedures to implement the requirements of this subsection and to approve the contents of the emergency kit will be determined by a committee composed of representatives of the medical and nursing staff and the pharmacist in charge or his/her designee.

3. The emergency kit shall be provided sealed or electronically secured by authorized personnel in accordance with established policies. The expiration date of the kit shall be clearly marked on the exterior of the kit to represent the earliest expiration date of any drug, device, or related materials contained in the kits.

4. Emergency kits shall be stored in a secured area at the institutional facility or patient care site to prevent unauthorized access. To ensure a proper environment for preservation of the drugs contained therein, appropriate policies and procedures shall be written to include storage at the site of patient care.

5. Only authorized individuals may obtain drugs, devices or related materials from the emergency kit in accordance with established policies and state and federal laws and regulations.

6. A list of the emergency kit contents shall be readily accessible and it shall include the drugs, devices, and related materials contained therein and include the name (trade and/or generic), strength, and quantity of the products contained therein.

7. A mechanism must be in place to ensure that the emergency kits are not in use after the expiration date.

8. Drugs contained within the emergency kit shall be properly labeled according to the United States Food and Drug Administration (FDA) labeling requirements for the drug or device and with additional information that may be required by the staff to prevent misunderstanding or risk of harm to the patients.

9. Removal of any drug, device, or related material from the emergency kit shall be pursuant to a valid medical or prescription order and must be documented by established policy which may include patients identification, name of the drug, strength, amount, date, time, and identification of the authorized individual removing the drug.

10. When an emergency kit is opened for any reason, the pharmacy practice site shall be notified, and the kit shall be restocked and resealed within a reasonable time so as to prevent risk of harm to patients.

(Rule 1140-4-.09, continued)

(2) Home Care Kits.

(a) A home care kit is a kit containing certain drugs, as determined by the board, to be kept in the home of the patient for use by a healthcare professional engaged in home healthcare of a patient as necessary to meet the therapeutic needs of patients and which are not available from any other source in sufficient time to prevent risk of harm to patients.

1. A home care kit may contain:

(i) Sodium Chloride for Injection 0.9% Bacteriostatic

(ii) Sterile Water for injection Bacteriostatic or Preservative Free

(iii) Epinephrine injection 1mg/ml

(iv) Diphenhydramine

(v) Heparin Flush <or = 100units/ml

(vi) Naloxone

(vii) Sodium Chloride for Irrigation

(viii) Sterile Water for Irrigation

(ix) Dextrose 50%

(x) Urokinase 5000units

(xi) Any other legend drug as approved by the board.

(b) Drugs contained in home care kits are to be used for emergencies only. Maintenance of a central venous catheter is considered an emergency if confirmed with the patient's physician or his/her designee.

(c) Policies and procedures for the dispensing, use, storage at the patient care site, security and expiration date review, and reconciliation of drug contents shall be determined as in section (1)(a)2 of this rule. Additional policies or protocols for treating anaphylactic reaction, maintaining patency of intravenous or central venous catheters, or flushing of intravenous devices shall be established, in the same manner.

(d) Removal of any drug from the Home Care Kit shall be pursuant to a valid medical or prescription order and/or protocol and must be documented in the patient's medical record.

(e) When a home care kit is opened for any reason, the pharmacy practice site shall be notified and the kit shall be restocked and resealed within a reasonable time so as to prevent risk of harm to patients.

Authority: *T.C.A. §§63-10-504 and 63-10-504(b)(1) and (2).* ***Administrative History:*** *Original rule filed February 7, 1983; effective March 9, 1983. Repeal and new rule filed May 11, 1998; effective July 25, 1998. Amendment filed August 19, 2002; effective November 2, 2002.*

1140-4-.10 UNUSED DRUGS, DEVICES, AND RELATED MATERIALS.

Discontinued, outdated, defective, or deteriorated drugs, devices, or related materials and containers with worn, illegible, or missing labels shall be returned to the pharmacy practice site for proper disposition. All such drugs, devices or related materials returned to the pharmacy practice site must be destroyed unless in unit dose packaging, unopened commercially prepackaged containers and in the professional judgment of the pharmacist in charge or designee, the medications or related materials meet all federal and state board standards for product integrity.

Authority: *T.C.A. §§63-10-404(8), (14), (16), (28) and 63-10-504(b)(1) and (2).* ***Administrative History:*** *Original rule filed February 7, 1983; effective March 9, 1983; effective March 9, 1983. Repeal and rule filed May 11, 1998; effective July 25, 1998.*

1140-4-.11 TAKE-HOME AND LEAVE OF ABSENCE DRUGS, DEVICES, AND RELATED MATERIALS.

(1) All prescription drugs prescribed for and dispensed to patients who are on leave of absence from the institutional facility must be dispensed in accordance with the institution's policies and procedures.

(2) All prescription drugs prescribed for and dispensed to patients who are being discharged from the institutional facility must be dispensed with labeling in accordance with 1140-3-.06.

(3) The pharmacist in charge in coordination with the medical and nursing staff committees of the facility shall establish policies and procedures to assure that this process meets state and federal guidelines appropriate for the facility.

Authority: *T.C.A. §§63-10-404(11), (14), (16), and (27) and 63-10-504(b)(1) and (2).* ***Administrative History:*** *Original rule filed February 7, 1983; effective March 9, 1983. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

1140-4-.12 DRUGS BROUGHT INTO THE FACILITY.

(1) The pharmacist in charge shall establish policies to control any drugs brought into the institutional facility.

(2) Administration of these drugs shall be pursuant to a medical or prescription order.

(3) Drugs brought into the facility shall not be administered until properly identified.

(4) Drugs which are not to be administered shall be packaged, sealed, and returned to an adult member of the patient's family for removal from the institutional facility or the drugs shall be securely stored and returned to the patient at discharge per facility policy.

Authority: *T.C.A. §§63-10-404(14), (19), (27), and (34) and 63-10-504(b)(1) and (2).* ***Administrative History:*** *Original rule filed February 7, 1983; effective March 9, 1983. Amendment filed December 17, 1984; effective March 16, 1985. Amendment filed August 30, 1991; effective November 27, 1991.*

1140-4-.13 RECALLS.

The recall procedure shall be readily activated to ensure that all prescription drugs and devices and related materials included on the recall are returned to the pharmacy practice site for proper disposition. The pharmacist in charge shall develop and implement policies and procedures for recalls.

Authority: *T.C.A. §§63-10-404(8), (14), (27), and (28) and 63-10-504(b)(1) and (2).* ***Administrative History:*** *Original rule filed February 7, 1983; effective March 9, 1983. Amendment field August 30, 1991; effective November 27, 1991. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

1140-4-.14 ABSENCE OF PHARMACIST.

(1) Institutional pharmacy practice site.

(a) General. During such times as an institutional pharmacy practice site is closed, facility policy as approved by the pharmacist in charge shall provide a process for authorized personnel to obtain drugs necessary for the provision of patient care. This function may also be accomplished as outlined in the After Hours Drug Provision of this section. A pharmacist must be "on call" twenty four (24) hours per day, seven (7) days per week.

(b) After Hours Drug Provision. When an institutional pharmacy practice site is closed, access to prescription drugs shall be by locked cabinet(s), automated dispensing machines or other enclosure(s) constructed and located outside of the pharmacy practice site, to which only personnel authorized by the pharmacist in charge may obtain access. Access should be sufficiently secured to deny entry to unauthorized persons by force or otherwise. Those practice sites utilizing automated dispensing devices for after hours drug provision shall meet the requirements of rule 1140-4-.15. The pharmacist in charge shall develop an inventory listing of those drugs to be included in such after hours storage, and shall ensure that:

1. such prescription drugs are available therein, properly labeled;

2. such prescription drugs are prepackaged in amounts not to exceed a seventy-two (72) hour medication period; unless available in a commercially prepared package dictating multiple dose therapy (e.g., ophthalmic products, topical products, otic products);

3. all prescription drugs therein are inventoried at least once a month;

4. a record shall be made at the after hours storage location including the following elements:

(i) the date and time of removal of a drug;

(ii) the patient's name and location;

(iii) the name, strength, dosage form, and quantity of the prescription drug; and

(iv) the identification of the authorized personnel removing the drug.

5. the prescription order shall be verified by a pharmacist or designee in a timely manner.

6. the above record shall be used by authorized pharmacy personnel to replenish the after hours storage location, and this record shall be kept at the institutional pharmacy practice site so as to be readily retrievable for at least two (2) years;

7. policies and procedures shall be established to implement the requirements of this section.

(c) Access to the Pharmacy Practice Site within an Institutional Facility. Whenever any prescription drug is not available from floor supplies, emergency kits, or other approved distribution system for the facility, and such prescription drug or device or related material is required to treat the immediate needs of a patient whose health would otherwise be jeopardized, such prescription drug, device or related material may be obtained from the pharmacy practice site in accordance with the requirements of this paragraph. Only authorized personnel, accompanied by a security guard or other authorized employee of the institution may have access to the pharmacy practice site and may remove the required drug, device or related material. Such person(s) shall be designated through policies of the facility and shall receive

(Rule 1140-4-.14, continued)

appropriate education and training in the proper methods of access and removal of prescription drugs, records and procedures required prior to such person(s) being permitted to obtain access to the pharmacy practice site. Such education and training shall be conducted by the pharmacist in charge or designee, who shall require, at a minimum, the following records and procedures;

1. Removal of any prescription drug, device or related material from the pharmacy practice site by an authorized person(s) must be recorded in a suitable form at the pharmacy practice site showing:

   (i) the date and time of removal of the drug;

   (ii) patient identification and location;

   (iii) the name, strength, dosage form, and quantity of the drug, device or related material removed; and

   (iv) the signatures of the authorized personnel and the accompanying witness;

2. The above record shall be maintained at least two (2) years at the pharmacy practice site in a separate file or log book;

3. The medication or prescription order shall be verified by a pharmacist or authorized personnel; and

4. The quantity of drug removed shall not exceed the amount needed plus one (1) dose until the pharmacy practice site reopens; unless available in a commercially prepared package dictating multiple dose therapy (e.g., ophthalmic products, topical products, otic products).

(2) Alternate or Alternative Infusion pharmacy practice site.

(a) During such times as an alternate or alternative infusion pharmacy practice site is closed, policies and procedures shall be established by the pharmacist in charge for the provision of prescription drugs, devices and related materials to patients on a twenty four (24) hours per day seven (7) days per week basis.

(b) A pharmacist must be "on call" during all absences.

Authority: *T.C.A. §§63-10-404(11), (14), (15), (19), (26), (27), (28), and (34) and 63-10-504(b)(1) and (2).* ***Administrative History:*** *Original rule filed February 7, 1983; effective March 9, 1983. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

1140-4-.15 AUTOMATED DISPENSING DEVICES IN INSTITUTIONAL PRACTICE SITES.

No prescription drug or device or related material shall be distributed or issued by the use of any automated dispensing device unless the device and the method of operation have been found by the board to ensure the purity, potency, and integrity of the prescription drug or device or related material, and to protect the prescription drug or device or related material from diversion.

(1) A pharmacist shall be designated to be accountable for this automated dispensing system.

(a) Individuals authorized by the facility policies and the pharmacist in charge will stock this device under the supervision of a pharmacist, if a pharmacist is not stocking the device.

(Rule 1140-4-.15, continued)

(b) The pharmacist will work collaboratively with healthcare professionals to ensure that appropriate controls and monitors are utilized to provide information that drugs dispensed were for the correct patient and that pilferage is identified and resolved.

(2) All persons authorized to have access to these automated devices shall have documentation that they have successfully completed a training program that teaches them to perform the functions they perform with the automated device.

(3) Automated dispensing systems shall be used only for the furnishing of drugs and devices and related materials or other products related to the care of patients of that institution or facility; and

(4) At the time of removal of any drug or device or related material from the device, it shall automatically make a record, to be retained by the pharmacy for a minimum of two (2) years, indicating:

(a) the date and time of removal of the drug or device or related material;

(b) the name, strength, dosage form, and quantity of drugs or devices or related material removed;

(c) the identification of the patient for whom the drug or device or related material was ordered; and

(d) the identification of the person authorized to remove the drug or device or related material from the device.

(5) The pharmacist in charge or designee is responsible for determining how access codes or other methods of access to automated devices are assigned.

(6) The facility shall have policies and procedures approved by the pharmacist in charge in coordination with members of the nursing and medical staff for the points outlined in this section for automated dispensing devices.

Authority: *T.C.A. §§63-10-404(8), (11), (14), (26), and (27) and 63-10-504(b)(1) and (2).* ***Administrative History:*** *Original rule filed February 7, 1983; effective March 9, 1983. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

1140-4-.16 EMERGENCY ROOMS.

If prescription drugs, devices and related materials in an emergency room are to be dispensed (other than by pharmacy staff) rather than administered, the drugs, devices or related materials must be dispensed by the physician or an emergency room nurse or certified physician assistant at the direction of a physician. If the physician in an emergency room does not personally dispense, then prescription drugs, devices and related materials for outpatient use must be packaged in containers from the pharmacy practice site in amounts not to exceed a twelve (12) hour period or with products commercially prepared for multiple dose therapy (e.g., ophthalmic products, topical products, otic drops) in the smallest available package. These prescription drugs, devices or related materials shall be dispensed only after a medical or prescription order has been issued and recorded in the emergency room and shall be labeled with appropriate labeling.

Authority: *T.C.A. §§63-10-404(1), (8), (11), (15), (19), (28), and (34) and 63-10-504(b)(1) and (2).* ***Administrative History:*** *Original rule filed February 7, 1983; effective March 9, 1983. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

1140-4-.17 INVESTIGATIONAL DRUGS.

The pharmacist in charge in coordination with the institutional facility, medical and nursing staff and, if appropriate, the pharmaceutical manufacturer, shall develop policies and procedures for the approval, management, distribution

(Rule 1140-4-.17, continued)

and control of investigational drug studies. The process shall ensure that such studies contain safeguards for the patient, for the institution and for the scientific integrity of the study. Each patient or the patient's legal guardian must freely consent, in writing, to treatment with the drugs, unless otherwise not required by federal law. The pharmacist is responsible to the institution and to the principal investigator for seeing that procedures for the control of investigational drugs are developed and implemented when needed.

Authority: *T.C.A. §§63-10-404(14) and (26) and 63-10-504(b)(1) and (2).* ***Administrative History:*** *Original rule filed February 7, 1983; effective March 9, 1983. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

1140-4-.18 MONTHLY INSPECTIONS.

The pharmacist in charge shall be responsible (personally or by qualified designee) for documented monthly inspections of all drugs, devices and related materials kept at nursing stations, surgery, delivery rooms, emergency rooms, clinics, and any other area of the facility. Records of such inspections shall be dated, signed and maintained so as to be readily retrievable at the pharmacy practice site for at least two (2) years. These inspections must assure the following:

(1) test reagents, germicides, and disinfectants are stored separately from drugs, devices and related materials;

(2) external drugs, devices and related materials are stored separately from internal drugs, devices and related materials;

(3) thermolabile drugs are stored at the proper temperature;

(4) drugs, devices and related materials requiring special storage conditions to ensure their stability are properly stored;

(5) there are no outdated or deteriorated drugs, devices or related materials;

(6) all drugs, devices and related materials are properly labeled;

(7) emergency drugs, devices and related materials are stored in accordance with rule 1140-4-.10;

(8) medicine cabinets, carts and storage areas are accessible to authorized personnel only;

(9) dispensing of controlled substances is properly and adequately documented;

(10) telephone numbers of regional poison control centers and other emergency assistance organizations are posted;

(11) metric-apothecaries' weight and measure conversion tables and charts are available; and

(12) adequate pharmaceutical references for the drugs administered in that location are available.

Authority: *T.C.A. §§63-10-404(8) (14), and (28) and 63-10-504(b)(1) and (2).* ***Administrative History:*** *Original rule filed February 7, 1983; effective March 9, 1983. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

OCCUPATIONS CODE
TITLE 3. HEALTH PROFESSIONS
SUBTITLE J. PHARMACY AND PHARMACISTS
CHAPTER 560. LICENSING OF PHARMACIES
SUBCHAPTER A. LICENSE REQUIRED

Sec. 560.053. ESTABLISHMENT OF ADDITIONAL PHARMACY CLASSIFICATIONS. The board by rule may establish classifications of pharmacy licenses in addition to the classifications under Section 560.051 if the board determines that:

(1) the practice setting will provide pharmaceutical care services to the public;

(2) the existing classifications of pharmacy licenses are not appropriate for that practice setting; and

(3) establishment of a new classification of pharmacy license is necessary to protect the public health, safety, and welfare.

Added by Acts 2003, 78th Leg., ch. 941, Sec. 2, eff. Sept. 1, 2003.

SUBCHAPTER C. RESTRICTIONS ON LICENSE

Sec. 560.101. LICENSE NOT TRANSFERABLE. A pharmacy license issued under this chapter is not transferable or assignable.

Acts 1999, 76th Leg., ch. 388, Sec. 1, eff. Sept. 1, 1999.

Texas Administrative Code

TITLE 22	EXAMINING BOARDS
PART 15	TEXAS STATE BOARD OF PHARMACY
CHAPTER 291	PHARMACIES
SUBCHAPTER D	INSTITUTIONAL PHARMACY (CLASS C)

Rules

§291.71 Purpose
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TITLE 22	EXAMINING BOARDS
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SUBCHAPTER D	INSTITUTIONAL PHARMACY (CLASS C)
RULE §291.71	**Purpose**

The purpose of these sections is to provide standards in the conduct, practice activities, and operation of a pharmacy located in a hospital or other inpatient facility that is licensed under the Texas Hospital Licensing Law, the Health and Safety Code, Chapter 241, or the Texas Mental Health Code, Chapter 6, Texas Civil Statutes, Article 5547-1 et seq., or a pharmacy located in a hospital maintained or operated by the state. The intent of these standards is to establish a minimum acceptable level of pharmaceutical care to the patient so that the patient's health is protected while contributing to positive patient outcomes.

Source Note: The provisions of this §291.71 adopted to be effective April 23, 1982, 7 TexReg 1469; amended to be effective September 14, 1988, 13 TexReg 4318; amended to be effective September 5, 1990, 15 TexReg 4810; amended to be effective March 16, 1995, 20 TexReg 1543.

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SUBCHAPTER D	INSTITUTIONAL PHARMACY (CLASS C)
RULE §291.72	**Definitions**

The following words and terms, when used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise.

(1) Accurately as prescribed--Distributing and/or delivering a medication drug order:

(A) to the correct patient (or agent of the patient) for whom the drug or device was prescribed;

(B) with the correct drug in the correct strength, quantity, and dosage form ordered by the practitioner; and

(C) with correct labeling as ordered by the practitioner and required by rule.

(2) Act--The Texas Pharmacy Act, Chapters 551 - 566 and 568 - 569, Occupations Code, as amended.

(3) Administer--The direct application of a prescription drug by injection, inhalation, ingestion, or any other means to the body of a patient by:

(A) a practitioner, an authorized agent under his supervision, or other person authorized by law; or

(B) the patient at the direction of a practitioner.

(4) Automated compounding or counting device--An automated device that compounds, measures, counts and/or packages a specified quantity of dosage units of a designated drug product.

(5) Automated medication supply system--A mechanical system that performs operations or activities relative to the storage and distribution of medications for administration and which collects, controls, and maintains all transaction information.

(6) Board--The State Board of Pharmacy.

(7) Clinical Pharmacy Program--An ongoing program in which pharmacists are on duty during the time the pharmacy is open for pharmacy services and pharmacists provide direct focused, medication-related care for the purpose of optimizing patients' medication therapy and achieving definite outcomes, which includes the following activities:

(A) prospective medication therapy consultation, selection, and adjustment;

(B) monitoring laboratory values and therapeutic drug monitoring;

(C) identifying and resolving medication-related problems; and

(D) disease state management.

(8) Confidential record--Any health-related record that contains information that identifies an individual and that is maintained by a pharmacy or pharmacist, such as a patient medication record, prescription drug order, or medication drug order.

(9) Consultant pharmacist--A pharmacist retained by a facility on a routine basis to consult with the facility in areas that pertain to the practice of pharmacy.

(10) Controlled substance--A drug, immediate precursor, or other substance listed in Schedules I - V or Penalty Groups 1 - 4 of the Texas Controlled Substances Act, as amended, or a drug, immediate precursor, or other substance included in Schedules I - V of the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended (Public Law 91-513).

(11) Dangerous drug--A drug or device that:

(A) is not included in Penalty Group 1, 2, 3, or 4, Chapter 481, Health and Safety Code, and is unsafe for self-medication; or

(B) bears or is required to bear the legend:

(i) "Caution: federal law prohibits dispensing without prescription" or "Rx only" or another legend that complies with federal law; or

(ii) "Caution: federal law restricts this drug to use by or on the order of a licensed veterinarian."

(12) Device--An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component part or accessory, that is required under federal or state law to be ordered or prescribed by a practitioner.

(13) Direct copy--Electronic copy or carbonized copy of a medication order, including a facsimile (FAX) or digital image.

(14) Dispense--Preparing, packaging, compounding, or labeling for delivery a prescription drug or device in the course of professional practice to an ultimate user or his agent by or pursuant to the lawful order of a practitioner.

(15) Distribute--The delivery of a prescription drug or device other than by administering or dispensing.

(16) Distributing pharmacist--The pharmacist who checks the medication order prior to distribution.

(17) Downtime--Period of time during which a data processing system is not operable.

(18) Drug regimen review--

(A) An evaluation of medication orders and patient medication records for:

(i) known allergies;

(ii) rational therapy--contraindications;

(iii) reasonable dose and route of administration;

(iv) reasonable directions for use;

(v) duplication of therapy;

(vi) drug-drug interactions;

(vii) drug-food interactions;

(viii) drug-disease interactions;

(ix) adverse drug reactions; and

(x) proper utilization, including overutilization or underutilization.

(B) The drug regimen review may be conducted prior to administration of the first dose (prospective) or after administration of the first dose (retrospective).

(19) Electronic signature--A unique security code or other identifier which specifically identifies the person entering information into a data processing system. A facility which utilizes electronic signatures must:

(A) maintain a permanent list of the unique security codes assigned to persons authorized to use the data processing system; and

(B) have an ongoing security program which is capable of identifying misuse and/or unauthorized use of electronic signatures.

(20) Expiration date--The date (and time, when applicable) beyond which a product should not be used.

(21) Facility--

(A) a hospital or other patient facility that is licensed under Chapter 241 or 577, Health and Safety Code;

(B) a hospice patient facility that is licensed under Chapter 142, Health and Safety Code;

(C) an ambulatory surgical center licensed under Chapter 243, Health and Safety Code; or

(D) a hospital maintained or operated by the state.

(22) Floor stock--Prescription drugs or devices not labeled for a specific patient and maintained at a nursing station or other hospital department (excluding the pharmacy) for the purpose of administration to a patient of the facility.

(23) Formulary--List of drugs approved for use in the facility by the committee which performs the

pharmacy and therapeutics function for the facility.

(24) Full-time pharmacist--A pharmacist who works in a pharmacy from 30 to 40 hours per week or if the pharmacy is open less than 60 hours per week, one-half of the time the pharmacy is open.

(25) Hard copy--A physical document that is readable without the use of a special device (i.e., data processing system, computer, etc).

(26) Hot water--The temperature of water from the pharmacy's sink maintained at a minimum of 105 degrees F (41 degrees C).

(27) Institutional pharmacy--Area or areas in a facility where drugs are stored, bulk compounded, delivered, compounded, dispensed, and distributed to other areas or departments of the facility, or dispensed to an ultimate user or his or her agent.

(28) Investigational new drug--New drug intended for investigational use by experts qualified to evaluate the safety and effectiveness of the drug as authorized by the Food and Drug Administration.

(29) Medical Practice Act--The Texas Medical Practice Act, Subtitle B, Occupations Code, as amended.

(30) Medication order--A written order from a practitioner or a verbal order from a practitioner or his authorized agent for administration of a drug or device.

(31) Part-time pharmacist--A pharmacist either employed or under contract, who routinely works less than full-time.

(32) Patient--A person who is receiving services at the facility (including patients receiving ambulatory procedures and patients conditionally admitted as observation patients), or who is receiving long term care services or Medicare extended care services in a swing bed on the hospital premise or an adjacent, readily accessible facility that is under the authority of the hospital's governing body. For the purposes of this definition, the term "long term care services" means those services received in a skilled nursing facility which is a distinct part of the hospital and the distinct part is not licensed separately or formally approved as a nursing home by the state, even though it is designated or certified as a skilled nursing facility. A patient includes a person confined in any correctional institution operated by the state of Texas.

(33) Perpetual inventory--An inventory which documents all receipts and distributions of a drug product, such that an accurate, current balance of the amount of the drug product present in the pharmacy is indicated.

(34) Pharmaceutical care--The provision of drug therapy and other pharmaceutical services intended to assist in the cure or prevention of a disease, elimination or reduction of a patient's symptoms, or arresting or slowing of a disease process.

(35) Pharmacist-in-charge--Pharmacist designated on a pharmacy license as the pharmacist who has the authority or responsibility for a pharmacy's compliance with laws and rules pertaining to the practice of pharmacy.

(36) Pharmacy and therapeutics function--Committee of the medical staff in the facility which assists

in the formulation of broad professional policies regarding the evaluation, selection, distribution, handling, use, and administration, and all other matters relating to the use of drugs and devices in the facility.

(37) Pharmacy technician--An individual who is registered with the board as a pharmacy technician and whose responsibility in a pharmacy is to provide technical services that do not require professional judgment regarding preparing and distributing drugs and who works under the direct supervision of and is responsible to a pharmacist.

(38) Pharmacy technician trainee--An individual who is registered with the board as a pharmacy technician trainee and is authorized to participate in a pharmacy's technician training program.

(39) Pre-packaging--The act of re-packaging and re-labeling quantities of drug products from a manufacturer's original container into unit-dose packaging or a multiple dose container for distribution within the facility except as specified in §291.74(f)(3)(B) of this title (relating to Operational Standards).

(40) Prescription drug--

(A) A substance for which federal or state law requires a prescription before it may be legally dispensed to the public;

(B) A drug or device that under federal law is required, prior to being dispensed or delivered, to be labeled with either of the following statements:

(i) Caution: federal law prohibits dispensing without prescription or "Rx only" or another legend that complies with federal law; or

(ii) Caution: federal law restricts this drug to use by or on order of a licensed veterinarian; or

(C) A drug or device that is required by any applicable federal or state law or regulation to be dispensed on prescription only or is restricted to use by a practitioner only.

(41) Prescription drug order--

(A) a written order from a practitioner or a verbal order from a practitioner or his authorized agent to a pharmacist for a drug or device to be dispensed; or

(B) a written order or a verbal order pursuant to Subtitle B, Chapter 157, Occupations Code.

(42) Rural hospital--A licensed hospital with 75 beds or fewer that:

(A) is located in a county with a population of 50,000 or less as defined by the United States Census Bureau in the most recent U.S. census; or

(B) has been designated by the Centers for Medicare and Medicaid Services as a critical access hospital, rural referral center, or sole community hospital.

(43) Sample--A prescription drug which is not intended to be sold and is intended to promote the sale of the drug.

(44) Supervision--

(A) Physically present supervision--In a Class C pharmacy, a pharmacist shall be physically present to directly supervise pharmacy technicians or pharmacy technician trainees.

(B) Electronic supervision--In a Class C pharmacy in a facility with 100 beds or less, a pharmacist licensed in Texas may electronically supervise pharmacy technicians or pharmacy technician trainees to perform the duties specified in §291.73(e)(2) of this title (relating to Personnel) provided:

(i) the pharmacy uses a system that monitors the data entry of medication orders and the filling of such orders by an electronic method that shall include the use of one or more the following types of technology:

(I) digital interactive video, audio, or data transmission;

(II) data transmission using computer imaging by way of still-image capture and store and forward; and

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SUBCHAPTER D	INSTITUTIONAL PHARMACY (CLASS C)
RULE §291.73	**Personnel**

(a) Requirements for pharmacist services.

(1) A Class C pharmacy in a facility with 101 beds or more shall be under the continuous on-site supervision of a pharmacist during the time it is open for pharmacy services; provided, however, that pharmacy technicians and pharmacy technician trainees may distribute prepackaged and prelabeled drugs from a drug storage area of the facility e.g., a surgery suite, in the absence of physical supervision of a pharmacist, under the following conditions:

(A) the distribution is under the control of a pharmacist; and

(B) a pharmacist is on duty in the facility.

(2) A Class C pharmacy in a facility with 100 beds or less shall have the services of a pharmacist at least on a part-time or consulting basis according to the needs of the facility except that a pharmacist shall be on-site at least once every seven days.

(3) A pharmacist shall be accessible at all times to respond to other health professional's questions and needs. Such access may be through a telephone which is answered 24 hours a day, e.g., answering or paging service, a list of phone numbers where the pharmacist may be reached, or any other system which accomplishes this purpose.

(b) Pharmacist-in-charge.

(1) General.

(A) Each institutional pharmacy in a facility with 101 beds or more shall have one full-time pharmacist-in-charge, who may be pharmacist-in-charge for only one such pharmacy except as specified in subparagraph (C) of this paragraph.

(B) Each institutional pharmacy in a facility with 100 beds or less shall have one pharmacist-in-charge who is employed or under contract, at least on a consulting or part-time basis, but may be employed on a full-time basis, if desired, and who may be pharmacist-in-charge for no more than three facilities or 150 beds.

(C) A pharmacist-in-charge may be in charge of one facility with 101 beds or more and one facility with 100 beds or less, including a rural hospital, provided the total number of beds does not exceed 150 beds.

(D) The pharmacist-in-charge shall be assisted by additional pharmacists, pharmacy technicians and pharmacy technician trainees commensurate with the scope of services provided.

(E) If the pharmacist-in-charge is employed on a part-time or consulting basis, a written agreement shall exist between the facility and the pharmacist, and a copy of the written agreement shall be made available to the board upon request.

(2) Responsibilities. The pharmacist-in-charge shall have the responsibility for, at a minimum, the following:

(A) providing the appropriate level of pharmaceutical care services to patients of the facility;

(B) ensuring that drugs and/or devices are prepared for distribution safely, and accurately as prescribed;

(C) supervising a system to assure maintenance of effective controls against the theft or diversion of prescription drugs, and records for such drugs;

(D) providing written guidelines and approval of the procedure to assure that all pharmaceutical requirements are met when any part of preparing, sterilizing, and labeling of sterile preparations is not performed under direct pharmacy supervision;

(E) participating in the development of a formulary for the facility, subject to approval of the appropriate committee of the facility;

(F) developing a system to assure that drugs to be administered to patients are distributed pursuant to an original or direct copy of the practitioner's medication order;

(G) developing a system for the filling and labeling of all containers from which drugs are to be distributed or dispensed;

(H) assuring that the pharmacy maintains and makes available a sufficient inventory of antidotes and other emergency drugs as well as current antidote information, telephone numbers of regional poison control center and other emergency assistance organizations, and such other materials and information as may be deemed necessary by the appropriate committee of the facility;

(I) maintaining records of all transactions of the institutional pharmacy as may be required by applicable law, state and federal, and as may be necessary to maintain accurate control over and accountability for all pharmaceutical materials including pharmaceuticals, components used in the compounding of preparations, and participate in policy decisions regarding prescription drug delivery devices;

(J) participating in those aspects of the facility's patient care evaluation program which relate to pharmaceutical utilization and effectiveness;

(K) participating in teaching and/or research programs in the facility;

(L) implementing the policies and decisions of the appropriate committee(s) relating to pharmaceutical services of the facility;

(M) providing effective and efficient messenger or delivery service to connect the institutional pharmacy with appropriate areas of the facility on a regular basis throughout the normal workday of the facility;

(N) developing a system for the labeling, storage, and distribution of investigational new drugs, including access to related drug information for healthcare personnel in the pharmacy and nursing station where such drugs are being administered, concerning the dosage form, route of administration, strength, actions, uses, side effects, adverse effects, interactions and symptoms of toxicity of investigational new drugs;

(O) assuring that records in a data processing system are maintained such that the data processing system is in compliance with Class C (Institutional) pharmacy requirements;

(P) assuring that a reasonable effort is made to obtain, record, and maintain patient medication records;

(Q) assuring the legal operation of the pharmacy, including meeting all inspection and other requirements of all state and federal laws or rules governing the practice of pharmacy; and

(R) if the pharmacy uses an automated medication supply system, shall be responsible for the following:

(i) reviewing and approving all policies and procedures for system operation, safety, security, accuracy and access, patient confidentiality, prevention of unauthorized access, and malfunction;

(ii) inspecting medications in the automated medication supply system, at least monthly, for expiration date, misbranding, physical integrity, security, and accountability; except that inspection of medications in the automated medication supply system may be performed quarterly if:

(I) the facility uses automated medication supply systems that monitors expiration dates of prescription drugs; and

(II) security of the system is checked at regularly defined intervals (e.g., daily or weekly);

(iii) assigning, discontinuing, or changing personnel access to the automated medication supply system;

(iv) ensuring that pharmacy technicians, pharmacy technician trainees, and licensed healthcare professionals performing any services in connection with an automated medication supply system have been properly trained on the use of the system and can demonstrate comprehensive knowledge of the written policies and procedures for operation of the system; and

(v) ensuring that the automated medication supply system is stocked accurately and an accountability record is maintained in accordance with the written policies and procedures of operation.

(c) Consultant pharmacist.

(1) The consultant pharmacist may be the pharmacist-in-charge.

(2) A written agreement shall exist between the facility and any consultant pharmacist, and a copy of the written agreement shall be made available to the board upon request.

(d) Pharmacists.

(1) General.

(A) The pharmacist-in-charge shall be assisted by a sufficient number of additional licensed pharmacists as may be required to operate the institutional pharmacy competently, safely, and adequately to meet the needs of the patients of the facility.

(B) All pharmacists shall assist the pharmacist-in-charge in meeting the responsibilities as outlined in subsection (b)(2) of this section and in ordering, administering, and accounting for pharmaceutical materials.

(C) All pharmacists shall be responsible for any delegated act performed by pharmacy technicians or pharmacy technician trainees under his or her supervision.

(D) All pharmacists while on duty, shall be responsible for complying with all state and federal laws or rules governing the practice of pharmacy.

(E) A distributing pharmacist shall be responsible for and ensure that the drug is prepared for distribution safely, and accurately as prescribed unless the pharmacy's data processing system can record the identity of each pharmacist involved in a specific portion of the preparation of medication orders for distribution, in which case each pharmacist involved in the preparation of medication orders shall be responsible for and ensure that the portion of the process the pharmacist is performing results in the safe and accurate distribution and delivery of the drug as ordered. The preparation and distribution process for medication orders shall include, but not be limited to, drug regimen review, and verification of accurate medication order data entry, preparation, and distribution, and performance of the final check of the prepared medication.

(2) Duties. Duties of the pharmacist-in-charge and all other pharmacists shall include, but need not be limited to the following:

(A) providing those acts or services necessary to provide pharmaceutical care;

(B) receiving, interpreting, and evaluating prescription drug orders, and reducing verbal medication orders to writing either manually or electronically;

(C) participating in drug and/or device selection as authorized by law, drug and/or device supplier selection, drug administration, drug regimen review, or drug or drug-related research;

(D) performing a specific act of drug therapy management for a patient delegated to a pharmacist by a written protocol from a physician licensed in this state in compliance with the Medical Practice Act Subtitle B, Chapter 157, Occupations Code;

(E) accepting the responsibility for:

(i) distributing prescription drugs and devices with drug components pursuant to medication orders;

(ii) compounding and labeling of prescription drugs and devices with drug components;

(iii) proper and safe storage of prescription drugs and devices with drug components; and

(iv) maintaining proper records for prescription drugs and devices with drug components.

(3) Special requirements for compounding.

(A) Non-Sterile Preparations. All pharmacists engaged in compounding non-sterile preparations shall meet the training requirements specified in §291.131 of this title (relating to Pharmacies Compounding Non-sterile Preparations).

(B) Sterile Preparations. All pharmacists engaged in compounding sterile preparations shall meet the training requirements specified in §291.133 of this title (relating to Pharmacies Compounding Sterile Preparations).

(e) Pharmacy technicians and pharmacy technician trainees.

(1) General.

(A) All pharmacy technicians and pharmacy technician trainees shall meet the training requirements specified in §297.6 of this title (relating to Pharmacy Technician and Pharmacy Technician Trainee Training).

(B) A pharmacy technician performing the duties specified in paragraph (2)(C) of this subsection shall complete training regarding:

(i) procedures for one pharmacy technician to verify the accuracy of actions performed by another pharmacy technician including required documentation; and

(ii) the duties that may be performed by one pharmacy technician and checked by another pharmacy technician.

(C) In addition to the training requirements specified in subparagraph (A) of this paragraph, pharmacy technicians working in a rural hospital and performing the duties specified in paragraph (2)(D)(ii) of this subsection shall complete the following. Training on the:

(i) procedures for verification of the accuracy of actions performed by pharmacy technicians including required documentation;

(ii) duties which may and may not be performed by pharmacy technicians in the absence of a pharmacist; and

(iii) the pharmacy technician's role in preventing dispensing and distribution errors.

(2) Duties. Duties may include, but need not be limited to, the following functions under the supervision of and responsible to a pharmacist:

(A) Facilities with 101 beds or more. The following functions must be performed under the physically present supervision of a pharmacist:

(i) pre-packing and labeling unit and multiple dose packages, provided a pharmacist supervises and conducts a final check and affixes his or her name, initials or electronic signature to the appropriate quality control records prior to distribution;

(ii) preparing, packaging, compounding, or labeling prescription drugs pursuant to medication

orders, provided a pharmacist supervises and checks the preparation prior to distribution;

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SUBCHAPTER D	INSTITUTIONAL PHARMACY (CLASS C)
RULE §291.74	**Operational Standards**

(a) Licensing requirements.

(1) A Class C pharmacy shall register annually or biennially with the board on a pharmacy license application provided by the board, following the procedures specified in §291.1 of this title (relating to Pharmacy License Application).

(2) If the institutional pharmacy is owned or operated by a hospital management or consulting firm, the following conditions apply.

(A) The pharmacy license application shall list the hospital management or consulting firm as the owner or operator.

(B) The hospital management or consulting firm shall obtain DEA and DPS controlled substance registrations that are issued in their name, unless the following occurs:

(i) the hospital management or consulting firm and the facility cosign a contractual pharmacy service agreement which assigns overall responsibility for controlled substances to the facility; and

(ii) such hospital pharmacy management or consulting firm maintains dual responsibility for the controlled substances.

(3) A Class C pharmacy which changes ownership shall notify the board within 10 days of the change of ownership and apply for a new and separate license as specified in §291.3 of this title (relating to Required Notifications).

(4) A Class C pharmacy which changes location and/or name shall notify the board within 10 days of the change and file for an amended license as specified in §291.3 of this title.

(5) A Class C pharmacy owned by a partnership or corporation which changes managing officers shall notify the board in writing of the names of the new managing officers within 10 days of the change following the procedures in §291.3 of this title.

(6) A Class C pharmacy shall notify the board in writing within 10 days of closing, following the procedures in §291.5 of this title (relating to Closing a Pharmacy).

(7) A fee as specified in §291.6 of this title (relating to Pharmacy License Fees) will be charged for the issuance and renewal of a license and the issuance of an amended license.

(8) A separate license is required for each principal place of business and only one pharmacy license may be issued to a specific location.

(9) A Class C pharmacy, licensed under the Act, §560.051(a)(3), which also operates another type of pharmacy which would otherwise be required to be licensed under the Act, §560.051(a)(1) (Community Pharmacy (Class A)) or the Act, §560.051(a)(2) (Nuclear Pharmacy (Class B)), is not required to secure a license for the such other type of pharmacy; provided, however, such licensee is required to comply with the provisions of §291.31 of this title (relating to Definitions), §291.32 of this title (relating to Personnel), §291.33 of this title (relating to Operational Standards), §291.34 of this title (relating to Records), and §291.35 of this title (relating to Official Prescription Records), contained in Community Pharmacy (Class A), or §291.51 of this title (relating to Purpose), §291.52 of this title (relating to Definitions), §291.53 of this title (relating to Personnel), §291.54 of this title (relating to Operational Standards), and §291.55 of this title (relating to Records), contained in Nuclear Pharmacy (Class B), to the extent such sections are applicable to the operation of the pharmacy.

(10) A Class C (Institutional) pharmacy engaged in the compounding of non-sterile preparations shall comply with the provisions of §291.131 of this title (relating to Pharmacies Compounding Non-sterile Preparations).

(11) A Class C (Institutional) pharmacy engaged in the compounding of sterile preparations shall comply with the provisions of §291.133 of this title (relating to Pharmacies Compounding Sterile Preparations).

(12) A Class C (Institutional) pharmacy engaged in the provision of remote pharmacy services, including storage and dispensing of prescription drugs, shall comply with the provisions of §291.121 of this title (relating to Remote Pharmacy Services).

(13) A Class C (Institutional) pharmacy engaged in centralized prescription dispensing and/or prescription drug or medication order processing shall comply with the provisions of §291.123 of this title (relating to Central Prescription Drug or Medication Order Processing) and/or §291.125 of this title (relating to Centralized Prescription Dispensing).

(14) A Class C (Institutional) pharmacy with an ongoing clinical pharmacy program that proposes to allow a pharmacy technician to verify the accuracy of work performed by another pharmacy technician relating to the filling of floor stock and unit dose distribution systems for a patient admitted to the hospital if the patient's orders have previously been reviewed and approved by a pharmacist shall make application to the board as follows.

(A) The pharmacist-in-charge must submit an application on a form provided by the board, containing the following information:

(i) name, address, and pharmacy license number;

(ii) name and license number of the pharmacist-in-charge;

(iii) name and registration numbers of the pharmacy technicians;

(iv) anticipated date the pharmacy plans to begin allowing a pharmacy technician to verify the accuracy of work performed by another pharmacy technician;

(v) documentation that the pharmacy has an ongoing clinical pharmacy program; and

(vi) any other information specified on the application.

(B) The pharmacy may not allow a pharmacy technician to check the work of another pharmacy technician until the board has reviewed and approved the application and issued an amended license to the pharmacy.

(C) Every two years, in connection with the application for renewal of the pharmacy license, the pharmacy shall provide updated documentation that the pharmacy continues to have an ongoing clinical pharmacy program as specified in subparagraph (A)(v) of this paragraph.

(15) A rural hospital that wishes to allow a pharmacy technician to perform the duties specified in §291.73(e)(2)(D) of this title (relating to Personnel), shall make application to the board as follows.

(A) For an initial applications prior to September 1, 2010, the pharmacist-in-charge must submit a letter to the board containing the following information:

(i) name, address, and pharmacy license number;

(ii) name and license number of the pharmacist-in-charge;

(iii) name and registration number of the pharmacy technicians;

(iv) a statement indicating that pharmacy technicians will be performing the duties specified in §291.73(e)(2)(D) of this title; and

(v) documentation that the hospital is a rural hospital with 75 or fewer beds and that the rural hospital is either:

(I) located in a county with a population of 50,000 or less as defined by the United States Census Bureau in the most recent U.S. census; or

(II) designated by the Centers for Medicare and Medicaid Services as a critical access hospital, rural referral center, or sole community hospital.

(B) After September 1, 2010 and prior to allowing a pharmacy technician to perform the duties specified in §291.73(e)(2)(D) of this title, the pharmacist-in-charge must submit an application on a form provided by the board, containing the following information:

(i) name, address, and pharmacy license number;

(ii) name and license number of the pharmacist-in-charge;

(iii) name and registration number of the pharmacy technicians;

(iv) proposed date the pharmacy wishes to start allowing pharmacy technicians to perform the duties specified in §291.73(e)(2)(D) of this title;

(v) documentation that the hospital is a rural hospital with 75 or fewer beds and that the rural hospital is either:

(I) located in a county with a population of 50,000 or less as defined by the United States Census Bureau in the most recent U.S. census; or

(II) designated by the Centers for Medicare and Medicaid Services as a critical access hospital, rural referral center, or sole community hospital; and

(vi) any other information specified on the application.

(C) A rural hospital that makes application after September 1, 2010 may not allow a pharmacy technician to perform the duties specified in §291.73(e)(2)(D) of this title until the board has reviewed and approved the application and issued an amended license to the pharmacy.

(D) Every two years in conjunction with the application for renewal of the pharmacy license, the pharmacist-in-charge shall update the application for pharmacy technicians to perform the duties specified in §291.73(e)(2)(D) of this title.

(b) Environment.

(1) General requirements.

(A) The institutional pharmacy shall have adequate space necessary for the storage, compounding, labeling, dispensing, and sterile preparation of drugs prepared in the pharmacy, and additional space, depending on the size and scope of pharmaceutical services.

(B) The institutional pharmacy shall be arranged in an orderly fashion and shall be kept clean. All required equipment shall be clean and in good operating condition.

(C) A sink with hot and cold running water exclusive of restroom facilities shall be available to all pharmacy personnel and shall be maintained in a sanitary condition at all times.

(D) The institutional pharmacy shall be properly lighted and ventilated.

(E) The temperature of the institutional pharmacy shall be maintained within a range compatible with the proper storage of drugs. The temperature of the refrigerator and/or freezer shall be maintained within a range compatible with the proper storage of drugs.

(F) If the institutional pharmacy has flammable materials, the pharmacy shall have a designated area for the storage of flammable materials. Such area shall meet the requirements set by local and state fire laws.

(G) The institutional pharmacy shall store antiseptics, other drugs for external use, and disinfectants separately from internal and injectable medications.

(2) Security requirements.

(A) The institutional pharmacy shall be enclosed and capable of being locked by key, combination or other mechanical or electronic means, so as to prohibit access by unauthorized individuals. Only individuals authorized by the pharmacist-in-charge shall enter the pharmacy.

(B) Each pharmacist on duty shall be responsible for the security of the institutional pharmacy, including provisions for adequate safeguards against theft or diversion of dangerous drugs, controlled substances, and records for such drugs.

(C) The institutional pharmacy shall have locked storage for Schedule II controlled substances and other drugs requiring additional security.

(c) Equipment and supplies. Institutional pharmacies distributing medication orders shall have the following equipment:

(1) data processing system including a printer or comparable equipment; and

(2) refrigerator and/or freezer and a system or device (e.g., thermometer) to monitor the temperature to ensure that proper storage requirements are met.

(d) Library. A reference library shall be maintained that includes the following in hard-copy or electronic format and that pharmacy personnel shall be capable of accessing at all times:

(1) current copies of the following:

(A) Texas Pharmacy Act and rules;

(B) Texas Dangerous Drug Act and rules;

(C) Texas Controlled Substances Act and regulations; and

(D) Federal Controlled Substances Act and regulations (or official publication describing the requirements of the Federal Controlled Substances Act and regulations);

(2) at least one current or updated reference from each of the following categories:

(A) drug interactions. A reference text on drug interactions, such as Drug Interaction Facts. A separate reference is not required if other references maintained by the pharmacy contain drug interaction information including information needed to determine severity or significance of the interaction and appropriate recommendations or actions to be taken;

(B) a general information reference text, such as:

(i) Facts and Comparisons with current supplements;

(ii) United States Pharmacopeia Dispensing Information Volume I (Drug Information for the Healthcare Provider);

(iii) AHFS Drug Information with current supplements;

(iv) Remington's Pharmaceutical Sciences; or

(v) Clinical Pharmacology;

(3) a current or updated reference on injectable drug products, such as Handbook of Injectable Drugs;

(4) basic antidote information and the telephone number of the nearest regional poison control center;

(5) metric-apothecary weight and measure conversion charts.

(e) Absence of a pharmacist.

(1) Medication orders.

(A) In facilities with a full-time pharmacist, if a practitioner orders a drug for administration to a bona fide patient of the facility when the pharmacy is closed, the following is applicable.

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TITLE 22	EXAMINING BOARDS
PART 15	TEXAS STATE BOARD OF PHARMACY
CHAPTER 291	PHARMACIES
SUBCHAPTER D	INSTITUTIONAL PHARMACY (CLASS C)
RULE §291.75	**Records**

(a) Maintenance of records.

(1) Every inventory or other record required to be kept under the provisions of §291.71 of this title (relating to Purpose), §291.72 of this title (relating to Definitions), §291.73 of this title (relating to Personnel), §291.74 of this title (relating to Operational Standards), and this section contained in Institutional Pharmacy (Class C) shall be:

(A) kept by the institutional pharmacy and be available, for at least two years from the date of such inventory or record, for inspecting and copying by the board or its representative, and to other authorized local, state, or federal law enforcement agencies; and

(B) supplied by the pharmacy within 72 hours, if requested by an authorized agent of the Texas State Board of Pharmacy. If the pharmacy maintains the records in an electronic format, the requested records must be provided in a mutually agreeable electronic format if specifically requested by the board or its representative. Failure to provide the records set out in this subsection, either on site or within 72 hours, constitutes prima facie evidence of failure to keep and maintain records in violation of the Act.

(2) Records of controlled substances listed in Schedule I and II shall be maintained separately from all other records of the pharmacy.

(3) Records of controlled substances listed in Schedules III - V shall be maintained separately or readily retrievable from all other records of the pharmacy. For purposes of this subsection, readily retrievable means that the controlled substances shall be asterisked, redlined, or in some other manner readily identifiable apart from all other items appearing on the record.

(4) Records, except when specifically required to be maintained in original or hard-copy form, may be maintained in an alternative data retention system, such as a data processing or direct imaging system, e.g., microfilm or microfiche, provided:

(A) the records in the alternative data retention system contain all of the information required on the manual record; and

(B) the alternative data retention system is capable of producing a hard copy of the record upon the request of the board, its representative, or other authorized local, state, or federal law enforcement or regulatory agencies.

(b) Outpatient records.

(1) Outpatient records shall be maintained as provided in §291.34 of this title (relating to Records),

and §291.35 of this title (relating to Official Prescription Records), contained in Community Pharmacy (Class A).

(2) Outpatient prescriptions, including, but not limited to, furlough and discharge prescriptions, that are written by the practitioner must be written on a form which meets the requirements of the Act, §562.006. Medication order forms or copies thereof do not meet the requirements for outpatient forms.

(3) Controlled substances listed in Schedule II must be written on an official prescription form in accordance with the Texas Controlled Substances Act, §481.075, and rules promulgated pursuant to the Texas Controlled Substances Act, unless exempted by the Texas controlled substances regulations, 37 TAC §13.74 (relating to Exceptions to Use of Forms). Outpatient prescriptions for Schedule II controlled substances that are exempted from the official prescription requirement must be manually signed by the practitioner.

(c) Patient records.

(1) Original medication orders.

(A) Each original medication order shall bear the following information:

(i) patient name and room number or identification number;

(ii) drug name, strength, and dosage form;

(iii) directions for use;

(iv) date; and

(v) signature or electronic signature of the practitioner or that of his or her authorized agent.

(B) Original medication order shall be maintained with the medication administration records of the patients.

(2) Patient medication records (PMR). A patient medication record shall be maintained for each patient of the facility. The PMR shall contain at a minimum the following information.

(A) Patient information:

(i) patient name and room number or identification number;

(ii) gender, and date of birth or age;

(iii) weight and height;

(iv) known drug sensitivities and allergies to drugs and/or food;

(v) primary diagnoses and chronic conditions;

(vi) primary physician; and

(vii) other drugs the patient is receiving.

(B) Medication order information:

(i) date of distribution;

(ii) drug name, strength, and dosage form; and

(iii) directions for use.

(3) Controlled substances records. Controlled substances records shall be maintained as follows.

(A) All records for controlled substances shall be maintained in a readily retrievable manner.

(B) Controlled substances records shall be maintained in a manner to establish receipt and distribution of all controlled substances.

(4) Schedule II controlled substances records. Records of controlled substances listed in Schedule II shall be maintained as follows.

(A) Records of controlled substances listed in Schedule II shall be maintained separately from records of controlled substances in Schedules III, IV, and V, and all other records.

(B) An institutional pharmacy shall maintain a perpetual inventory of any controlled substance listed in Schedule II.

(C) Distribution records for controlled substances listed in Schedule II shall bear the following information:

(i) patient's name;

(ii) prescribing or attending practitioner;

(iii) name of drug, dosage form, and strength;

(iv) time and date of administration to patient and quantity administered;

(v) name, initials, or electronic signature of the individual administering the controlled substance;

(vi) returns to the pharmacy; and

(vii) waste (waste is required to be witnessed and cosigned, electronically or manually, by another individual).

(5) Floor stock records.

(A) Distribution records for Schedule II - V controlled substances floor stock shall include the following information:

(i) patient's name;

(ii) prescribing or attending practitioner;

(iii) name of controlled substance, dosage form, and strength;

(iv) time and date of administration to patient;

(v) quantity administered;

(vi) name, initials, or electronic signature of the individual administering drug;

(vii) returns to the pharmacy; and

(viii) waste (waste is required to be witnessed and cosigned, manually or electronically, by another individual).

(B) The record required by subparagraph (A) of this paragraph shall be maintained separately from patient records.

(C) A pharmacist shall review distribution records with medication orders on a periodic basis to verify proper usage of drugs, not to exceed 30 days between such reviews.

(6) General requirements for records maintained in a data processing system.

(A) Noncompliance with data processing requirements. If a hospital pharmacy's data processing system is not in compliance with the Board's requirements, the pharmacy must maintain a manual recordkeeping system.

(B) Requirements for back-up systems. The facility shall maintain a back-up copy of information stored in the data processing system using disk, tape, or other electronic back-up system and update this back-up copy on a regular basis, at least monthly, to assure that data is not lost due to system failure.

(C) Change or discontinuance of a data processing system.

(i) Records of distribution and return for all controlled substances and nalbuphine (e.g., Nubain). A pharmacy that changes or discontinues use of a data processing system must:

(I) transfer the records to the new data processing system; or

(II) purge the records to a printout which contains the same information as required on the audit trail printout as specified in paragraph (7)(B) of this subsection. The information on this printout shall be sorted and printed by drug name and list all distributions/returns chronologically.

(ii) Other records. A pharmacy that changes or discontinues use of a data processing system must:

(I) transfer the records to the new data processing system; or

(II) purge the records to a printout which contains all of the information required on the original document.

(iii) Maintenance of purged records. Information purged from a data processing system must be

maintained by the pharmacy for two years from the date of initial entry into the data processing system.

(D) Loss of data. The pharmacist-in-charge shall report to the board in writing any significant loss of information from the data processing system within 10 days of discovery of the loss.

(7) Data processing system maintenance of records for the distribution and return of all controlled substances and nalbuphine (e.g., Nubain) to the pharmacy.

(A) Each time a controlled substance or nalbuphine (e.g., Nubain) is distributed from or returned to the pharmacy, a record of such distribution or return shall be entered into the data processing system.

(B) The data processing system shall have the capacity to produce a hard copy printout of an audit trail of drug distribution and return for any strength and dosage form of a drug (by either brand or generic name or both) during a specified time period. This printout shall contain the following information:

(i) patient's name and room number or patient's facility identification number;

(ii) prescribing or attending practitioner's name;

(iii) name, strength, and dosage form of the drug product actually distributed;

(iv) total quantity distributed from and returned to the pharmacy;

(v) if not immediately retrievable via electronic image, the following shall also be included on the printout:

(I) prescribing or attending practitioner's address; and

(II) practitioner's DEA registration number, if the medication order is for a controlled substance.

(C) An audit trail printout for each strength and dosage form of these drugs distributed during the preceding month shall be produced at least monthly and shall be maintained in a separate file at the facility unless the pharmacy complies with subparagraph (D) of this paragraph. The information on this printout shall be sorted by drug name and list all distributions/returns for that drug chronologically.

(D) The pharmacy may elect not to produce the monthly audit trail printout if the data processing system has a workable (electronic) data retention system which can produce an audit trail of drug distribution and returns for the preceding two years. The audit trail required in this paragraph shall be supplied by the pharmacy within 72 hours, if requested by an authorized agent of the Texas State Board of Pharmacy, or other authorized local, state, or federal law enforcement or regulatory agencies.

(8) Failure to maintain records. Failure to provide records set out in this subsection, either on site or within 72 hours for whatever reason, constitutes prima facie evidence of failure to keep and maintain records.

(9) Data processing system downtime. In the event that a hospital pharmacy which uses a data processing system experiences system downtime, the pharmacy must have an auxiliary procedure which will ensure that all data is retained for on-line data entry as soon as the system is available for use again.

(10) Ongoing clinical pharmacy program records. If a pharmacy has an ongoing clinical pharmacy program and allows pharmacy technicians to verify the accuracy of work performed by other pharmacy technicians, the pharmacy must have a record of the pharmacy technicians and the duties performed.

(d) Distribution of controlled substances to another registrant. A pharmacy may distribute controlled substances to a practitioner, another pharmacy or other registrant, without being registered to distribute, under the following conditions.

(1) The registrant to whom the controlled substance is to be distributed is registered under the Controlled Substances Act to dispense that controlled substance.

(2) The total number of dosage units of controlled substances distributed by a pharmacy may not exceed 5.0% of all controlled substances dispensed or distributed by the pharmacy during the 12-month period in which the pharmacy is registered; if at any time it does exceed 5.0%, the pharmacy is required to obtain an additional registration to distribute controlled substances.

(3) If the distribution is for a Schedule III, IV, or V controlled substance, a record shall be maintained which indicates:

(A) the actual date of distribution;

(B) the name, strength, and quantity of controlled substances distributed;

(C) the name, address, and DEA registration number of the distributing pharmacy; and

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TITLE 22	EXAMINING BOARDS
PART 15	TEXAS STATE BOARD OF PHARMACY
CHAPTER 291	PHARMACIES
SUBCHAPTER D	INSTITUTIONAL PHARMACY (CLASS C)
RULE §291.76	**Class C Pharmacies Located in a Freestanding Ambulatory Surgical Center**

(a) Purpose. The purpose of this section is to provide standards in the conduct, practice activities, and operation of a pharmacy located in a freestanding ambulatory surgical center that is licensed by the Texas Department of State Health Services. Class C pharmacies located in a freestanding ambulatory surgical center shall comply with this section, in lieu of §§291.71 - 291.75 of this title (relating to Purpose; Definitions; Personnel; Operational Standards; and Records).

(b) Definitions. The following words and terms, when used in these sections, shall have the following meanings, unless the context clearly indicates otherwise.

(1) Act--The Texas Pharmacy Act, Chapters 551 - 566 and 568 - 569, Occupations Code, as amended.

(2) Ambulatory surgical center (ASC)--A freestanding facility that is licensed by the Texas Department of State Health Services to provide surgical services to patients who do not require overnight hospital care.

(3) Automated drug dispensing system--An automated device that measures, counts, and/or packages a specified quantity of dosage units for a designated drug product.

(4) Board--The Texas State Board of Pharmacy.

(5) Consultant pharmacist--A pharmacist retained by a facility on a routine basis to consult with the ASC in areas that pertain to the practice of pharmacy.

(6) Controlled substance--A drug, immediate precursor, or other substance listed in Schedules I - V or Penalty Groups 1 - 4 of the Texas Controlled Substances Act, as amended, or a drug immediate precursor, or other substance included in Schedule I - V of the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended (Public Law 91-513).

(7) Direct copy--Electronic copy or carbonized copy of a medication order including a facsimile (FAX) or digital image.

(8) Dispense--Preparing, packaging, compounding, or labeling for delivery a prescription drug or device in the course of professional practice to an ultimate user or his agent by or pursuant to the lawful order of a practitioner.

(9) Distribute--The delivery of a prescription drug or device other than by administering or dispensing.

(10) Downtime--Period of time during which a data processing system is not operable.

(11) Electronic signature--A unique security code or other identifier which specifically identifies the person entering information into a data processing system. A facility which utilizes electronic signatures must:

(A) maintain a permanent list of the unique security codes assigned to persons authorized to use the data processing system; and

(B) have an ongoing security program which is capable of identifying misuse and/or unauthorized use of electronic signatures.

(12) Floor stock--Prescription drugs or devices not labeled for a specific patient and maintained at a nursing station or other ASC department (excluding the pharmacy) for the purpose of administration to a patient of the ASC.

(13) Formulary--List of drugs approved for use in the ASC by an appropriate committee of the ambulatory surgical center.

(14) Hard copy--A physical document that is readable without the use of a special device (i.e., data processing system, computer, etc.).

(15) Investigational new drug--New drug intended for investigational use by experts qualified to evaluate the safety and effectiveness of the drug as authorized by the federal Food and Drug Administration.

(16) Medication order--A written order from a practitioner or a verbal order from a practitioner or his authorized agent for administration of a drug or device.

(17) Pharmacist-in-charge--Pharmacist designated on a pharmacy license as the pharmacist who has the authority or responsibility for a pharmacy's compliance with laws and rules pertaining to the practice of pharmacy.

(18) Pharmacy--Area or areas in a facility, separate from patient care areas, where drugs are stored, bulk compounded, delivered, compounded, dispensed, and/or distributed to other areas or departments of the ASC, or dispensed to an ultimate user or his or her agent.

(19) Prescription drug--

(A) A substance for which federal or state law requires a prescription before it may be legally dispensed to the public;

(B) A drug or device that under federal law is required, prior to being dispensed or delivered, to be labeled with either of the following statements:

(i) Caution: federal law prohibits dispensing without prescription or "Rx only" or another legend that complies with federal law; or

(ii) Caution: federal law restricts this drug to use by or on order of a licensed veterinarian; or

(C) A drug or device that is required by any applicable federal or state law or regulation to be dispensed on prescription only or is restricted to use by a practitioner only.

(20) Prescription drug order--

(A) A written order from a practitioner or verbal order from a practitioner or his authorized agent to a pharmacist for a drug or device to be dispensed; or

(B) A written order or a verbal order pursuant to Subtitle B, Chapter 157, Occupations Code.

(21) Full-time pharmacist--A pharmacist who works in a pharmacy from 30 to 40 hours per week or if the pharmacy is open less than 60 hours per week, one-half of the time the pharmacy is open.

(22) Part-time pharmacist--A pharmacist who works less than full-time.

(23) Pharmacy technician--An individual who is registered with the board as a pharmacy technician and whose responsibility in a pharmacy is to provide technical services that do not require professional judgment regarding preparing and distributing drugs and who works under the direct supervision of and is responsible to a pharmacist.

(24) Pharmacy technician trainee--An individual who is registered with the board as a pharmacy technician trainee and is authorized to participate in a pharmacy's technician training program.

(25) Texas Controlled Substances Act--The Texas Controlled Substances Act, the Health and Safety Code, Chapter 481, as amended.

(c) Personnel.

(1) Pharmacist-in-charge.

(A) General. Each ambulatory surgical center shall have one pharmacist-in-charge who is employed or under contract, at least on a consulting or part-time basis, but may be employed on a full-time basis.

(B) Responsibilities. The pharmacist-in-charge shall have the responsibility for, at a minimum, the following:

(i) establishment of specifications for procurement and storage of all materials, including drugs, chemicals, and biologicals;

(ii) participation in the development of a formulary for the ASC, subject to approval of the appropriate committee of the ASC;

(iii) distribution of drugs to be administered to patients pursuant to an original or direct copy of the practitioner's medication order;

(iv) filling and labeling all containers from which drugs are to be distributed or dispensed;

(v) maintaining and making available a sufficient inventory of antidotes and other emergency drugs, both in the pharmacy and patient care areas, as well as current antidote information, telephone numbers of regional poison control center and other emergency assistance organizations, and such other materials and information as may be deemed necessary by the appropriate committee of the ASC;

(vi) records of all transactions of the ASC pharmacy as may be required by applicable state and

federal law, and as may be necessary to maintain accurate control over and accountability for all pharmaceutical materials;

(vii) participation in those aspects of the ASC's patient care evaluation program which relate to pharmaceutical material utilization and effectiveness;

(viii) participation in teaching and/or research programs in the ASC;

(ix) implementation of the policies and decisions of the appropriate committee(s) relating to pharmaceutical services of the ASC;

(x) effective and efficient messenger and delivery service to connect the ASC pharmacy with appropriate areas of the ASC on a regular basis throughout the normal workday of the ASC;

(xi) labeling, storage, and distribution of investigational new drugs, including maintenance of information in the pharmacy and nursing station where such drugs are being administered, concerning the dosage form, route of administration, strength, actions, uses, side effects, adverse effects, interactions, and symptoms of toxicity of investigational new drugs;

(xii) meeting all inspection and other requirements of the Texas Pharmacy Act and this subsection; and

(xiii) maintenance of records in a data processing system such that the data processing system is in compliance with the requirements for a Class C (institutional) pharmacy located in a freestanding ASC.

(2) Consultant pharmacist.

(A) The consultant pharmacist may be the pharmacist-in-charge.

(B) A written contract shall exist between the ASC and any consultant pharmacist, and a copy of the written contract shall be made available to the board upon request.

(3) Pharmacists.

(A) General.

(i) The pharmacist-in-charge shall be assisted by a sufficient number of additional licensed pharmacists as may be required to operate the ASC pharmacy competently, safely, and adequately to meet the needs of the patients of the facility.

(ii) All pharmacists shall assist the pharmacist-in-charge in meeting the responsibilities as outlined in paragraph (1)(B) of this subsection and in ordering, administering, and accounting for pharmaceutical materials.

(iii) All pharmacists shall be responsible for any delegated act performed by pharmacy technicians or pharmacy technician trainees under his or her supervision.

(iv) All pharmacists while on duty shall be responsible for complying with all state and federal laws or rules governing the practice of pharmacy.

(B) Duties. Duties of the pharmacist-in-charge and all other pharmacists shall include, but need not be limited to, the following:

(i) receiving and interpreting prescription drug orders and oral medication orders and reducing these orders to writing either manually or electronically;

(ii) selection of prescription drugs and/or devices and/or suppliers; and

(iii) interpreting patient profiles.

(C) Special requirements for compounding.

(i) Non-Sterile Preparations. All pharmacists engaged in compounding non-sterile preparations shall meet the training requirements specified in §291.131 of this title (relating to Pharmacies Compounding Non-Sterile Preparations).

(ii) Sterile Preparations. All pharmacists engaged in compounding sterile preparations shall meet the training requirements specified in §291.133 of this title (relating to Pharmacies Compounding Sterile Preparations).

(4) Pharmacy technicians and pharmacy technician trainees.

(A) General. All pharmacy technicians and pharmacy technician trainees shall meet the training requirements specified in §297.6 of this title (relating to Pharmacy Technician and Pharmacy Technician Trainee Training).

(B) Duties. Duties may include, but need not be limited to, the following functions, under the direct supervision of a pharmacist:

(i) prepacking and labeling unit and multiple dose packages, provided a pharmacist supervises and conducts a final check and affixes his or her name, initials, electronic signature to the appropriate quality control records prior to distribution;

(ii) preparing, packaging, compounding, or labeling prescription drugs pursuant to medication orders, provided a pharmacist supervises and checks the preparation;

(iii) compounding non-sterile preparations pursuant to medication orders provided the pharmacy technicians or pharmacy technician trainees have completed the training specified in §291.131 of this title;

(iv) compounding sterile preparations pursuant to medication orders provided the pharmacy technicians or pharmacy technician trainees:

(I) have completed the training specified in §291.133 of this title; and

(II) are supervised by a pharmacist who has completed the sterile preparations training specified in §291.133 of this title, conducts in-process and final checks, and affixes his or her name, initials, or electronic signature to the label or if batch prepared to the appropriate quality control records. (The name, initials, or electronic signature are not required on the label if it is maintained in a permanent record of the pharmacy.)

(v) bulk compounding, provided a pharmacist supervises and conducts in-process and final checks and affixes his or her name, initials, or electronic signature to the appropriate quality control records prior to distribution;

(vi) distributing routine orders for stock supplies to patient care areas;

(vii) entering medication order and drug distribution information into a data processing system, provided judgmental decisions are not required and a pharmacist checks the accuracy of the information entered into the system prior to releasing the order or in compliance with the absence of pharmacist requirements contained in subsection (d)(6)(E) and (F) of this section;

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PHARMACY PRACTICE ACT

Part 1. General Provisions

58-17b-101. Title.

This chapter is known as the "Pharmacy Practice Act."

58-17b-102. Definitions.

In addition to the definitions in Section 58-1-102, as used in this chapter:

(1) "Administering" means:
- (a) the direct application of a prescription drug or device, whether by injection, inhalation, ingestion, or by any other means, to the body of a human patient or research subject by another person; or
- (b) the placement by a veterinarian with the owner or caretaker of an animal or group of animals of a prescription drug for the purpose of injection, inhalation, ingestion, or any other means directed to the body of the animal by the owner or caretaker in accordance with written or verbal directions of the veterinarian.

(2) "Adulterated drug or device" means a drug or device considered adulterated under 21 U.S.C.S. Sec. 351 (2003).

(3)
- (a) "Analytical laboratory" means a facility in possession of prescription drugs for the purpose of analysis.
- (b) "Analytical laboratory" does not include a laboratory possessing prescription drugs used as standards and controls in performing drug monitoring or drug screening analysis if the prescription drugs are prediluted in a human or animal body fluid, human or animal body fluid components, organic solvents, or inorganic buffers at a concentration not exceeding one milligram per milliliter when labeled or otherwise designated as being for in vitro diagnostic use.

(4) "Animal euthanasia agency" means an agency performing euthanasia on animals by the use of prescription drugs.

(5) "Automated pharmacy systems" includes mechanical systems which perform operations or activities, other than compounding or administration, relative to the storage, packaging, dispensing, or distribution of medications, and which collect, control, and maintain all transaction information.

(6) "Beyond-use-date" means the date determined by a pharmacist and placed on a prescription label at the time of dispensing that indicates to the patient or caregiver a time beyond which the contents of the prescription are not recommended to be used.

(7) "Board of pharmacy" or "board" means the Utah State Board of Pharmacy created in Section 58-17b-201.

(8) "Branch pharmacy" means a pharmacy or other facility in a rural or medically underserved area, used for the storage and dispensing of prescription drugs, which is dependent upon, stocked by, and supervised by a pharmacist in another licensed pharmacy designated and approved by the division as the parent

pharmacy.

(9) "Centralized prescription processing" means the processing by a pharmacy of a request from another pharmacy to fill or refill a prescription drug order or to perform processing functions such as dispensing, drug utilization review, claims adjudication, refill authorizations, and therapeutic interventions.

(10) "Class A pharmacy" means a pharmacy located in Utah that is authorized as a retail pharmacy to compound or dispense a drug or dispense a device to the public under a prescription order.

(11) "Class B pharmacy":

(a) means a pharmacy located in Utah:

(i) that is authorized to provide pharmaceutical care for patients in an institutional setting; and

(ii) whose primary purpose is to provide a physical environment for patients to obtain health care services; and

(b) (i) includes closed door, hospital, clinic, nuclear, and branch pharmacies; and

(ii) pharmaceutical administration and sterile product preparation facilities.

(12) "Class C pharmacy" means a pharmacy located in Utah that is authorized to engage in the manufacture, production, wholesale, or distribution of drugs or devices.

(13) "Class D pharmacy" means a nonresident pharmacy.

(14) "Class E pharmacy" means all other pharmacies.

(15) "Closed door pharmacy" means a pharmacy that provides pharmaceutical care to a defined and exclusive group of patients who have access to the services of the pharmacy because they are treated by or have an affiliation with a specific entity, including a health maintenance organization or an infusion company, but not including a hospital pharmacy, a retailer of goods to the general public, or the office of a practitioner.

(16) "Collaborative pharmacy practice" means a practice of pharmacy whereby one or more pharmacists have jointly agreed, on a voluntary basis, to work in conjunction with one or more practitioners under protocol whereby the pharmacist may perform certain pharmaceutical care functions authorized by the practitioner or practitioners under certain specified conditions or limitations.

(17) "Collaborative pharmacy practice agreement" means a written and signed agreement between one or more pharmacists and one or more practitioners that provides for collaborative pharmacy practice for the purpose of drug therapy management of patients and prevention of disease of human subjects.

(18) (a) "Compounding" means the preparation, mixing, assembling, packaging, or labeling of a limited quantity drug, sterile product, or device:

(i) as the result of a practitioner's prescription order or initiative based on the practitioner, patient, or pharmacist relationship in the course of professional practice;

(ii) for the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale or

dispensing; or

(iii) in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.

(b) "Compounding" does not include:

(i) the preparation of prescription drugs by a pharmacist or pharmacy intern for sale to another pharmacist or pharmaceutical facility;

(ii) the preparation by a pharmacist or pharmacy intern of any prescription drug in a dosage form which is regularly and commonly available from a manufacturer in quantities and strengths prescribed by a practitioner; or

(iii) the preparation of a prescription drug, sterile product, or device which has been withdrawn from the market for safety reasons.

(19) "Confidential information" has the same meaning as "protected health information" under the Standards for Privacy of Individually Identifiable Health Information, 45 C.F.R. Parts 160 and 164.

(20) "Controlled substance" has the same definition as in Section 58-37-2.

(21) "Dietary supplement" has the same meaning as Public Law Title 103, Chapter 417, Sec. 3a(ff) which is incorporated by reference.

(22) "Dispense" means the interpretation, evaluation, and implementation of a prescription drug order or device or nonprescription drug or device under a lawful order of a practitioner in a suitable container appropriately labeled for subsequent administration to or use by a patient, research subject, or an animal.

(23) "Distribute" means to deliver a drug or device other than by administering or dispensing.

(24) (a) "Drug" means:

(i) a substance recognized in the official United States Pharmacopoeia, Official Homeopathic Pharmacopoeia of the United States, or Official National Formulary, or any supplement to any of them, intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals;

(ii) a substance that is required by any applicable federal or state law or rule to be dispensed by prescription only or is restricted to administration by practitioners only;

(iii) a substance other than food intended to affect the structure or any function of the body of humans or other animals; and

(iv) substances intended for use as a component of any substance specified in Subsections (24)(a)(i), (ii), (iii), and (iv).

(b) "Drug" does not include dietary supplements.

(25) "Drug product equivalent" means a drug product that is designated as the therapeutic equivalent of another drug product in the Approved Drug Products with Therapeutic Equivalence Evaluations prepared by the Center for Drug Evaluation and Research of the

Federal Food and Drug Administration.

(26) "Drug regimen review" includes the following activities:

(a) evaluation of the prescription drug order and patient record for:

(i) known allergies;

(ii) rational therapy-contraindications;

(iii) reasonable dose and route of administration; and

(iv) reasonable directions for use;

(b) evaluation of the prescription drug order and patient record for duplication of therapy;

(c) evaluation of the prescription drug order and patient record for the following interactions:

(i) drug-drug;

(ii) drug-food;

(iii) drug-disease; and

(iv) adverse drug reactions; and

(d) evaluation of the prescription drug order and patient record for proper utilization, including over- or under-utilization, and optimum therapeutic outcomes.

(27) "Drug sample" means a prescription drug packaged in small quantities consistent with limited dosage therapy of the particular drug, which is marked "sample", is not intended to be sold, and is intended to be provided to practitioners for the immediate needs of patients for trial purposes or to provide the drug to the patient until a prescription can be filled by the patient.

(28) "Electronic signature" means a trusted, verifiable, and secure electronic sound, symbol, or process attached to or logically associated with a record and executed or adopted by a person with the intent to sign the record.

(29) "Electronic transmission" means transmission of information in electronic form or the transmission of the exact visual image of a document by way of electronic equipment.

(30) "Extern" means a college of pharmacy student enrolled in a college coordinated practical experience program in a health care setting under the supervision of a preceptor, as defined in this act, and approved by a college of pharmacy.

(31) "Hospital pharmacy" means a pharmacy providing pharmaceutical care to inpatients of a general acute hospital or specialty hospital licensed by the Department of Health under Title 26, Chapter 21, Health Care Facility Licensing and Inspection Act.

(32) "Legend drug" has the same meaning as prescription drug.

(33) "Licensed pharmacy technician" means an individual licensed with the division, that may, under the supervision of a pharmacist, perform the activities involved in the technician practice of pharmacy.

(34) "Manufacturer" means a person or business physically located in Utah licensed to be engaged in the manufacturing of drugs or devices.

(35) (a) "Manufacturing" means:

(i) the production, preparation, propagation, conversion, or processing of a drug or device, either directly or indirectly, by extraction from substances of natural

The Vermont Statutes Online

Title 26: Professions and Occupations

Chapter 36: PHARMACY

§ 2061. Registration and licensure

(a) All drug outlets shall biennially register with the board of pharmacy.

(b) Each drug outlet shall apply for a license in one of the following classifications:

(1) Retail drug outlet;

(2) Institutional drug outlet;

(3) Manufacturing drug outlet;

(4) Wholesale drug outlet or wholesale drug distributor;

(5) Investigative and research projects.

(c) No individual who is employed by a corporation which is licensed under any classification listed in subsection (b) of this section need obtain a license under the provisions of this subchapter.

(d) The board shall establish by rule under the powers granted to it under section 2032 of this title and chapter 25 of Title 3, the criteria which each drug outlet, that has employees or personnel engaged in the practice of pharmacy, must meet to qualify for licensure in each classification designated in subsection (b) of this section. The board may issue various types of licenses with varying restrictions to such outlets referred to in this subsection where the board deems it necessary by reason of the type drug outlet requesting a license.

(e) Retail and institutional drug outlets shall be managed by licensed pharmacists who have held an unrestricted license in this or another state for at least one year. A pharmacist who holds a restricted license may petition the board for permission to be a pharmacist manager, which may be granted by the board for good cause shown.

(f) Any nonpublic corporation owning a retail or institutional drug outlet, upon application, shall declare all owners of five percent or more of the stock of the corporation.

(g) Any nonpharmacist owner of a retail or institutional drug outlet may be denied the right to own another pharmacy for a period to be determined by the board, if he is found to be in violation of any of the grounds listed under section 2051 of this title. (Added 1977, No. 266

(Adj. Sess.), § 1; amended 1981, No. 244 (Adj. Sess.), § 12; 1991, No. 240 (Adj. Sess.), § 3; 2005, No. 27, § 52.)

§ 2062. Application

(a) The board shall specify by rule the procedures to be followed for licensure.

(b) Applications for licenses shall include the following information about the proposed drug outlet:

(1) Ownership;

(2) Location;

(3) Identity of pharmacist licensed to practice in the state, who shall be the pharmacist in charge of the drug outlet, in a retail or institutional drug outlet and such further information as the board may deem necessary.

(c) Licenses issued by the board pursuant to this chapter shall not be transferable or assignable.

(d) The board shall specify by rule minimum standards for the professional responsibility in the conduct of any drug outlet that has employees or personnel engaged in the practice of pharmacy. The board is specifically authorized to require that the portion of the facility to which such license applies be operated only under the direct supervision of no less than one pharmacist licensed to practice in this state and not otherwise, and to provide such other special requirements as deemed necessary. (Added 1977, No. 266 (Adj. Sess.), § 1; amended 1981, No. 244 (Adj. Sess.), § 13.)

Administrative Rules Vermont Board of Pharmacy
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(effective October 1, 2009)

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9.35 Independent Practice of Pharmacists A pharmacist may provide pharmacist care services outside of a licensed pharmacy if all the following conditions are met:

(a) the pharmacist has access to prescription records, patient profiles, or other relevant medical information for purposes of pharmacist care services and appropriately reviews such information before performing any such functions;

(b) access to the information described in paragraph (a) of this rule is secure from unauthorized access and use, and all access by pharmacists is documented; and

(c) a pharmacist providing pharmacist care services outside the premises of a licensed pharmacy shall maintain the records or other patient-specific information used in such activities in a readily retrievable form in a system that is secured and managed by the pharmacy with whom the pharmacist is providing such services or, if acting independent of a pharmacy, a secure system maintained by the pharmacist. Such records or information shall:

(1) provide accountability and an audit trail;
(2) be provided to the Board upon request; and
(3) be preserved for a period of at least three years from the date relied upon or consulted for the purposes of performing any such function.

Part 10 Institutional Pharmacy

10.1 Applicability The following rules are applicable to all institutions and institutional pharmacies as defined below. In addition, all relevant sections of the rules for Pharmacy Practice, Part 9 apply to institutional pharmacies that are engaged in filling prescriptions for employees or outpatients.

10.2 Definitions

(a) "Institutional facility" means any organization whose primary purpose is to provide a physical environment for patients to obtain health care services, including but not limited to a(n):

(1) Hospital;
(2) Convalescent home;
(3) Nursing home;
(4) Extended or long-term care facility;
(5) Mental health facility;
(6) Rehabilitation center;
(7) Psychiatric center;
(8) Developmental disability center;
(9) Drug abuse treatment center;
(10) Family planning clinic;
(11) Penal institution or correctional facility;
(12) Hospice;
(13) Public health facility;
(14) Athletic facility; and
(15) Residential care home.

(b) "Institutional pharmacy" means any drug outlet licensed by the Board which provides

pharmaceutical care to current residents or patients in an institutional facility where drugs, devices, and other materials used in the diagnosis and treatment of injury, illness, and disease (hereinafter referred to as "drugs") are dispensed, compounded, and distributed and pharmaceutical care is rovided. A pharmacy that provides services to patients who do not reside in institutional settings (with the exception of a one time dispensing upon discharge from an institution) can not be classified as an "institutional pharmacy."

10.3 Personnel The institutional pharmacy shall:

(a) Be under the direct supervision of a full-time Vermont licensed pharmacist-manager;
(b) Employ support personnel to perform technical and secretarial duties appropriate to their training and skill level;
(c) Employ licensed pharmacists as needed to adequately direct and supervise the work of support personnel; and
(d) Employ registered pharmacy technicians as needed to perform appropriate tasks.

10.4 Responsibilities of the Pharmacist-Manager The pharmacist-manager shall be responsible for:

(a) The safe and efficient distribution and control of all pharmaceutical products;
(b) Preparation, sterilization, and admixture of parenteral medications;
(c) Inservice education of nursing personnel about incompatibility of parenteral admixtures;
(d) Compounding within the institutional pharmacy;
(e) Participation in developing a formulary for the institution;
(f) Correct filling and labeling of containers;
(g) Supply and inventory of emergency antidote drugs, if not kept in the emergency room;
(h) Record keeping;
(I) Participation in the institution's patient care evaluation program;
(j) Cooperation with teaching and research programs in the institution;
(k) Implementation of the institution's policies and procedures;
(l) Efficient and effective messenger and delivery service within the institution regarding medication use;
(m) Setting quality assurance standards;
(n) Development and implementation of written policies and procedures; and
(o) Inspections of medication storage areas.

10.5 Written Policies The pharmacist-manager shall develop and implement written policies and procedures for the safe and efficient distribution of drugs and for the provision of pharmaceutical care. An annual updated copy of such procedures shall be on hand for inspection by the Board. Written policies and procedures shall include:

(a) Duties of support personnel;
(b) Night cabinets;
(c) Emergency drug kits;
(d) Distribution of pharmaceutical products;
(e) Disposition of adulterated, misbranded or discontinued drugs;
(f) Recall of drugs; and
(g) Storing and returning drugs brought into the institution by patients.

10.6 Absence of Pharmacist During such times as an institutional pharmacy may be inattended by a pharmacist, arrangements shall be made in advance by the pharmacist-manager for provision of drugs to the medical staff and other authorized personnel of the institutional facility by use of night cabinets and, in emergency circumstances, by access to the pharmacy. A pharmacist

must be "on call" during all absences.

10.7 Night Cabinets/Temporary Storage In the absence of a pharmacist, drugs for distribution to patients shall be stored in a locked cabinet ("night cabinet") or other enclosure constructed and located outside of the pharmacy area, to which only specifically authorized personnel may obtain access by key or combination, and which is sufficiently secure to deny access to unauthorized persons. The pharmacist-manager shall, in conjunction with the appropriate committee of the institutional facility, develop inventory listings of those drugs to be included in the night cabinet(s) and determine who may have access, and shall insure that:

(a) Drugs are properly labeled;
(b) Only prepackaged drugs are available, in amounts sufficient for immediate therapeutic requirements until a pharmacist is available;
(c) Whenever access to the cabinet occurs, date and time of access, written practitioner's orders and proofs-of-use are provided;
(d) All drugs in the night cabinet are inventoried by a pharmacist or designee no less than once per week;
(e) A pharmacist reviews all medication orders for drugs removed from the night cabinet within 24 hours of their removal;
(f) A complete audit of all activity concerning the night cabinet is conducted no less than once per month; and
(g) Written policies and procedures are established to implement the requirements of this section.

10.8 Access to Pharmacy During Emergency The institutional pharmacy shall be secure from access by unauthorized persons at all times. Whenever any drug is not available from floor supplies or night cabinets, and the drug is required to treat the immediate needs of a patient whose health would otherwise be jeopardized, the drug may be obtained from the pharmacy in accordance with the requirements of this section.

10.9 Designated Nurse Access

(a) One supervisory nurse in any given eight-hour shift is responsible for obtaining drugs from the pharmacy.

(b) The responsible nurse shall be designated in writing by the appropriate committee of the institutional facility.

10.10 Nurse Removal of Drugs Removal of any drug from the pharmacy by an authorized nurse must be recorded on a suitable form showing:

(a) patient name;
(b) room number;
(c) name of drug;
(d) strength, amount,
(e) date and time of removal, and
(f) signature of nurse.

10.11 Doses Doses should be in unit-of-use (unit-dose) packaging whenever possible. The physician order shall be left in the institutional pharmacy with the container from which the drug was removed, as notice to the next pharmacist on duty. The amount should be sufficient only for the patient's emergency needs.

10.12 Emergency Kits An institutional facility lacking an institutional pharmacy may provide drugs from emergency kits. The drugs may be administered by authorized personnel, provided that such kits meet the following requirements:

(a) Emergency kits contain those drugs which may be required to meet the immediate therapeutic needs of patients;
(b) The drugs are not available from any other authorized source in sufficient time to prevent risk of harm to patients;
(c) All drugs are properly labeled;
(d) All emergency kit drugs are equipped with a breakable seal, are sealed by a pharmacist, and are secure from access by unauthorized personnel;
(e) The supplying pharmacist, nursing staff, and the medical staff of the institutional facility shall jointly determine the drugs, by identity and quantity, to be included in emergency kits;
(f) The emergency kits shall be stored in secured areas to prevent unauthorized access and to ensure a proper environment for preservation of drugs in the kits;
(g) The exterior of each emergency kit shall be labeled so as to clearly indicate that it is an emergency drug kit and that it is for use in emergencies only.
(h) The label on the emergency kit shall contain a listing of the drugs contained in the kit, including name, strength, quantity, earliest expiration date and the name, address(es) and telephone number(s) of the supplying pharmacist;
(I) Drugs shall be removed from emergency kits pursuant to a valid prescription drug order only;
(j) Whenever an emergency kit is opened, the supplying pharmacist shall be notified within 24 hours, and the pharmacist shall ensure that the kit is restocked and resealed within a reasonable time so as to prevent risk of harm to patients;
(k) The expiration date of an emergency kit shall be the earliest date of expiration of any drug supplied in the kit. Upon the occurrence of the expiration date, the supplying pharmacist shall replace the expired drug; and
(l) The pharmacist and medical staff shall develop and implement written policies and procedures for using emergency drug kits.

10.13 Emergency Kits in Non-Federal Registered Long-term Care Facilities (LTCF)
(a) An LTCF may obtain controlled substances for emergency kits from a DEA-registered hospital, clinic, pharmacy, or practitioner.

(b) An LTCF must have security safeguards for each emergency kit stored in the LTCF which include the designation of individuals who may have access to the emergency kits and a specific limitation of the type and quantity of controlled substances permitted to be placed in each emergency kit.

10.14 Emergency Kit Records The LTCF and the providing registered DEA hospital, clinic, pharmacy, or practitioner must maintain complete and accurate records of the controlled substances placed in the emergency kits and the disposition of these controlled substances, and must take periodic physical inventories.

10.15 Authorized Emergency Kit Users Controlled substances in emergency kits may be administered to patients in an LCTF only by personnel expressly authorized by an individual practitioner and in compliance with federal regulations on controlled substances.

(a) It is the Board's intent that the last person to inspect and seal an emergency drug kit must be a **pharmacist**. This task may **not be delegated to a technician or a nurse**. To further clarify this point, if the emergency drug kit is to be exchanged in its entirety and leaves the pharmacy after being sealed by a pharmacist, the intent of the rules has been met.

(b) If the drugs in the emergency drug kit are individually sealed in tamper proof containers, such as plastic cubes which are sealed either by plastic locks or tamper evident tape, then individual drugs may be "swapped" out of kits as long as they are properly labeled and it is done by authorized personnel.

(c) If an automated dispensing system is utilized in the LTCF, only those systems that are designed to prevent improper placement of medications, such as the Pyxis CUBIE system may be utilized.

(d) A nurse or technician at the long term care facility may replenish emergency drug kits with a drug item, provided the drug item is pre-sealed in an individual container and placed in a pre-designated part of the kit. This requirement is to prevent loose unit-dosed medications from being placed in the wrong locations in an emergency drug kit.

10.16 Physical Requirements The institutional pharmacy shall meet the same standards as a retail drug outlet.

(a) Prescription area: The pharmacist-manager, or the pharmacist designated by him or her, shall have 24 hour access to the institutional pharmacy. The prescription area shall be large enough to properly store and prepare a prescription. The Board recommends 200 square feet.

(b) If the institutional facility is open at times when the institutional pharmacy is closed, the pharmacy must be permanently enclosed by a partition or Board-approved barrier device from floor to ceiling, or at least nine feet six inches in height, the lesser.

(c) The institutional pharmacy must be secure from access when the institutional facility is closed. It must be secure from access by unauthorized personnel at all times. Only support personnel directly involved in the prescription dispensing process and non-pharmacist management shall be allowed entry into the institutional pharmacy and then only when a pharmacist is present in the institution.

(d) The prescription counter shall be kept free of any items not being used in the practice of pharmacy. No television monitors shall be located in the institutional pharmacy, and no such equipment shall be placed so as to distract the pharmacist from the practice of pharmacy. The aisle space behind the prescription counter shall be wide enough to allow free movement and shall be kept free of obstructions. The institutional pharmacy shall have a sink of appropriate size, exclusive of drainboard area, necessary to fulfill the needs of the pharmacy. The sink shall be connected to hot and cold running water and shall have a working drain.

10.17 Hygiene Standards The institutional pharmacy shall:

(a) comply with all federal, state, and local health laws;
(b) have walls, ceilings, windows, and floors kept clean and in good repair;
(c) have waste receptacles located in convenient areas;
(d) have equipment kept clean and stored in an orderly manner;
(e) be well lighted;
(f) be dry and well ventilated; and
(g) have adequate restroom facilities for employees.

10.18 Equipment The following equipment and miscellaneous supplies shall be present:

(a) One class A prescription balance with weights or automatic sensitivity requirement of six

mg. with no load;
(b) One set of metric weights from 10 milligrams to 50 grams;
(c) A refrigerator with a temperature control and thermometer;
(d) Distilled and/or sterile water;
(e) An automated data processing system;
(f) At least one telephone in the prescription area, with the same number as the telephone number printed on the drug outlet prescription labels;
(g) A tablet and capsule counting tray;
(h) Containers which meet official compendia standards, available with closures that meet Federal Poison Prevention Packaging Act of 1970 requirements, as well as regular closures;
(I) Prescription labels imprinted or computer-generated with the name, address, and telephone number of the institutional pharmacy that do not contain any symbol or background logo that interferes with the reading and interpretation of any information written by the pharmacist on the label;
(j) Auxiliary labels;
(k) Prescription filing devices for record keeping;
(l) Sufficient equipment, graduates, mortars, funnels, etc., to maintain the scope of practice;
(m) A current copy of the Vermont Pharmacy Laws and Rules and Regulations;
(n) Any institutional pharmacy involved in the preparation of sterile pharmaceutical must meet the requirements of the "Sterile Pharmaceuticals" provisions of these rules; and
(o) Telephone number of a poison control center.

10.19 Reference Materials Each pharmacy shall maintain on file at least one reference in each of the following categories. Computerized, on-line versions are acceptable instead of a hard copy of the current manual. Whether in hard copy or computerized, this reference work must be complete and must include an explanation of drug interactions, either in the form of a manual or otherwise:

(a) State and federal drug laws relating to the practice of pharmacy, including a current copy of these statutes and rules, and the legal distribution of drugs and any rules or regulations adopted pursuant thereto;

(b) Current manual of drug interactions equivalent to ***Hansten's*** or ***Drug Facts***, with quarterly updates, which has been pre-approved by the Board.

(c) Current Facts and Comparisons, with monthly updates;

(d) Current reference on pediatric dosages;

(e) IV admixture compatibility reference (such as ***King's Guide to Parenteral Admixtures***);

(f) Injectable Drug Handbook (***Trissel's***); and

(g) American Hospital Formulary Service Drug Information text.

10.20 Storage All drugs shall be stored in designated areas within the institutional pharmacy, at temperatures recommended by the U.S. Pharmacopoeia.

10.21 Security The institutional pharmacy shall be locked by key or combination when unattended.

10.22 Labeling All drugs dispensed for use within the institution shall:

(a) Be in appropriate containers; and
(b) Be labeled with the patient's name, patient's location, brand or generic name, strength, quantity of drug, and expiration date.

10.23 Dispensed Drugs All drugs dispensed for use outside the institution shall comply with standards set for a retail drug outlet.

10.24 Unit Dose Packaging All drugs shall be in unit dose packaging specifying drug name, strength, and expiration date. Either the drug manufacturer and lot number must be labeled on the package, or there must be a system that allows for retrieval of such information.

10.25 Discontinued Drugs All discontinued, outdated, or misbranded drugs shall be returned to the institutional pharmacy and properly disposed of by the pharmacist-manager or his or her authorized designee.

10.26 Physician's Orders Drugs may be dispensed from the institutional pharmacy if:

(a) Ordered by an authorized practitioner;

(b) The drug order includes the name and location of the patient, name and dosage of the drug, directions for use, date of order, and signature of the physician or his or her authorized designee;

(c) Telephone or verbal orders are transcribed into the patient record and noted as a telephone or verbal order. Telephone or verbal orders shall be countersigned by the prescribing physician within 30 days. The authority to receive telephone or verbal orders must be officially granted in the institutions's rules and regulations or medical staff bylaws.

(d) All abbreviations and symbols used in written orders are approved for use by the institution.

(e) Pharmacists may adjust medication doses if the order is part of a medication or dosing protocol that has been approved by the medical staff of the institution. This section should not be construed as giving prescribing privileges to pharmacists.

10.27 Telephone Orders Prescription orders issued by an authorized practitioner may be telephoned to a retail drug outlet by a nurse licensed by the Vermont Board of Nursing.

10.28 Controlled Drug Accountability The following information must be recorded each time a controlled drug is administered;

(a) Name of drug;
(b) Dosage;
(c) Name of patient;
(d) Date and time the drug was administered;
(e) Name of person administering the drug; and
(f) Name of prescriber.

10.29 Recall All recalled drugs and pharmaceutical devices shall be retrieved from within the institution for safe and proper disposal in the institutional pharmacy.

10.30 Adverse Drug Reactions All adverse drug reactions shall be reported to the patient's physician and documented in the patient chart and shall also be entered into the patient profile.

0.31 Medications Brought Into the Institution By Patients Drugs brought into an institutional facility by a patient shall not be administered unless they can be identified and the quality of the drug assured. If such drugs are not to be administered, then the pharmacist-manager shall, according to procedures specified in writing, have them turned in to the pharmacy, which shall package and seal them and return them to an adult member of the patient's immediate family, or store and return them to the patient upon discharge.

10.32 Investigational Drugs Investigational drugs shall be stored in and dispensed from the pharmacy only. Investigational drugs may be administered if:

(a) Prior approval of the protocol has been granted by the institution's investigational drug review board or committee;

(b) Informed consent to treatment with these drugs has been given in writing by the patient or authorized representative;

(c) Administered under the direct and personal supervision of the principal physician-investigator, or his or her authorized clinician, or a nurse educated and trained in administration of investigational drugs;

(d) All essential information pertaining to the investigational drug is maintained, stored, updated, and dispensed by the institutional pharmacy;

(e) The institution participating in investigational studies assures that such studies contain adequate safeguards for the patient, the institution, and the scientific integrity of the study;

(f) The institution participating in investigational studies has written policies and procedures for the approval, management, and control of these studies; and

(g) The pharmacist is responsible to the institution and to the principal investigator for seeing that procedures for the control of investigational drug use are developed and maintained.

10.33 Records and Reports The following records and reports shall be kept on file for three years and submitted to the Board upon request:

(a) The practitioner's orders, or direct copies. The ability to retrieve these orders from a patient's medical record is acceptable;
(b) Records of medications dispensed;
(c) Reports of suspected adverse drug reactions;
(d) Inventories of night cabinets, emergency kits, the institutional pharmacy, and controlled substances;
(e) Alcohol and flammables reports;
(f) Authorized removal of drugs from the institutional pharmacy by a nurse.

10.34 Inspection of Medication Areas Every month, the pharmacist-manager or his or her qualified designee shall inspect all matters for which he or she is responsible, to verify compliance with these rules, and document the following:

(a) Drugs are dispensed only under the direct supervision of a licensed pharmacist;
(b) Support personnel are properly directed and supervised;

(c) Disinfectants and drugs for external use are stored separately from drugs for internal or injectable use;
(d) Compliance with all special storage conditions for each drug;
(e) Outdated drugs are not stocked in the institution or the institutional pharmacy;
(f) Distribution and administration of controlled substances are adequately documented by pharmacy, medical, and nursing personnel;
(g) There is an adequate supply of emergency drugs;
(h) All security and storage standards are met;
(I) Metric-apothecary weight and measure conversion tables and charts are reasonably available to all medical and nursing personnel; and
(j) Compliance with policies and procedures pertaining to the pharmacy.

Part 11 Computer Systems for Data Processing

11.1 Permitted Practices Computer systems for data processing may be used for record keeping in licensed pharmacies, if:

(a) Patient records may be viewed at any time on the computer screen;
(b) Patient records are available as printed documents;
(c) Information in the computer is backed up at least once each business day;
(d) An auxiliary record keeping system is established for use when the computer system is temporarily inoperable, and such records are entered into the system when operations are restored;
(e) A backup copy must be kept off-site or in fire-proof storage;
(f) A software provision must be implemented that will flag or otherwise warn of allergies or medication interactions.

11.2 Common files or Data bases Pharmacies accessing a common electronic file or database used to maintain required dispensing information are not required to transfer prescription drug orders or information for dispensing purposes between or among pharmacies participating in the same common prescription file. Provided, however, that any such common file shall contain complete records of each prescription drug order and refill dispensed and further, that a hard copy record of each prescription drug order accessed for purposes of refilling shall be generated and maintained at the pharmacy refilling the prescription drug order.

11.3 Printouts The computerized system shall have the capability of producing a printout of any prescription drug order data. The system shall provide a refill-by-refill audit trail for any specified strength and dosage form of any drug. Such an audit trail shall be by printout, and include the name of the prescribing practitioner, name and location of the patient, quantity dispensed on each refill, date of dispensing of each refill, name or identification code of the dispensing pharmacist, and unique identifier of the prescription drug order.

11.4 Retrievability Any facility maintaining centralized prescription records shall be capable of sending a requested printout to the pharmacy within 72 hours.

11.5 Sight Readable Information The system shall have the capability of producing sight-readable information on all original and refill prescription drug orders. The term "sight-readable" means that an authorized individual shall be able to examine the record and read the information from the computer monitor, microfiche, microfilm, printout, or other method acceptable to the Board.

THE PHARMACY ACT AND THE DRUG CONTROL ACT WITH RELATED STATUTES

COMMONWEALTH OF VIRGINIA

Department of Health Professions
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§ 54.1-3434. Permit to conduct pharmacy.

No person shall conduct a pharmacy without first obtaining a permit from the Board.

The application for such permit shall be made on a form provided by the Board and signed by a pharmacist who will be in full and actual charge of the pharmacy and who will be fully engaged in the practice of pharmacy at the location designated on the application.

The application shall (i) show the corporate name and trade name, (ii) list any pharmacist in addition to the pharmacist-in-charge practicing at the location indicated on the application, and (iii) list the hours during which the pharmacy will be open to provide pharmacy services. Any change in the hours of operation, which is expected to last more than one week, shall be reported to the Board in writing and posted, at least fourteen days prior to the anticipated change, in a conspicuous place to provide notice to the public. The Board shall promulgate regulations to provide exceptions to this prior notification.

If the owner is other than the pharmacist making the application, the type of ownership shall be indicated and shall list any partner or partners, and, if a corporation, then the corporate officers and directors. Further, if the owner is not a pharmacist, he shall not abridge the authority of the pharmacist-in-charge to exercise professional judgment relating to the dispensing of drugs in accordance with this act and Board regulations.

The permit shall be issued only to the pharmacist who signs the application as the pharmacist-in-charge and as such assumes the full responsibilities for the legal operation of the pharmacy. This permit and responsibilities shall not be construed to negate any responsibility of any pharmacist or other person.

Upon termination of practice by the pharmacist-in-charge, or upon any change in partnership composition, or upon the acquisition, as defined in Board regulations, of the existing corporation by another person or the closing of a pharmacy, the permit previously issued shall be immediately surrendered to the Board by the pharmacist-in-charge to whom it was issued, or by his legal representative, and an application for a new permit may be made in accordance with the requirements of this chapter.

The Board shall promulgate regulations (i) defining acquisition of an existing permitted, registered or licensed facility or of any corporation under which the facility is directly or indirectly organized; (ii) providing for the transfer, confidentiality, integrity, and security of the pharmacy's prescription dispensing records and other patient records, regardless of where located; and (iii) establishing a reasonable time period for designation of a new pharmacist-in-charge. At the conclusion of the time period for designation of a new pharmacist-in-charge, a pharmacy which has failed to designate a new pharmacist-in-charge shall not operate as a pharmacy nor maintain a stock of prescription drugs on the premises. The Director shall immediately notify the owner of record that the pharmacy no longer holds a valid permit and that the owner shall make provision for the proper disposition of all Schedule II through VI drugs and devices on the premises within fifteen days of receipt of this notice. At the conclusion of the fifteen-day period, the Director or his authorized agent shall seize and indefinitely secure all Schedule II through VI drugs and devices still on the premises, and notify the owner of such seizure. The Director may properly dispose of the seized drugs and devices after six months from the date of the notice of seizure if the owner has not claimed and provided for the proper disposition of the property. The Board shall assess a fee of not less than the cost of storage of said drugs upon the owner for reclaiming seized property.

The succeeding pharmacist-in-charge shall cause an inventory to be made of all Schedule I, II, III, IV and V drugs on hand. Such inventory shall be completed as of the date he becomes pharmacist-in-charge and prior to opening for business on that date.

The pharmacist to whom such permit is issued shall provide safeguards against diversion of all controlled substances.

An application for a pharmacy permit shall be accompanied by a fee determined by the Board. All permits shall expire annually on a date determined by the Board in regulation.

Every pharmacy shall be equipped so that prescriptions can be properly filled. The Board of Pharmacy shall prescribe the minimum of such professional and technical equipment and reference material which a pharmacy shall at all times possess. Nothing shall prevent a pharmacist who is eligible to receive information from the Prescription Monitoring Program from requesting and receiving such information; however, no pharmacy shall be required to maintain Internet access to the Prescription Monitoring Program. No permit shall be issued or continued for the conduct of a pharmacy until or unless there is compliance with the provisions of this chapter and regulations promulgated by the Board.

Each day during which a person is in violation of this section shall constitute a separate offense.

(1970, c. 650, § 54-524.31; 1972, c. 798; 1976, c. 614; 1977, c. 302; 1980, c. 288; 1983, c. 286; 1986, c. 207; 1988, cc. 445, 765; 1994, c. 299; 1998, c. 470; 2000, c. 135; 2008, c. 320; 2011, c. 610.)

Commonwealth of Virginia

REGULATIONS

GOVERNING THE PRACTICE OF PHARMACY

Title of Regulations: 18 VAC 110-20-10 et seq.

Statutory Authority: § 54.1-2400 and Chapters 33 and 34 of Title 54.1 of the *Code of Virginia*

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e. Performing routine maintenance of robotic pharmacy system as indicated by manufacturer's schedules and recommendations;

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g. Appropriately investigating, identifying and correcting sources of discrepancies or errors associated with the robotic pharmacy system; and

h. Maintaining quality assurance reports.

5. Pharmacists shall perform a daily random check of medications picked by the robot for 5.0% of all patients' bins and 5.0% of all first doses or cart updates. Documentation of this check shall include the pharmacist's initials for each medication checked and a description of all discrepancies found.

6. All manual picks shall be checked by pharmacists.

7. If the robot picks an incorrect medication, the pharmacy shall immediately institute a 100% check of all patients' bins or doses and shall immediately report the error to the board. The 100% check procedure shall continue until such time as the pharmacy provides documentation to the board showing that the cause of the error has been determined and addressed and that the robot is no longer making errors, and the board allows the pharmacy to return to a reduction in checking.

8. Quarterly quality assurance reports demonstrating the accuracy of the robot shall be maintained. At a minimum, these reports shall include:

a. A summary indicating the date and description of all discrepancies that include but are not limited to discrepancies involving the packaging, repackaging and dispensing of drugs via the robotic pharmacy system found during that quarter plus a cumulative summary since initiation of the robotic pharmacy system.

b. The total number of doses packaged for the robotic pharmacy system and total number of doses picked by the robot during the quarter.

c. The total number of doses picked by the robot that were checked in conducting the 5.0% patient bin check, 5.0% cart updates check, and 5.0% first dose check.

d. Dates and time associated with any scheduled or unanticipated downtime with an explanation of the problem to include the time span of the downtime and the resolution.

9. All unanticipated downtime shall be immediately reported to the board.

10. All records required by this section shall be maintained at the address of the pharmacy for a minimum of two years. Records may be maintained in offsite storage or as an electronic image that provides an exact image of the document that is clearly legible provided such offsite or electronic storage is

retrievable and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.

Part XI. Pharmacy Services to Hospitals

18VAC110-20-440. Responsibilities of the pharmacist-in-charge.

A. The PIC in a pharmacy located within a hospital or the PIC of any outside pharmacy providing pharmacy services to a hospital shall be responsible for establishing procedures for and assuring maintenance of the proper storage, security, and dispensing of all drugs used throughout the hospital.

B. The PIC of a pharmacy serving a hospital shall be responsible for maintaining a policy and procedure for providing reviews of drug therapy to include at a minimum any irregularities in drug therapy consistent with § 54.1-3319 A of the Code of Virginia.

C. Prior to the opening of a satellite pharmacy within the hospital, the PIC shall notify the board as required by 18VAC110-20-140 and shall ensure compliance with subsections B through G of 18VAC110-20-150, 18VAC110-20-160, 18VAC110-20-170, 18VAC110-20-180 and 18VAC110-20-190. No drugs shall be stocked in a satellite pharmacy until an inspection has been completed and approval given for opening.

D. For the following list of Schedule VI controlled substances, the PIC of a pharmacy serving a hospital may authorize the storage in an area of the hospital outside the pharmacy, and may delegate the ordering and distribution within the hospital to non-pharmacy personnel provided the conditions for proper storage and adequate security and the procedures for distribution are set forth in the pharmacy's policy and procedure manual, and provided that the PIC assures that these storage areas are checked monthly for compliance. The storage areas must be locked when authorized staff is not present in the area. Except for nitrous oxide, medical gases may be stored in an unlocked area.

1. Large volume parenteral solutions that contain no active therapeutic drugs other than electrolytes;

2. Irrigation solutions;

3. Contrast media;

4. Medical gases;

5. Sterile sealed surgical trays that may include a Schedule VI drug; and

6. Blood components and derivatives, and synthetic blood components and products.

18VAC110-20-450. After-hours access to the pharmacy.

A. When authorized by the PIC, an authorized nurse may have access to a supply of drugs maintained by the pharmacy at a location outside the pharmacy in order to obtain emergency medication during hours the pharmacy is closed, provided that such drug is available in the manufacturer's original package or in units which have been prepared and labeled by a pharmacist and provided further that a separate record shall be made and left at the location of the stock of drugs on a form prescribed by the PIC and such records are maintained within the pharmacy for a period of one year showing:

1 The date of withdrawal;

2. The patient's name;

3. The name of the drug, strength, dosage form and dose prescribed;

4. Number of doses removed; and

5. The signature of the authorized nurse.

B. If the after-hours supply of drugs is in an area that is continuously open and staffed, such as a patient floor or emergency room, then the area does not need to be alarmed. If the after-hours supply is maintained in an area of the hospital that is not open and continuously staffed, such as a floor that primarily houses departments that are closed daily, then an alarm that meets the requirements of 18VAC110-20-180 shall be installed and activated at all times.

18VAC110-20-460. Floor stock drugs; proof of delivery; distribution records.

A. A pharmacist shall check all Schedule II-VI drugs delivered to a hospital unit as floor-stock before the drugs leave the pharmacy and shall initial or sign manually or electronically the record of distribution verifying the accuracy of the distribution.

B. A delivery receipt shall be obtained for Schedule II through V drugs supplied as floor stock. This record shall include the date, drug name and strength, quantity, hospital unit receiving drug and the manual or electronic signatures of the dispensing pharmacist and the receiving nurse.

C. A record of disposition/administration shall be used to document administration of Schedule II through V drugs when a floor stock system is used for such drugs. The record shall be returned to the pharmacy within three months of its issue. The PIC or his designee shall:

1. Match returned records with delivery receipts to verify that all records are returned;

2. Periodically audit returned administration records for completeness as to patient's names, dose, date and time of administration, signature or initials of person administering the drug, and date the record is returned;

3. Verify that all additions to inventory are recorded, that all additions to and deductions from inventory are correctly calculated, that sums carried from one record to the next are correctly recorded, and periodically verify that doses documented on administration records are reflected in the medical record; and

4. Initial the returned record.

D. All records required by this section shall be filed chronologically by date of issue, and retained for two years from the date of return at the address of the pharmacy. Schedule VI records may be maintained in offsite storage or as an electronic image that provides an exact image of the document that is clearly legible provided such offsite or electronic storage is retrievable and made available for inspection or audit within 48 hours of a request by the board or an authorized agent. Schedule II-V records may only be stored offsite or

electronically as described in this subsection if authorized by DEA or in federal law or regulation. The filing requirements of 18VAC110-20-240 A 1 for separation of Schedule II records shall be met for administration records if the Schedule II drugs are listed in a separate section on a page that contains other schedules of drugs.

18VAC110-20-470. Emergency room.

All drugs in the emergency department shall be under the control and supervision of the PIC and shall be subject to the following additional requirements:

1. All drugs kept in the emergency room shall be in a secure place from which unauthorized personnel and the general public are excluded.

2. Oral orders for medications shall be reduced to writing and shall be signed by the practitioner.

3. A medical practitioner may dispense drugs to his patients if in a bona fide medical emergency or when pharmaceutical services are not readily available and if permitted to do so by the hospital; the drug container and the labeling shall comply with the requirements of this chapter and the Drug Control Act.

4. A record shall be maintained of all drugs administered in the emergency room.

5. A separate record shall be maintained on all drugs, including drug samples, dispensed in the emergency room. The records shall be maintained for a period of two years showing:

a. Date and time dispensed;

b. Patient's name;

c. Prescriber's name;

d. Name of drug dispensed, strength, dosage form, quantity dispensed, and dose.

18VAC110-20-480. (Repealed)

18VAC110-20-490. Automated devices for dispensing and administration of drugs.

A hospital may use automated devices for the dispensing and administration of drugs pursuant to § 54.1-3301 of the Code of Virginia and §§ 54.1-3401 and 54.1-3434.02 of the Drug Control Act and in accordance with 18VAC110-20-270, 18VAC110-20-420, or 18VAC110-20-460 as applicable. The following conditions shall apply:

1. Prior to removal of drugs from the pharmacy, a delivery record shall be generated for all drugs to be placed in an automated dispensing device which shall include the date; drug name, dosage form, and strength; quantity; hospital unit and a unique identifier for the specific device receiving the drug; initials of the person loading the automated dispensing device; and initials of the pharmacist checking the drugs to be removed from the pharmacy and the delivery record for accuracy.

2. Automated dispensing devices in hospitals shall be capable of producing a hard-copy record of distribution which shall show patient name, drug name and strength, dose withdrawn, dose to be administered, date and time of withdrawal from the device, and identity of person withdrawing the drug.

3. The PIC or his designee shall conduct at least a monthly audit to review distribution and administration of Schedule II through V drugs from each automated dispensing device as follows:

a. The audit shall reconcile records of all quantities of Schedule II through V drugs dispensed from the pharmacy with records of all quantities loaded into each device to detect whether any drugs recorded as removed from the pharmacy were diverted rather than being placed in the proper device.

b. A discrepancy report shall be generated for each discrepancy in the count of a drug on hand in the device. Each such report shall be resolved by the PIC or his designee within 72 hours of the time the discrepancy was discovered or, if determined to be a theft or an unusual loss of drugs, shall be immediately reported to the board in accordance with § 54.1-3404 E of the Drug Control Act.

c. The audit shall include a review of a sample of administration records from each device per month for possible diversion by fraudulent charting. A sample shall include all Schedule II-V drugs administered for a time period of not less than 24 consecutive hours during the audit period.

d. The audit shall include a check of medical records to ensure that a valid order exists for a random sample of doses recorded as administered.

e. The audit shall also check for compliance with written procedures for security and use of the automated dispensing devices, accuracy of distribution from the device, and proper recordkeeping.

f. The hard-copy distribution and administration records printed out and reviewed in the audit shall be initialed and dated by the person conducting the audit. If nonpharmacist personnel conduct the audit, a pharmacist shall review the record and shall initial and date the record.

4. If an automated dispensing device is used to obtain drugs for dispensing from an emergency room, a separate dispensing record is not required provided the automated record distinguishes dispensing from administration and records the identity of the physician who is dispensing.

5. Automated dispensing devices shall be inspected monthly by pharmacy personnel to verify proper storage, proper location of drugs within the device, expiration dates, the security of drugs and validity of access codes.

6. Personnel allowed access to an automated dispensing device shall have a specific access code which records the identity of the person accessing the device.

7. Proper use of the automated dispensing devices and means of compliance with requirements shall be set forth in the pharmacy's policy and procedure manual.

8. All records required by this section shall be filed in chronological order from date of issue and maintained for a period of not less than two years. Records shall be maintained at the address of the pharmacy providing services to the hospital except:

a. Manual Schedule VI distribution records may be maintained in offsite storage or electronically as an electronic image that provides an exact image of the document that is clearly legible provided such offsite or electronic records are retrievable and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.

b. Distribution and delivery records and required signatures may be generated or maintained electronically provided:

(1) The system being used has the capability of recording an electronic signature that is a unique identifier and restricted to the individual required to initial or sign the record.

(2) The records are maintained in a read-only format that cannot be altered after the information is recorded.

(3) The system used is capable of producing a hard-copy printout of the records upon request.

c. Schedule II-V distribution and delivery records may only be stored offsite or electronically as described in subdivisions 9 a and b of this section if authorized by DEA or in federal law or regulation.

d. Hard-copy distribution and administration records that are printed and reviewed in conducting required audits may be maintained at an off-site location or electronically provided they can be readily retrieved upon request; provided they are maintained in a read-only format that does not allow alteration of the records; and provided a separate log is maintained for a period of two years showing dates of audit and review, the identity of the automated dispensing device being audited, the time period covered by the audit and review, and the initials of all reviewers.

18VAC110-20-500. Licensed emergency medical services agencies program.

The pharmacy may prepare a drug kit for a licensed emergency medical services agency provided:

1. The PIC of the hospital pharmacy shall be responsible for all prescription drugs contained in this drug kit. A pharmacist shall check each drug kit after filling the kit, and initial the filling record certifying the accuracy and integrity of the contents of the kit.

2. The drug kit is sealed in such a manner that it will deter theft or loss of drugs and aid in detection of such.

3. Drugs may be administered by an emergency medical technician upon an oral order or written standing order of an authorized medical practitioner in accordance with §54.1-3408 of the Code of Virginia. Oral orders shall be reduced to writing by the technician and shall be signed by a medical practitioner. Written standing orders shall be signed by the operational medical director for the emergency medical services agency. The emergency medical technician shall make a record of all drugs administered to a patient. This administration record shall be signed by the medical practitioner who assumes responsibility for the patient at the hospital. If the patient is not transported to the hospital or if the attending medical practitioner at the hospital refuses to sign the record, a copy of this record shall be signed and placed in delivery to the hospital pharmacy who was responsible for that kit exchange by the agency's operational medical director within seven days of the administration.

4. When the drug kit has been opened, the kit shall be returned to the pharmacy and exchanged for an unopened kit. The record of the drugs administered shall accompany the opened kit when exchanged. An accurate record shall be maintained by the pharmacy on the exchange of the drug kit for a period of one year.

5. The record of the drugs administered shall be maintained as a part of the pharmacy records pursuant to state and federal regulations for a period of not less than two years.

6. Intravenous solutions provided by a hospital pharmacy to an emergency medical services agency may be stored separately outside the drug kit.

18VAC110-20-510. Identification for medical intern or resident prescription form in hospitals.

The prescription form for the prescribing of drugs for use by medical interns or residents who prescribe only in a hospital shall bear the prescriber's signature, the legibly printed name, address, and telephone number of the prescriber and an identification number assigned by the hospital. The identification number shall be the Drug Enforcement Administration number assigned to the hospital pharmacy plus a suffix assigned by the institution. The assigned number shall be valid only within the course of duties as part of the residency program.

18VAC110-20-515. Remote prescription order processing for hospitals and long term care facilities.

A. Remote processing of a prescription does not include the dispensing of a drug, but does include any of the following activities related to the dispensing process:

1. Receiving, interpreting, analyzing, or clarifying prescriptions;

2. Entering prescription and patient data into a data processing system;

3. Transferring prescription information;

4. Performing a prospective drug review to include an evaluation of a prescription order and patient records for over- or under-utilization of medication, therapeutic duplication of medication, drug-disease contraindications, drug interactions, incorrect drug dosage or duration of drug treatment, or clinical abuse or misuse of medication;

5. Obtaining substitution authorizations, or otherwise communicating with the prescriber concerning a patient's order;

6. Interpreting or acting on clinical data;

7. Performing therapeutic interventions;

8. Providing drug information to the medical or nursing staff of the hospital or long term care facility; or

9. Authorizing the administration of the drug to the patient by appropriate hospital or long term care facility staff.

B. The primary pharmacy providing pharmacy services to a hospital or long term care facility may outsource certain order processing functions as described in subsection A to another pharmacy in Virginia or a registered non-resident pharmacy under the following conditions:

1. The pharmacies shall either have the same owner or have a written contract describing the scope of services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with all federal and state laws and regulations related to the practice of pharmacy;

2. Any central or remote pharmacy shall comply with Virginia law and regulation with respect to requirements for supervision of pharmacy technicians and the duties which are restricted to pharmacists and pharmacy technicians. Pharmacy technicians at the remote pharmacy shall either be registered in Virginia or possess credentials substantially equivalent to those required for a technician registered in Virginia;

3. Any pharmacist participating in remote prescription order processing shall be a Virginia licensed pharmacist; and

4. The pharmacies shall share a common electronic file or have technology which allows sufficient information necessary to process a prescription order.

C. A policy and procedure manual that relates to remote processing shall be maintained at each pharmacy involved in the processing of a prescription and available for inspection. The manual shall at a minimum include the following:

1. The responsibilities of each pharmacy;

2. A list of the name, address, telephone numbers, and permit/registration numbers of all pharmacies involved in remote processing;

3. Procedures for protecting the confidentiality and integrity of patient information;

4. Procedures for ensuring that pharmacists performing prospective drug reviews have access to appropriate drug information resources;

5. Procedures for maintaining required records;

6. Procedures for complying with all applicable laws and regulations;

7. Procedures for objectively and systematically monitoring and evaluating the quality of the program to resolve problems and improve services; and

8. Procedures for annually reviewing the written policies and procedures for needed modifications and documenting such review.

D. A pharmacy involved in remote prescription order processing shall maintain a record that identifies each person who performed a processing function for every order.

1. The record shall be available by prescription order or by patient name.

2. The record may be maintained in a common electronic file if the record is maintained in such a manner that the data processing system can produce a printout which identifies every person who performed a task involved in processing a prescription order and the location where the task was processed.

3. The record shall be readily retrievable for at least the past two years through the primary dispensing pharmacy, and shall be available for inspection by the board.

E. Nothing in this section shall prohibit an individual employee licensed as a pharmacist in Virginia from accessing the employer pharmacy's database from a remote location for the purpose of performing certain prescription processing functions as described in subsection A, provided the pharmacy establishes controls to protect the privacy and security of confidential records.

Part XII. Pharmacy Services to Long-Term Care Facilities

18VAC110-20-520. Drugs in long-term care facilities.

Prescription drugs, as defined in the Drug Control Act, shall not be floor stocked by a long-term care facility, except those in the stat drug box or emergency drug box or as provided for in 18VAC110-20-560 within this chapter.

18VAC110-20-530. Pharmacy's responsibilities to long-term care facilities.

The pharmacy serving a long-term care facility shall:

1. Receive a valid order prior to the dispensing of any drug.

2. Ensure that personnel administering the drugs are trained in using the dispensing system provided by the pharmacy.

3. Ensure that the drugs for each patient are kept and stored in the originally received containers and that the medication of one patient shall not be transferred to another patient.

4. Ensure that each cabinet, cart or other area utilized for the storage of drugs is locked and accessible only to authorized personnel.

5. Ensure that the storage area for patients' drugs is well lighted, of sufficient size to permit storage without crowding, and is maintained at appropriate temperature.

6. Ensure that poison and drugs for "external use only" are kept in a cabinet and separate from other medications.

7. Provide for the disposition of discontinued drugs under the following conditions:

a. Discontinued drugs may be returned to the pharmacy for resale or transferred to another pharmacy for redispensing to the indigent if authorized by §54.1-3411.1 and 18VAC110-20-400, or disposed of by appropriate means in compliance with 18VAC110-20-210 and any applicable local, state, and federal laws and regulations.

b. Drug destruction at the pharmacy shall be witnessed by the PIC and by another pharmacy employee. The pharmacy may transfer the drugs for destruction to an entity appropriately licensed to accept returns for destruction. Drug destruction at the facility shall be witnessed by the director of nursing or, if there is no director, then by the facility administrator and by a pharmacist providing pharmacy services to the facility or by another employee authorized to administer medication.

c. A complete and accurate record of the drugs returned or destroyed or both shall be made. The original of the record of destruction shall be signed and dated by the persons witnessing the destruction and maintained at the long-term care facility for a period of two years. A copy of the destruction record shall be maintained at the provider pharmacy for a period of two years.

d. Long term care facilities shall destroy discontinued or unused drugs or return them to the pharmacy within 30 days of the date the drug was discontinued.

8. Ensure that appropriate drug reference materials are available in the facility units.

9. Ensure that a monthly review of drug therapy by a pharmacist is conducted for each patient in long-term care facilities except those licensed under Title 63.2 of the Code of Virginia. Such review shall be used to determine any irregularities, which may include but not be limited to drug therapy, drug interactions, drug administration or transcription errors. The pharmacist shall sign and date the notation of the review. All significant irregularities shall be brought to the attention of the attending practitioner or other party having authority to correct the potential problem.

18VAC110-20-535. Repackaging of already dispensed prescriptions.

The primary provider pharmacy for a long-term care facility may, but shall not be required to, repackage a resident's prescription drugs dispensed by another pharmacy into the unit-dose or compliance packaging system used by the long-term care facility to assist in maintaining a uniform or more accurate system of administration.

1. Such repackaging shall only be done at the provider pharmacy.

2. Unit dose repackaging shall comply with requirements of 18VAC110-20-420 and compliance packaging shall comply with 18VAC110-20-340 B.

3. Records shall be maintained of all such repackaging of previously dispensed medications to include date; repackaging pharmacist's initials (or those of the checking pharmacist); and the pharmacy name, address, and prescription number of the original dispensing.

4. Any portion of a resident's medication not placed into unit dose or compliance packaging may be returned to the resident or kept for subsequent repackaging at the provider pharmacy in the original labeled container. If kept at the pharmacy, the medication shall be stored within the prescription department but separate from any working stock of drugs used for dispensing by the pharmacy, and shall only be used for the patient to whom the medication was originally dispensed.

18VAC110-20-536. Prescription drugs sent outside the facility.

RCW 18.64.011
Definitions.

Unless the context clearly requires otherwise, definitions of terms shall be as indicated when used in this chapter.

(1) "Administer" means the direct application of a drug or device, whether by injection, inhalation, ingestion, or any other means, to the body of a patient or research subject.

(2) "Board" means the Washington state board of pharmacy.

(3) "Compounding" shall be the act of combining two or more ingredients in the preparation of a prescription.

(4) "Controlled substance" means a drug or substance, or an immediate precursor of such drug or substance, so designated under or pursuant to the provisions of chapter 69.50 RCW.

(5) "Deliver" or "delivery" means the actual, constructive, or attempted transfer from one person to another of a drug or device, whether or not there is an agency relationship.

(6) "Department" means the department of health.

(7) "Device" means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended (a) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in human beings or other animals, or (b) to affect the structure or any function of the body of human beings or other animals.

(8) "Dispense" means the interpretation of a prescription or order for a drug, biological, or device and, pursuant to that prescription or order, the proper selection, measuring, compounding, labeling, or packaging necessary to prepare that prescription or order for delivery.

(9) "Distribute" means the delivery of a drug or device other than by administering or dispensing.

(10) The words "drug" and "devices" shall not include surgical or dental instruments or laboratory materials, gas and oxygen, therapy equipment, X-ray apparatus or therapeutic equipment, their component parts or accessories, or equipment, instruments, apparatus, or contrivances used to render such articles effective in medical, surgical, or dental treatment, or for use or consumption in or for mechanical, industrial, manufacturing, or scientific applications or purposes, nor shall the word "drug" include any article or mixture covered by the Washington pesticide control act (chapter 15.58 RCW), as enacted or hereafter amended, nor medicated feed intended for and used exclusively as a feed for animals other than human beings.

(11) "Drugs" means:

(a) Articles recognized in the official United States pharmacopoeia or the official homeopathic pharmacopoeia of the United States;

(b) Substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in human beings or other animals;

(c) Substances (other than food) intended to affect the structure or any function of the body of human beings or other animals; or

(d) Substances intended for use as a component of any substances specified in (a), (b), or (c) of this subsection, but not including devices or their component parts or accessories.

(12) "Health care entity" means an organization that provides health care services in a setting that is not otherwise licensed by the state. Health care entity includes a freestanding outpatient surgery center or a freestanding cardiac care center. It does not include an individual practitioner's office or a multipractitioner clinic.

(13) "Labeling" shall mean the process of preparing and affixing a label to any drug or device container. The label must include all information required by current federal and state law and pharmacy rules.

(14) "Legend drugs" means any drugs which are required by any applicable federal or state law or regulation to be dispensed on prescription only or are restricted to use by practitioners only.

(15) "Manufacture" means the production, preparation, propagation, compounding, or processing of a drug or other substance or device or the packaging or repackaging of such substance or device, or the labeling or relabeling of the commercial container of such substance or device, but does not include the activities of a practitioner who, as an incident to his or her administration or dispensing such substance or device in the course of his or her professional practice, prepares, compounds, packages, or labels such substance or device.

(16) "Manufacturer" shall mean a person, corporation, or other entity engaged in the manufacture of drugs or devices.

(17) "Master license system" means the mechanism established by chapter 19.02 RCW by which master licenses, endorsed for individual state-issued licenses, are issued and renewed utilizing a master application and a master license expiration date common to each renewable license endorsement.

(18) "Nonlegend" or "nonprescription" drugs means any drugs which may be lawfully sold without a prescription.

(19) "Person" means an individual, corporation, government, governmental subdivision or agency, business trust, estate, trust, partnership or association, or any other legal entity.

(20) "Pharmacist" means a person duly licensed by the Washington state board of pharmacy to engage in the practice of pharmacy.

(21) "Pharmacy" means every place properly licensed by the board of pharmacy where the practice of pharmacy is conducted.

(22) The word "poison" shall not include any article or mixture covered by the Washington pesticide control act (chapter 15.58 RCW), as enacted or hereafter amended.

(23) "Practice of pharmacy" includes the practice of and responsibility for: Interpreting prescription orders; the compounding, dispensing, labeling, administering, and distributing of drugs and devices; the monitoring of drug therapy and use; the initiating or modifying of drug therapy in accordance with written guidelines or protocols previously established and approved for his or her practice by a practitioner authorized to prescribe drugs; the participating in drug utilization reviews and drug product selection; the proper and safe storing and distributing of drugs and devices and maintenance of proper records thereof; the providing of information on legend drugs which may include, but is not limited to, the advising of therapeutic values, hazards, and the uses of drugs and devices.

(24) "Practitioner" means a physician, dentist, veterinarian, nurse, or other person duly authorized by law or rule in the state of Washington to prescribe drugs.

(25) "Prescription" means an order for drugs or devices issued by a practitioner duly authorized by law or rule in the state of Washington to prescribe drugs or devices in the course of his or her professional practice for a legitimate medical purpose.

(26) "Secretary" means the secretary of health or the secretary's designee.

(27) "Wholesaler" shall mean a corporation, individual, or other entity which buys drugs or

devices for resale and distribution to corporations, individuals, or entities other than consumers.

[2009 c 549 § 1008; 1997 c 129 § 1; 1995 c 319 § 2; 1989 1st ex.s. c 9 § 412; 1984 c 153 § 3; 1982 c 182 § 29; 1979 c 90 § 5; 1963 c 38 § 1.]

Notes:

Reviser's note: The definitions in this section have been alphabetized pursuant to RCW 1.08.015(2)(k).

Effective date -- Severability -- 1989 1st ex.s. c 9: See RCW 43.70.910 and 43.70.920.

Washington Administrative Code (WAC)

The WACs that related to Pharmacy are listed below. If the WAC you are looking for is not listed below please use the searchable database of all WACs at the legislative website.

Relevant WACs are:

WAC 246-11	Model procedural rules for boards
WAC 246-12	Administrative Procedures and Requirements for Credentialed Health Care Providers
WAC 246-15	Whistleblower Complaints in Health Care Settings
WAC 246-16	Standards of professional conduct
WAC 246-856	Board of Pharmacy - General
WAC 246-858	Internship Requirements
WAC 246-860	Standards of Professional Conduct
WAC 246-861	Professional Pharmaceutical Education
WAC 246-863	Pharmacists - Licensing
WAC 246-865	Pharmaceutical Services - Extended Care Facility
WAC 246-867	Impaired Pharmacist Rehabilitation
WAC 246-869	Pharmacy - Licensing
WAC 246-870	Electronic Transmission Of Prescription Information
WAC 246-871	Parenteral Products - Nonhospital Patients
WAC 246-872	Automated drug distribution devices
WAC 246-873	Hospital Pharmacy Standards
WAC 246-875	Patient Medication Record Systems

Chapter 246-873 WAC **Last Update: 5/28/92**
Pharmacy — hospital standards

WAC Sections

246-873-010 Definitions.

246-873-020 Applicability.

246-873-030 Licensure.

246-873-040 Personnel.

246-873-050 Absence of a pharmacist.

246-873-060 Emergency outpatient medications.

246-873-070 Physical requirements.

246-873-080 Drug procurement, distribution and control.

246-873-090 Administration of drugs.

246-873-100 Investigational drugs.

246-873-110 Additional responsibilities of pharmacy service.

246-873-010
Definitions.

For the purpose of these rules and regulations, the following definitions apply:

(1) "Authenticated" or "authentication" means authorization of a written entry in a record by means of a signature which shall include, minimally, first initial, last name, and title.

(2) "Controlled substance" means those drugs, substances or immediate precursors listed in Schedule I through V, chapter 69.50 RCW, State Uniform Controlled Substance Act, as now or hereafter amended.

(3) "Drug" means any product referenced in RCW 18.64.011(3) as now or hereafter amended.

(4) "Drug administration" means an act in which a single dose of a prescribed drug or biological is given to a patient by an authorized person in accordance with all laws and regulations governing such acts. The complete act of administration entails removing an individual dose from a previously dispensed, properly labeled container (including a unit dose container) reviewing it with a verified transcription, a direct copy, or the original medical practitioner's orders, giving the individual dose to the proper patient, and properly recording the time and dose given.

(5) "Drug dispensing" means an act entailing the interpretation of an order for a drug or biological and, pursuant to that order, proper selection, measuring, labeling, packaging, and issuance of the drug for a patient or for a service unit of the facility.

(6) "Hospital" means any institution licensed pursuant to chapters 70.41 or 71.12 RCW or designated pursuant to RCW 72.23.020.

(7) "Hospital pharmacy" means that portion of a hospital which is engaged in the manufacture, production, preparation, dispensing, sale, and/or distribution of drugs, components, biologicals, chemicals, devices and other materials used in the diagnosis and treatment of injury, illness and diseases; and which is licensed by the state board of pharmacy pursuant to the Washington State Pharmacy Practice Act, chapter 18.64 RCW.

(8) "Immediate supervision" means visual and/or physical proximity that insure adequate safety and controls.

(9) "Investigational drug" means any article which has not been approved for use in the United States, but for which an investigational drug application (IND) has been approved by the FDA.

(10) "Nurse" means a registered nurse or a licensed practical nurse licensed pursuant to chapters 18.88 or 18.78 RCW.

(11) "Practitioner" means any person duly authorized by law or rule in the state of Washington to prescribe drugs in RCW 18.64.011(9).

(12) "Pharmacist" means a person duly licensed by the state board of pharmacy to engage in the practice of pharmacy.

(13) "Pharmacy" means every place properly licensed by the board of pharmacy where the practice of pharmacy is conducted.

(14) "Pharmacy Assistant Level A and Level B" means persons certified under chapter 18.64A RCW.

(15) "Physician" means a doctor of medicine or a doctor of osteopathy licensed to practice in the state of Washington.

(16) "Practice of pharmacy" means the definition given in RCW 18.64.011(11) now or hereafter amended.

(17) "Protocol" means a written set of guidelines.

(18) "Registered nurse" means an individual licensed under the provisions of chapter 18.88 RCW, regulating the practice of registered nursing in the state of Washington.

(19) "Self-administration of drugs" means that a patient administers or takes his/her own drugs from properly labeled containers: Provided, That the facility maintains the responsibility for seeing that the drugs are used correctly and that the patient is responding appropriately.

(20) "Shall" means that compliance with regulation is

mandatory.

(21) "Should" means that compliance with a regulation or standard is recommended.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-873-010, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(12). 82-12-041 (Order 168), § 360-17-010, filed 5/28/82. Statutory Authority: RCW 18.64.005(11). 81-16-036 (Order 162), § 360-17-010, filed 7/29/81.]

246-873-020
Applicability.

The following rules and regulations are applicable to all facilities licensed pursuant to chapters 70.41 and 71.12 RCW or designated pursuant to RCW 72.23.020.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-873-020, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(12). 82-12-041 (Order 168), § 360-17-020, filed 5/28/82. Statutory Authority: RCW 18.64.005(11). 81-16-036 (Order 162), § 360-17-020, filed 7/29/81.]

246-873-030
Licensure.

Hospital pharmacists shall be licensed by the board of pharmacy in accordance with chapter 18.64 RCW.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-873-030, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(11). 81-16-036 (Order 162), § 360-17-030, filed 7/29/81.]

246-873-040
Personnel.

(1) Director of pharmacy. The pharmacy, organized as a separate department or service, shall be directed by a licensed pharmacist appropriately qualified by education, training, and experience to manage a hospital pharmacy. The patient care and management responsibilities of the director of pharmacy shall be clearly delineated in writing and shall be in accordance with currently accepted principles of management, safety, adequate patient care and treatment. The responsibilities shall include the establishment and maintenance of policies and procedures, ongoing monitoring and evaluation of pharmaceutical service, use and control of drugs, and participation in relevant planning, policy and decision-making activities. Hospitals which do not require, or are unable to obtain the services of a fulltime director shall be held responsible for the principles contained herein and shall establish an ongoing arrangement in writing with an appropriately qualified pharmacist to provide the services. Where the director of pharmacy is not employed fulltime, then the hospital shall establish an ongoing arrangement in writing with an appropriately qualified pharmacist to provide the services described herein. The director of pharmacy shall be responsible to the chief executive officer of the hospital or his/her designee.

(2) Supportive personnel. The director of pharmacy shall be assisted by sufficient numbers of additional pharmacists and/or pharmacy assistants and clerical personnel required to operate safely and efficiently to meet the needs of the patients.

(3) Supervision. All of the activities and operations of each hospital pharmacy shall be professionally managed by the director or a pharmacist designee. Functions and activities shall be under the immediate supervision of a pharmacist and shall be performed according to written policies and procedures. When the hospital pharmacy is decentralized, each decentralized section(s) or separate organizational element(s) shall be under the immediate supervision of a pharmacist responsible to the director.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-873-040, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(11). 81-16-036 (Order 162), § 360-17-040, filed 7/29/81.]

246-873-050
Absence of a pharmacist.

(1) General. Pharmaceutical services shall be available on a 24-hour basis. If round-the-clock services of a pharmacist are not feasible, arrangements shall be made in advance by the director of pharmacy to provide reasonable assurance of pharmaceutical services.

(2) Access to the pharmacy. Whenever a drug is required to treat an immediate need and not available from floor stock when the pharmacy is closed, the drug may be obtained from the pharmacy by a designated registered nurse, who shall be accountable for his/her actions. One registered nurse shall be designated in each hospital shift for removing drugs from the pharmacy.

(a) The director of pharmacy shall establish written policy and recording procedures to assist the registered nurse who may be designated to remove drugs from the pharmacy, when a pharmacist is not present, in accordance with Washington State Pharmacy Practice Act, RCW 18.64.255(2), which states that the director of pharmacy and the hospital be involved in designating the nurse.

(b) The stock container of the drug or similar unit dose package of the drug removed shall be left with a copy of the order of the authorized practitioner to be checked by a

pharmacist, when the pharmacy reopens, or as soon as is practicable.

(c) Only a sufficient quantity of drugs shall be removed in order to sustain the patient until the pharmacy opens.

(d) All drugs removed shall be completely labeled in accordance with written policy and procedures, taking into account state and federal rules and regulations and current standards.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-873-050, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(11). 81-16-036 (Order 162), § 360-17-050, filed 7/29/81.]

246-873-060
Emergency outpatient medications.

The director of pharmacy of a hospital shall, in concert with the appropriate committee of the hospital medical staff, develop policies and procedures, which shall be implemented, to provide emergency pharmaceuticals to outpatients during hours when normal community or hospital pharmacy services are not available. The delivery of a single dose for immediate administration to the patient shall not be subject to this regulation. Such policies shall allow the designated registered nurse(s) to deliver medications other than controlled substances, pursuant to the policies and procedures which shall require that:

(1) An order of a practitioner authorized to prescribe a drug is presented. Oral or electronically transmitted orders must be verified by the prescriber in writing within 72 hours.

(2) The medication is prepackaged by a pharmacist and has a label that contains:

(a) Name, address, and telephone number of the hospital.

(b) The name of the drug (as required by chapter 246-899 WAC), strength and number of units.

(c) Cautionary information as required for patient safety and information.

(d) An expiration date after which the patient should not use the medication.

(3) No more than a 24-hour supply is provided to the patient except when the pharmacist has informed appropriate hospital personnel that normal services will not be available within 24 hours.

(4) The container is labeled by the designated registered nurse(s) before presenting to the patient and shows the following:

(a) Name of patient;

(b) Directions for use by the patient;

(c) Date;

(d) Identifying number;

(e) Name of prescribing practitioner;

(f) Initials of the registered nurse;

(5) The original or a direct copy of the order by the prescriber is retained for verification by the pharmacist after completion by the designated registered nurse(s) and shall bear:

(a) Name and address of patient;

(b) Date of issuance;

(c) Units issued;

(d) Initials of designated registered nurse.

(6) The medications to be delivered as emergency pharmaceuticals shall be kept in a secure place in or near the emergency room in such a manner as to preclude the necessity for entry into the pharmacy.

(7) The procedures outlined in this rule may not be used for controlled substances except at the following rural hospitals which met all three of the rural access project criteria on May 17, 1989:

Hospital		City
1.	Lake Chelan Community Hospital	Chelan
2.	St. Joseph's Hospital	Chewelah
3.	Whitman Community Hospital	Colfax
4.	Lincoln Hospital	Davenport
5.	Dayton General Hospital	Dayton
6.	Ocean Beach Hospital	Ilwaco

7.	Newport Community Hospital	Newport
8.	Jefferson General Hospital	Port Townsend
9.	Ritzville Memorial Hospital	Ritzville
10.	Willapa Harbor Hospital	South Bend

[Statutory Authority: RCW 18.64.005. 92-12-035 (Order 277B), § 246-873-060, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-873-060, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. 89-12-011 (Order 225), § 360-17-055, filed 5/26/89; 83-23-109 (Order 179), § 360-17-055, filed 11/23/83.]

246-873-070
Physical requirements.

(1) Area. The pharmacy facilities shall include:

(a) Appropriate transportation and communications systems for the distribution and control of drugs within the hospital.

(b) Sufficient space and equipment for secure, environmentally controlled storage of drugs and other pharmaceutical supplies.

(2) In order to meet the medical services' need for drugs throughout the hospital, the pharmacy facilities should include:

(a) Space for the management and clinical functions of the pharmaceutical service.

(b) Space and equipment for the preparation of parenteral admixtures, radiopharmaceuticals, and other sterile compounding and packaging.

(c) Other equipment necessary.

(3) Access to unattended areas. All areas occupied by the hospital pharmacy shall be locked by key or combination in order to prevent access by unauthorized personnel. The director of pharmacy shall designate in writing, by title and/or position those individuals who shall be authorized access to particular areas within the pharmacy, including authorization of access to keys and/or combinations.

(4) Drug storage areas. Drugs shall be stored under proper conditions of sanitation, temperature, light, moisture, ventilation, segregation, and security.

(a) It is the joint responsibility of the director of pharmacy and the director of nursing to ensure that drug handling, storage, and preparation are carried out in conformance with established policies, procedures, and accepted standards.

(b) Locked storage or locked medication carts shall be provided for use on each nursing service area or unit.

(5) Flammable storage. All flammable material shall be stored and handled in accordance with applicable local and state fire regulations, and there shall be written policy and procedures for the destruction of these flammable materials.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-873-070, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. 85-11-066 (Order 194), § 360-17-060, filed 5/21/85. Statutory Authority: RCW 18.64.005(11). 81-16-036 (Order 162), § 360-17-060, filed 7/29/81.]

246-873-080
Drug procurement, distribution and control.

(1) General. Pharmaceutical service shall include:

(a) Procurement, preparation, storage, distribution and control of all drugs throughout the hospital.

(b) A monthly inspection of all nursing care units or other areas of the hospital where medications are dispensed, administered or stored. Inspection reports shall be maintained for one year.

(c) Monitoring the drug therapy.

(d) Provisions for drug information to patients, physicians and others.

(e) Surveillance and reporting of adverse drug reactions and drug product defect(s).

(2) Additional pharmaceutical services should include:

(a) Obtaining and recording comprehensive drug histories and participation in discharge planning in order to affect appropriate drug use.

(b) Preparation of all sterile products (e.g., IV admixtures, piggybacks, irrigation solutions), except in emergencies.

(c) Distribution and control of all radiopharmaceuticals.

(d) Administration of drugs.

(e) Prescribing.

(3) The director shall be responsible for establishing specifications for procurement, distribution and the maintenance of a system of accountability for drugs, IV solutions, chemicals, and biologicals related to the practice of pharmacy.

(4) The director shall establish, annually review and update when necessary comprehensive written policies and procedures governing the responsibilities and functions of the pharmaceutical service. Policies affecting patient care and treatment involving drug use shall be established by the director of pharmacy with the cooperation and input of the medical staff, nursing service and the administration.

(5) Labeling:

(a) Inpatient. All drug containers in the hospital shall be labeled clearly, legibly and adequately to show the drug's name (generic and/or trade) and strength when applicable. Accessory or cautionary statements and the expiration date shall be applied to containers as appropriate.

(b) Outpatients. Labels on medications used for outpatients, emergency room, and discharge drug orders shall meet the requirements of RCW 18.64.246.

(c) Parenteral and irrigation solutions. When drugs are added to intravenous solutions, a suitable label shall be affixed to the container. As a minimum the label shall indicate name and location of the patient, name and amount of drug(s) added, appropriate dating, initials of the personnel who prepared and checked the solution.

(6) Medication orders. Drugs are to be dispensed and administered only upon orders of authorized practitioners. A pharmacist shall review the original order or direct copy thereof, prior to dispensing any drug, except for emergency use or as authorized in WAC 246-873-050.

(7) Controlled substance accountability. The director of pharmacy shall establish effective procedures and maintain adequate records regarding use and accountability of controlled substances, and such other drugs as appropriate, in compliance with state and federal laws and regulations.

(a) Complete, accurate, and current records shall be kept of receipt of all controlled substances and in addition, a Schedule II perpetual inventory shall be maintained.

(b) The pharmacy shall maintain records of Schedule II drugs issued from the pharmacy to other hospital units which include:

(i) Date

(ii) Name of the drug

(iii) Amount of drug issued

(iv) Name and/or initials of the pharmacist who issued the drug

(v) Name of the patient and/or unit to which the drug was issued.

(c) Records shall be maintained by any unit of the hospital which utilizes Schedule II drugs indicating:

(i) Date

(ii) Time of administration

(iii) Name of the drug (if not already indicated on the records

(iv) Dosage of the drug which was used which shall include both the amount administered and any amount destroyed.

(v) Name of the patient to whom the drug was administered

(vi) Name of the practitioner who authorized the drug

(vii) Signature of the licensed individual who administered the drug.

(d) When it is necessary to destroy small amounts of controlled substances following the administration of a dose by a nurse, the destruction shall be witnessed by a second nurse who shall countersign the records of destruction.

(e) The director of the pharmacy shall develop written procedures for the proper destruction of controlled substances not covered by (d) above conforming with federal and state statutes. A copy of the procedures shall be forwarded to the Drug Enforcement Administration (DEA) and the state board of pharmacy. As a minimum, procedures shall include the following:

(i) All destructions shall render the drugs unrecoverable.

(ii) Destruction shall be accomplished by the pharmacist and one other licensed health professional.

(iii) Records of all destructions shall be maintained by the pharmacy. Quarterly summary reports shall be mailed to the DEA with copies to the state board of pharmacy.

(iv) A copy of the destruction record shall be maintained in the pharmacy for two years.

(f) Periodic monitoring of controlled substances records shall be performed by a nurse or a pharmacist to determine whether the drugs recorded on usage records have also been recorded on the patient's chart.

(g) Use of multiple dose vials of controlled substances shall be discouraged.

(h) Controlled substances, Schedule II and III, which are floor stocked, in any hospital patient or nursing service area

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-873-100, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(11). 81-16-036 (Order 162), § 360-17-090, filed 7/29/81.]

246-873-110
Additional responsibilities of pharmacy service.

(1) General. The pharmacy service shall participate in other activities and committees within the hospital affecting pharmaceutical services, drugs and drug use.

(2) Quality assurance. The pharmaceutical service shall establish a pharmacy quality assurance program.

(3) Clinical activities. The director of pharmacy should develop clinically oriented programs, including but not limited to obtaining and recording comprehensive drug histories and participation in discharge planning to affect appropriate drug use, a formal drug information service, prescribing, and administration of drugs.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-873-110, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(11). 81-16-036 (Order 162), § 360-17-100, filed 7/29/81.]

WEST VIRGINIA CODE

CHAPTER 30. PROFESSIONS AND OCCUPATIONS.
ARTICLE 5. PHARMACISTS, PHARMACY TECHNICIANS, PHARMACY INTERNS AND PHARMACIES.

§30-5-1. Legislative findings.
The Legislature hereby finds and declares that the practice of pharmacy is a privilege and not a natural or fundamental right of any individual. As a matter of public policy, it is necessary to protect the public through the enactment of this article and to regulate the granting of such privileges and their use. This article shall be liberally construed to carry out these purposes.

§**30-5-1a. Statement of purpose.**
It is the purpose of this article to promote, preserve and protect the public health, safety and welfare by the effective regulation of the practice of pharmacy; the licensure of pharmacists; the licensure, and regulation of all sites or persons who distribute, manufacture, or sell drugs or devices used in the dispensing and administration of drugs or devices within this state.

§30-5-1b. Definitions.
The following words and phrases, as used in this article, have the following meanings, unless the context otherwise requires:

(1) "Administer" means the direct application of a drug to the body of a patient or research subject by injection, inhalation, ingestion or any other means.

(2) "Board of Pharmacy" or "board" means the West Virginia State Board of Pharmacy.

(3) "Charitable clinic pharmacy" means a clinic or facility organized as a not-for-profit corporation that offers pharmaceutical care and dispenses prescriptions free of charge to appropriately screened and qualified indigent patients. The Board of Pharmacy shall promulgate rules regarding the minimum standards for a charitable clinic pharmacy and rules regarding the applicable definition of a pharmacist-in-charge, who may be a volunteer, at charitable clinic pharmacies: *Provided,* That the charitable clinic pharmacies shall be exempt from licensure by the board until rules are in effect for a charitable clinic pharmacy. A charitable clinic pharmacy may not be charged any applicable licensing fees and such clinics may receive donated drugs.

(4) "Collaborative pharmacy practice" is that practice of pharmacy where one or more pharmacists have jointly agreed, on a voluntary basis, to work in conjunction with one or more physicians under written protocol where the pharmacist or pharmacists may perform certain patient care functions authorized by the physician or physicians under certain specified conditions and limitations.

(5) "Collaborative pharmacy practice agreement" is a written and signed agreement between a pharmacist, a physician and the individual patient, or the patient's authorized representative who has granted his or her informed consent, that provides for collaborative pharmacy practice for the purpose of drug therapy management of a patient, which has been approved by the Board of Pharmacy, the Board of Medicine in the case of an allopathic physician or the West Virginia Board of Osteopathy in the case of an osteopathic physician.

(6) "Compounding" means:

(A) The preparation, mixing, assembling, packaging or labeling of a drug or device:

(I) As the result of a practitioner's prescription drug order or initiative based on the practitioner/patient/pharmacist relationship in the course of professional practice for sale or dispensing; or

(ii) For the purpose of, or as an incident to, research, teaching or chemical analysis and not for sale or dispensing; and

and includes any packaging or repackaging of the substance or substances or labeling or relabeling of its contents and the promotion and marketing of the drugs or devices. Manufacturing also includes the preparation and promotion of commercially available products from bulk compounds for resale by pharmacies, practitioners or other persons.

(22) "Nonprescription drug" means a drug which may be sold without a prescription and which is labeled for use by the consumer in accordance with the requirements of the laws and rules of this state and the federal government.

(23) "Patient counseling" means the oral communication by the pharmacist of information, as defined in the rules of the board, to the patient to improve therapy by aiding in the proper use of drugs and devices.

(24) "Person" means an individual, corporation, partnership, association or any other legal entity, including government.

(25) "Pharmaceutical care" is the provision of drug therapy and other pharmaceutical patient care services intended to achieve outcomes related to the cure or prevention of a disease, elimination or reduction of a patient's symptoms or arresting or slowing of a disease process as defined in the rules of the board.

(26) "Pharmacist" or "registered pharmacist" means an individual currently licensed by this state to engage in the practice of pharmacy and pharmaceutical care.

(27) "Pharmacist-in-charge" means a pharmacist currently licensed in this state who accepts responsibility for the operation of a pharmacy in conformance with all laws and rules pertinent to the practice of pharmacy and the distribution of drugs and who is personally in full and actual charge of the pharmacy and personnel.

(28) "Pharmacist's scope of practice pursuant to the collaborative pharmacy practice agreement" means those duties and limitations of duties placed upon the pharmacist by the collaborating physician, as jointly approved by the Board of Pharmacy and the Board of Medicine or the Board of Osteopathy.

(29) "Pharmacy" means any drugstore, apothecary or place within this state where drugs are dispensed and sold at retail or displayed for sale at retail and pharmaceutical care is provided and any place outside of this state where drugs are dispensed and pharmaceutical care is provided to residents of this state.

(30) "Physician" means an individual currently licensed, in good standing and without restrictions, as an allopathic physician by the West Virginia Board of Medicine or an osteopathic physician by the West Virginia Board of Osteopathy.

(31) "Pharmacy technician" means registered supportive personnel who work under the direct supervision of a pharmacist who have passed an approved training program as described in this article.

(32) "Practitioner" means an individual currently licensed, registered or otherwise authorized by any state, territory or district of the United States to prescribe and administer drugs in the course of professional practices, including allopathic and osteopathic physicians, dentists, physician assistants, optometrists, veterinarians, podiatrists and nurse practitioners as allowed by law.

(33) "Preceptor" means an individual who is currently licensed as a pharmacist by the board, meets the qualifications as a preceptor under the rules of the board and participates in the instructional training of pharmacy interns.

(34) "Prescription drug" or "legend drug" means a drug which, under federal law, is required, prior to being dispensed or delivered, to be labeled with either of the following statements:

(A) "Caution: Federal law prohibits dispensing without prescription"; or

(B) "Caution: Federal law restricts this drug to use by, or on the order of, a licensed veterinarian"; or a drug which is required by any applicable federal or state law or rule to be dispensed pursuant only to a prescription drug order or is restricted to use by practitioners only.

(35) "Prescription drug order" means a lawful order of a practitioner for a drug or device for a specific patient.

(36) "Prospective drug use review" means a review of the patient's drug therapy and prescription drug order, as defined in the rules of the board, prior to dispensing the drug as part of a drug regimen review.

(37) "USP-DI" means the United States pharmacopeia-dispensing information.

2009-10 Wisconsin Statutes & Annotations

450.06 Pharmacies located in this state; licensure.

(1) Except as provided in s. 450.062, no pharmacist may dispense at any location in this state that is not licensed as a pharmacy by the board. No person in this state may use or display the title "pharmacy," "drugstore," "apothecary," or any other title, symbol, or insignia having the same or similar meanings, except for a place of practice which is licensed under this section as a pharmacy by the board.

(2) The board shall issue a license to operate a pharmacy at a specific location in this state if:

(a) An application is made on forms provided by the board showing all of the following:

1. The location of the pharmacy.

2. A floor plan of the pharmacy.

3. The name and address of the person holding title and ownership control of the location.

4. The name of the managing pharmacist of the pharmacy under s. 450.09 (1).

(b) The location of the pharmacy is inspected and found to meet all the requirements of this chapter.

(c) The initial credential fee determined by the department under s. 440.03 (9) (a) is paid.

(2m) The board may request, but may not require, that practice-related information be submitted on the application under sub. (2) (a).

(3) No pharmacy located in this state may be opened or kept open for practice following a change of ownership or change of location unless the pharmacy is licensed for the new owner or at the new location, notwithstanding any remaining period of validity under the pharmacy's license under the previous owner or at the previous location.

(4) Any person who fails to license his or her place of practice as required under this section may be assessed a forfeiture of not less than $25 nor more than $50 for each separate offense. Each day of violation constitutes a separate offense.

History: 1985 a. 146; 1991 a. 39; 2005 a. 242; 2007 a. 20, 202.

Cross-reference: See also ch. Phar 6, Wis. adm. code.

CHAPTER 24
PHARMACY

ARTICLE 1
IN GENERAL

33-24-113. Licensing of resident pharmacy; exceptions; display of license; suspension, revocation, letter of admonition, administrative penalty or refusal to renew; appeals.

(a) Any pharmacy located in this state which dispenses, mails or in any manner delivers controlled substances or dangerous drugs or devices in this state pursuant to a prescription or provides pharmaceutical care in this state shall:

(i) Submit a license application to the board on a form prescribed by the board and pay the license fee established by the board in its rules and regulations. Where pharmaceutical operations are conducted at more than one (1) location, each location shall be separately licensed;

(ii) Notify the board of the occurrence of any of the following:

(A) Permanent closing of the pharmacy;

(B) Change in pharmacy ownership, name, management, location or pharmacist in charge;

(C) Conviction of any pharmacy owner or employee for violation of any state or federal drug law;

(D) Any substantial theft or loss of dangerous drugs, controlled substances or medical devices;

(E) Any other matter required to be reported by rule and regulation of the board.

(b) The license shall be displayed in a conspicuous place in the pharmacy for which it is issued, and shall be renewed annually on or before June 30 by submitting a renewal application to the board.

(c) It is unlawful for any person or commercial operation to operate a pharmacy unless a license has been issued to the operator by the board of pharmacy.

(d) The board may deny, suspend, revoke or refuse to renew a license issued under the section, may issue a letter of admonition to a resident pharmacy licensee and may assess an administrative penalty, not to exceed two thousand dollars ($2,000.00) per violation, against a resident pharmacy licensee on any of the following grounds:

(i) Failure to comply with any requirement of this chapter or the Wyoming Controlled Substances Act;

(ii) Failure to comply with rules and regulations of the board;

(iii) Conviction of a pharmacy owner, pharmacist in charge, staff pharmacist or pharmacy technician for a felony

under any state or federal law, if the conviction is related to the practice of pharmacy;

(iv) Obtaining any remuneration by fraud, misrepresentation or deception;

(v) Suspension or revocation of a pharmacy license in any other state;

(vi) Knowing submission of false, misleading or fraudulent information to the board in connection with an initial or renewal application for a resident pharmacy license;

(vii) Purchase or receipt of a dangerous drug, controlled substance or medical device from a source other than a manufacturer, wholesaler or pharmacy licensed by the board;

(viii) Purchase or receipt of a dangerous drug, controlled substance or medical device that is not approved by the federal drug administration;

(ix) Keeping the pharmacy open for business without a licensed pharmacist in charge on site;

(x) Allowing a person who is not licensed by the board to perform duties as a pharmacist, pharmacy technician or pharmacy technician in training.

(e) Before any final adverse administrative action is taken against a pharmacy licensee, the licensee is entitled to a hearing by the board of pharmacy upon due notice of the time and place where the hearing will be held. The accused may be represented by legal counsel, is entitled to compulsory attendance of witnesses and may appeal to the district court of the county in which the pharmacy is situated, in accordance with the Wyoming Administrative Procedure Act.

(f) Any administrative penalty assessed shall be paid to the board who shall remit the monies to the county treasurer to the credit of the public school fund of the county in which the violation occurred.

Wyoming
State Board of Pharmacy

Highlights

Items of Interest

Prescription Drug Monitoring Program

Submit a Complaint

Contact Info

State Board Of Pharmacy
Mary K. Walker, Executive Director
1712 Carey Avenue, Ste 200
Cheyenne, WY 82002
Email: bop@wyo.gov

Phone: (307) 634-9636
Fax: (307) 634-6335

State of Wyoming Pharmacy Laws

Title 33, Chapter 24, Wyoming Pharmacy Act
Title 35, Chapter 7, Wyoming Controlled Substance Act

These documents are also available on the Wyoming State Legislature's Website.

State of Wyoming Pharmacy Act Rules and Regulations

Rules and Regulations (All Chapters)

		Date Filed
Chapter 1	Rules Of Practice And Procedure Of The Wyoming State Board Of Pharmacy	12-08-2000
Chapter 2	General Practice Of Pharmacy Regulations	07-06-2011
Chapter 3	Pharmacy Internship Regulations	07-06-2011
Chapter 4	Code Of Ethics	12-31-2007
Chapter 5	Poison Regulations	07-06-2011
Chapter 6	Continuing Pharmaceutical Education Regulations	12-13-2005
Chapter 7	Computer Regulations	07-06-2011
Chapter 8	Manufacturer, Distributor, Wholesaler Prescription Drug Regulations	11-15-2009
Chapter 9	Patient Counseling And Prospective Drug Use Review Regulations	11-18-2002
Chapter 10	Pharmacy Technician Regulations	09-10-2008
Chapter 11	Dangerous Drug Regulations	11-24-1999
Chapter 12	Institutional Pharmacy Practice Regulations	11-15-2009
Chapter 13	Compounding	11-15-2009
Chapter 14	Telepharmacy Rules and Regulations	07-06-2011
Chapter 15	Long Term Care Pharmacy Services Rules and Regulations	12-13-2005
Chapter 16	Immunization Regulations	11-15-2009
Chapter 17	Sterile Compounding	11-15-2009

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These documents are also available on the Secretary of State's Website.

State of Wyoming Controlled Substance Act Rules and Regulations

Rules and Regulations (All Chapters)

		Date Filed
Chapter 1	Authority And Definitions	02-19-1986
Chapter 2	General Information	02-19-1986
Chapter 3	Fees For Registration And Re-Registration	07-06-2011
Chapter 4	Records And Inventories Of Registrants	07-06-2011
Chapter 5	Rules Of Practice And Procedure Governing Hearings	02-19-1986
Chapter 6	Issuing, Filing And Filling Of Prescriptions	07-06-2011
Chapter 7	Administrative Inspections	02-19-1986
Chapter 8	Prescriptions Drug Monitoring Program	07-06-2011

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CHAPTER 12

INSTITUTIONAL PHARMACY PRACTICE REGULATIONS

Section 1. Authority.

These regulations are promulgated as authorized by the Act.

Section 2. Purpose.

The purpose of this Chapter is to provide standards for the conduct, practice activities, and operation of a pharmacy located in a hospital or other inpatient facility that is licensed under the Wyoming Department of Health. The intent of these standards is to establish a minimum acceptable level of pharmaceutical care to the patient so that the patient's health is protected while contributing to positive patient outcomes.

Section 3. Scope of Chapter.

This Chapter applies to any person, partnership, corporation, limited liability company, or other entity engaging in the practice of pharmacy in an Institutional Facility, as defined below, within this state.

Section 4. Definitions.

(a) "Institutional Facility" means a hospital, convalescent home, nursing home, extended care facility, correctional or penal facility, or any other organization, public or private, which provides a physical environment for patients to obtain medical, surgical, and/or nursing services, except those places where physicians, dentists, veterinarians, or other practitioners of the healing arts engage in private office practice.

(b) "Institutional Pharmacy" means a pharmacy where medications are dispensed to other health care professionals for administration to institutionalized patients served by an Institutional Facility, and which is:

(i) Located within the Institutional Facility, or

(ii) Located outside the Institutional Facility but only provides pharmaceutical services to institutionalized patients.

(c) "Drug Room" means a secure and lockable location within an inpatient care facility that does not have an Institutional Pharmacy.

(d) "Floor Stock" means prescription drugs not labeled for a specific patient and maintained at a nursing station or other Institutional Facility department (excluding the Institutional Pharmacy) for the purpose of administration to a patient of the Institutional Facility.

(e) "Formulary" means a continually revised compilation of pharmaceuticals that reflects the current clinical judgment of the medical staff of the Institutional Facility.

(f) "Medication Order" means a written, electronic, or verbal order from a practitioner (or his/her agent) authorized by law to prescribe medications for administration to a patient.

(g) "Emergency Drug Cart (crash cart)" means a cart containing those drugs that may be required to meet the immediate therapeutic needs of inpatients or emergency room patients and are not available from any other authorized source in sufficient time to prevent risk of harm to patients by delay resulting from obtaining such drugs from such other source.

(h) "Clean Room" means a room with a minimum of an ISO Class 7 environment:

(i) in which the concentration of airborne particles is controlled;

(ii) that is constructed and used in a manner to minimize the introduction, generation, and retention of particles inside the room;

(iii) in which other relevant variables (e.g., temperature, humidity, and pressure) are controlled as necessary; and

(iv) in which microorganisms in the environment are monitored so that a microbial level for air, surface, and personnel gear is not exceeded for a specific cleanliness class.

(i) "Investigational Drug" means:

(i) a substance in a clinical stage of evaluation not released by the Food and Drug Administration for general use or for sale in interstate commerce; or

(ii) Commercial drugs that are proposed for a new use, contain a new component, have a new dosage or mode of administration, or are in a new combination or combined in new proportions.

(j) "Remote Order Processing for Institutional Pharmacies" includes any of the following activities performed for an Institutional Pharmacy from a remote location:

(i) Receiving, interpreting, or clarifying medication orders;

(ii) Entering or transferring medication order data;

(iii) Performing prospective drug use review;

(iv) Obtaining substitution authorizations;

(v) Interpreting and acting on clinical data;

(vi) Performing therapeutic interventions;

(vii) Providing drug information;

(viii) Authorizing the release of a medication for administration.

Section 5. Licensing.

(a) All institutional pharmacies shall register annually with the Board of Pharmacy on a form provided by the Board. Institutional Pharmacies that also provide outpatient pharmacy services shall also register as a retail pharmacy.

(b) All Institutional Pharmacy licenses shall expire on June 30. Renewal notices will be sent by the Board's office at least sixty days prior to June 30.

(c) The fee established in Wyoming Pharmacy Act, Rules and Regulations Chapter 2, Section 25(a)(xi), will be charged for issuance of a new license and renewal. The late fee established in Wyoming Pharmacy Act, Rules and Regulations, Chapter 2, Section 25 (b)(vi), will be charged, in addition to the renewal fee, for any license renewal application that is postmarked after June 30 or is hand-delivered to the Board office after June 30.

Section 6. Change of Ownership.

(a) If an Institutional Pharmacy changes ownership, it must obtain a new and separate registration from the Board. In the case of a corporation, limited liability company, or partnership holding an Institutional Pharmacy license, the Board shall be notified and a new license applied for any time the majority of stock in the corporation is sold or a majority of the partners of the partnership or members of the limited liability company change.

Section 7. Personnel.

(a) A pharmacist, hereinafter referred to as the Pharmacist-in-Charge (PIC), who is licensed to engage in the practice of pharmacy in Wyoming, shall direct each Institutional Pharmacy.

(b) The storage, compounding, repackaging, dispensing, and distribution of drugs by an Institutional Pharmacy shall be under the direction, supervision, and responsibility of the PIC. Depending upon the size and needs of the Institutional Facility, pharmacy service may be provided on a full or part-time basis.

(i) In hospital Institutional Facilities with fifty (50) or more acute care beds, a pharmacist shall be in the hospital Institutional Facility during the time the Institutional Pharmacy is open for pharmacy services, except in case of emergencies.

Pharmacy services shall be provided for a minimum of forty (40) hours per week, unless an exception is made upon written request by the hospital Institutional Facility and with express permission of the Board.

(ii) In hospital Institutional Facilities with less than fifty (50) acute care beds, a pharmacist shall be in the hospital Institutional Facility during the time the Institutional Pharmacy is open for pharmacy services. Upon written request by the hospital Institutional Facility, and with the express permission of the Board, the services of a pharmacist may be on a part-time basis, according to the needs of the hospital Institutional Facility. The services of a pharmacist shall be required as follows:

(A) In hospital Institutional Facilities with one to twenty-five (1-25) acute care beds, a pharmacist shall be available a minimum of five (5) hours per week.

(B) In hospital Institutional Facilities with twenty-six to forty-nine (26-49) acute care beds, a pharmacist shall be available a minimum of twenty (20) hours per week.

(iii) In a non-hospital Institutional Facility, a pharmacist shall be available commensurate with the needs of the Institutional Facility. The hours shall be identified on the initial application and provided with each license renewal.

(c) Policies and procedures defining the pharmaceutical services to be provided and the responsibilities of the Institutional Pharmacy shall be established. Such policies and procedures shall be made available to the Board and/or its authorized representative upon request.

(d) The responsibilities of the PIC shall include, at a minimum, the following:

(i) Providing the appropriate level of pharmaceutical care services to patients of the Institutional Facility;

(ii) Ensuring that drugs and/or devices are dispensed and distributed safely and accurately as prescribed;

(iii) Developing a system for the compounding, sterility assurance, quality assurance, and quality control of sterile pharmaceuticals compounded within the Institutional Pharmacy;

(iv) Developing a system to assure that all Institutional Pharmacy personnel responsible for compounding and/or supervising the compounding of sterile pharmaceuticals within the Institutional Pharmacy receive appropriate education, training, and competency evaluation;

(v) Providing guidelines and approval of the procedure to assure that all pharmaceutical requirements are met when any part of preparing, sterilizing, and labeling of sterile pharmaceuticals is not performed under direct Institutional Pharmacy supervision;

(vi) Participating in the development of a Formulary for the Institutional Facility which is approved by the appropriate committee, including the medical staff of the Institutional Facility;

(vii) Developing a system to assure that drugs to be administered to inpatients are distributed pursuant to an original or direct copy of the practitioner's Medication Order;

(viii) Maintaining records of all transactions of the Institutional Pharmacy as may be required by applicable state and federal law, and as may be necessary to maintain accurate control over and accountability for all pharmaceutical materials, including pharmaceuticals and components used in the compounding of pharmaceuticals;

(ix) Participating in those aspects of the Institutional Facility's patient care evaluation program that relate to pharmaceutical utilization and effectiveness;

(x) Assuring that a reasonable effort is made to obtain, record, and maintain patient medication records;

(xi) Assuring the legal operation of the Institutional Pharmacy, including meeting all inspection and other requirements of state and federal laws or rules governing the practice of pharmacy; and

(xii) Collaborating with the nursing staff and the medical staff to develop a list of standardized concentrations of medications that will be used in the Institutional Facility (e.g., therapeutic heparin intravenous infusions). Pediatric formulations will be considered as a separate listing from adult formations.

(e) The PIC shall be assisted by a sufficient number of additional licensed pharmacists as may be required to operate the Institutional Pharmacy competently, safely, and adequately to meet the needs of the patients of the Institutional Facility. All pharmacists shall assist the PIC in meeting the responsibilities as outlined in Subsection (c) of this Section and in ordering, accounting for, and other administrative duties regarding pharmaceutical products.

(f) Pharmacy technicians may assist the PIC, provided the ratio of pharmacy technicians and pharmacy technicians-in-training to licensed pharmacists does not exceed three to one (3:1). The duties of the pharmacy technicians or pharmacy technicians-in-training shall be established by the PIC and may not exceed the responsibilities as outlined in Wyoming Pharmacy Act, Rules and Regulations, Chapter 10.

(g) The PIC may be assisted by secretarial and clerical assistance as required to assist with record-keeping, report submission, and other administrative duties.

Section 8. Environment.

(a) The Institutional Pharmacy shall be enclosed and lockable.

(b) The Institutional Pharmacy shall have adequate space necessary for the storage, compounding, labeling, dispensing, and sterile preparation of drugs prepared in the Institutional Pharmacy, depending on the size and scope of pharmaceutical services provided.

(c) A sink with hot and cold running water, exclusive of restroom facilities, shall be available to all Institutional Pharmacy personnel and shall be maintained in a sanitary condition at all times.

(d) The Institutional Pharmacy shall be arranged in an orderly fashion and shall be kept clean. All required equipment shall be clean and in good operating condition.

(e) The Institutional Pharmacy shall be properly lighted and ventilated.

(f) The temperature of the Institutional Pharmacy shall be maintained within a range of 59 to 86 degrees Fahrenheit (15 to 30 degrees Centigrade). The temperature of the refrigerator shall be maintained within a range of 36 to 46 degrees Fahrenheit (2 to 8 degrees Centigrade) and the freezer shall be maintained within a range of –13 to +14 degrees Fahrenheit (-25 to –10 degrees Centigrade).

(g) The Institutional Pharmacy shall store antiseptics, other drugs for external use, and disinfectants separately from internal and injectable medications.

(h) If the Institutional Pharmacy compounds sterile pharmaceuticals, they shall be prepared in accordance with Wyoming Pharmacy Act, Rules and Regulations, Chapter 17.

Section 9. References.

Each Institutional Pharmacy shall maintain in its library at least one current reference (text or electronic format, including online access or PDA) from each category listed below. The Board reserves the right to accept new references in lieu of the following:

(a) Drug Monograph Reference:

(i) American Hospital Formulary Service®

(ii) Drug Facts and Comparisons®;

(iii) Thomson's Micromedex®;

(iv) USPDI® Volume I, Drug Information for the Health Care Professional; or

(v) Drug Information Handbook (Lexi-Comp).

(b) Stability and Incompatibility Reference:

(i) Handbook on Injectable Drugs, Lawrence A. Trissel;

(ii) King Guide to Parenteral Admixtures; or

(iii) Thomson's Micromedex®.

(c) Reference on Drug Availability and Identification:

(i) American Hospital Formulary Service® ;

(ii) Drug Facts and Comparisons®;

(iii) American Drug Index; or

(iv) Drug Information Handbook (Lexi-Comp) .

(d) Drug Interactions:

(i) American Hospital Formulary Service®

(ii) Thomson's Micromedex®;

(iii) Drug Interactions Facts;

(iv) USPDI® Volume I, Drug Information for the Health Care Professional;

(v) Drug Information Handbook (Lexi-Comp) ;

(vi) Drug Interactions Analysis and Management (DIAM) ;

(e) Reference on Pharmacology and Therapeutics:

(i) Conn's Current Therapy (Rakel and Bope) ;

(ii) Drug Information Handbook (Lexi-Comp) ;

(iii) Applied Therapeutics: The Clinical Use of Drugs (Koda-Kimble);

(iv) Pharmacotherapy (DiPiro); or

(v) Textbook of Therapeutics (Herfindal and Gourley) .

(f) Current copies of the Wyoming Pharmacy Act and Rules and Regulations, and Wyoming Controlled Substance Act and Rules and Regulations, text or electronic format, and including internet access to the Board website.

(g) Wyoming State Board of Pharmacy Quarterly Newsletter, maintained in a binder.

Section 10. Equipment.

(a) Institutional pharmacies distributing Medication Orders shall have the following equipment:

(i) Refrigerator, including a system or device to monitor the temperature daily to ensure that proper storage requirements are met;

(ii) Computer and software appropriate for the Institutional Facility; and

(iii) Facsimile capability located in the Institutional Pharmacy.

(b) If the Institutional Pharmacy compounds Medication Orders that require the use of a balance, a Class A prescription balance or electronic scale with 10 mg sensitivity shall be available. Such balance or electronic scale shall be properly maintained by the PIC and may be inspected at least every three (3) years by the Board of Pharmacy.

(c) If the Institutional Pharmacy compounds sterile pharmaceuticals, the Institutional Pharmacy shall have equipment and supplies listed in Wyoming Pharmacy Act, Rules and Regulations Chapter 17.

Section 11. Security.

(a) No one shall be permitted in the Institutional Pharmacy unless the pharmacist is on duty, except as provided in this Chapter, Section 12. If the pharmacist must leave the Institutional Pharmacy for an emergency or patient care duties, pharmacy technicians may remain to perform duties as authorized by the Pharmacist-in-Charge (PIC), provided that the pharmacist remains in the Institutional Facility.

(b) All Institutional Pharmacy areas shall be capable of being locked by key or programmable lock, so as to prevent access by unauthorized personnel. The Director shall designate in writing, by title and specific area, those persons who shall have access to specific Institutional Pharmacy areas.

(c) Each pharmacist on duty shall be responsible for the security of the Institutional Pharmacy, including provisions for adequate safeguards against theft or diversion of drugs including controlled substances and the records thereof.

(d) Pharmacists, technicians, clerical staff, and interns working in the Institutional Pharmacy shall wear identification badges, including name and position, whenever on duty.

(e) The PIC shall be responsible for policies and procedures for the safe distribution and control of prescription blanks bearing identification of the Institutional Facility.

Section 12. Absence of Pharmacist.

(a) General. During such times as Institutional Pharmacy services are not available on-site, arrangements shall be made in advance by the Pharmacist-in-Charge (PIC) for provision of drugs to the medical staff and other authorized personnel of the Institutional Facility by use of Floor Stock and/or access to the Institutional Pharmacy under the standing order of the PIC.

(b) If Floor Stock is used, the following shall prevail:

(i) In the absence of a registered pharmacist, medication for inpatients shall be obtained from a locked cabinet(s) or other enclosure(s) located outside the Institutional Pharmacy to which only nurses, specifically authorized in writing by the PIC, may obtain access by key or combination, and which is sufficiently secure to deny access to unauthorized persons.

(ii) The PIC shall, in conjunction with the appropriate committee, if any, of the Institutional Facility, develop inventory listings of those drugs to be included in such Floor Stock, and shall ensure that:

(A) Such drugs are available therein, properly labeled;

(B) Such drugs are prepackaged in appropriate small amounts, unless commercially prepared package, e.g. ophthalmics, otics, topicals, etc.

(C) All drugs therein shall be checked and replenished as needed;

(D) A record shall be made on a copy of the physician's order or in a separate file or logbook located where the Floor Stock is maintained, and shall include:

(I) The date and time of removal of a drug;

(II) The patient's name and location;

(III) The name, strength, dosage form, and quantity of drug removed; and

(IV) The signature of the nurse removing the drug.

(E) The nurse removing the drug shall leave a direct copy of the new physician's order for the medication with the above record or, if the copy of the physician's order is utilized in place of the log book, then this copy must be left in a designated area where Floor Stock is maintained; and

(F) Written policies and procedures are established to implement the requirements of this Paragraph.

(c) Access to the Institutional Pharmacy. Whenever any drug is not available from Floor Stock, and such drug is required to treat the immediate needs of a patient

whose health would otherwise be jeopardized, such drug may be obtained from the Institutional Pharmacy, in accordance with the requirements of this Paragraph. Only supervisory or charge nurses may have access to the Institutional Pharmacy and may remove drugs therefrom. Such nurses shall be designated in writing by the PIC.

(i) Removal of any drug from the Institutional Pharmacy by an authorized nurse must be recorded on a suitable form at the Institutional Pharmacy showing:

(A) The date and time of the removal of the drug;

(B) The patient's name and location;

(C) The name, strength, dosage form, and quantity of drug removed; and

(D) The signature of the nurse.

(ii) The nurse removing the drug shall leave a copy of the physician's order for the new drug with the above record.

(iii) The quantity of drug removed shall not exceed the amount of medication needed until the Institutional Pharmacy reopens. Drugs that are usually dispensed as a unit of use package, such as MDIs, otics, topicals, insulin, and ophthalmics, are excluded.

(iv) A procedure shall be established to allow verification by the pharmacist of the drug removed (such as by leaving the identifying container or unit-dose sample of the drug with the records).

(d) If off-site pharmaceutical care is provided whenever an Institutional Pharmacy is closed, then the following requirements must be met:

(i) The Institutional Pharmacy shall have a pharmacist on duty at the Institutional Facility the minimum number of hours required in this Chapter, Section 7.

(ii) Any pharmacist providing off-site pharmaceutical care under this Section shall be licensed to practice pharmacy in Wyoming.

(iii) The Board shall be notified in writing by the Institutional Pharmacy of any arrangement whereby pharmaceutical care is provided off-site. This notification shall include the following:

(A) The name, address, and Wyoming license number of each pharmacist who will be providing this service.

(B) The name, address, and Wyoming license number of each pharmacy exchanging information with the Institutional Facility.

(C) Description of the audio, video, and data link that will be utilized to exchange information between the Institutional Facility and the off-site pharmacist.

(D) Description of the scope of work of any pharmacist who provides off-site pharmaceutical care under this Section.

(E) Description of patient information that is to be shared between the Institutional Facility and the off-site pharmacist. At minimum, the off-site pharmacist shall have access to the patient's medical record.

(iv) A pharmacist providing off-site pharmaceutical care may perform Remote Order Processing, if the pharmacist has access to appropriate patient information, including laboratory results.

(v) A pharmacist providing off-site pharmaceutical care shall provide the following services as a minimum:

(A) Review of any new Medication Order or change in existing Medication Order prior to administration by the nursing staff at the Institutional Facility.

(B) Review of all sterile compounding performed by nursing staff. Medications compounded during cardiopulmonary resuscitation or similar medical emergency or procedure shall be exempt from an off-site pharmacist review prior to administration. In all other circumstances, all sterile compounding is subject to review by the off-site pharmacist.

(C) The off-site pharmacist shall communicate with the Institutional Pharmacy staff on a daily basis or, if the Institutional Pharmacy is not opened on a daily basis, then communication shall occur whenever the Institutional Pharmacy is open for business.

Section 13. Emergency Outpatient Medication.

(a) Institutional Facilities, which provide for the administration and distribution of emergency pharmaceuticals to outpatients and/or inpatients being discharged during hours when normal community or outpatient Institutional pharmacy services are not available, may:

(i) Allow a designated nurse on the original written or electronic order of a practitioner to administer and distribute medications pursuant to the following requirements:

(A) A written or electronic order of a practitioner authorized to prescribe a drug is presented.

(B) The medication is prepackaged by a pharmacist or a technician under a pharmacist's supervision or is administered and distributed utilizing an automated drug dispensing device;

(C) The quantity of medication administered and distributed is limited to a seventy-two hour (72-hour) supply. Exceptions to the 72-hour supply include: pediatric antibiotic preparations (PO), otics, ophthalmics, topicals, or metered dose inhalers; and

(D) The labeling of the administered and distributed medication includes:

(I) Name, address, and telephone number of the l Institutional Facility;

(II) Name of patient;

(III) Name of drug, strength, and quantity;

(IV) Directions for use;

(V) Date;

(VI) Accessory cautionary information, as required for patient safety;

(VII) Name of practitioner; and

(VIII) Initials of the nurse administering and distributing the medication.

(b) The order may be in the form of a separate written or electronic prescription or a prescription entered in the patient's medical record. A practitioner must sign the order. A copy of the prescription order must be readily available for review by the pharmacist.

(c) A record shall be maintained for recording all medications administered and distributed from the Institutional Facility's emergency room. The record shall include the following information:

(i) Name of patient;

(ii) Date of issuance;

(iii) Name of drug;

(iv) Patient's Institutional Facility record number; and

(v) Initials of the nurse who administered and distributed the drug.

(d) The emergency room log for drugs administered and distributed after hours shall be reviewed by the pharmacist at least weekly. Inventory levels will be compared to drugs administered and distributed. Discrepancies will be reviewed with the emergency room nursing supervisor.

(e) Security of all drugs prepackaged must be maintained in a locked cabinet or storeroom location in the emergency room area to which only specifically authorized personnel shall have a key or combination.

Section 14. Emergency Drug Carts.

Emergency Drug Carts may be used by Institutional Facilities if:

(a) All drug kits are supplied, and kept up-to-date, under the supervision of a licensed pharmacist;

(b) A committee composed of the Pharmacist-in-Charge, nursing staff, and medical staff of the Institutional Facility develops a standard drug inventory, including kind and quantity of each drug;

(c) All drug kits are equipped with a breakable seal, and are secure from access by unauthorized persons;

(d) A listing of all drugs, their respective strength, quantity, and location, shall be placed on the cart in a conspicuous location. If the pharmacy which services this Emergency Drug Cart is not located within the Institutional Facility, the name, address, and telephone number of the pharmacy shall be displayed in a conspicuous location;

(e) All drugs are properly labeled;

(f) The drugs are distributed, pursuant to a valid order, by authorized personnel, and the pharmacist is notified of entry into the Emergency Drug Cart; and

(g) The pharmacist, nursing staff, and medical staff develop and implement written policies and procedures for using Emergency Drug Carts

Section 15. Automated Dispensing Devices.

(a) No drug shall be distributed or issued by the use of any automated dispensing device unless the device and method of operation have been found by the Board to ensure the purity, potency, and integrity of the drug, and to protect the drug from diversion, and provided that:

(i) The device shall be stocked with drugs only by or under the supervision of a pharmacist;

(ii) The device shall be used only for the furnishing of drugs for administration to patients of that Institutional Facility; and

(iii) At the time of removal of any drug from the device, it shall automatically make a written or electronic record to be retained by the pharmacist for at least one (1) year, indicating:

(A) The date of removal of the drug;

(B) The name, strength, dosage form, and quantity of drug removed;

(C) The name of the patient for whom the drug was ordered; and

(D) The name or identification code of the nurse removing the drug from the device.

Section 16. Parenteral Medications.

(a) The Pharmacist-in-Charge (PIC) shall be responsible for the preparation, sterilization, labeling, and dispensing of parenteral medications prepared within the Institutional Facility and shall participate in the education and training, including the provision of appropriate incompatibility information, of all personnel involved in the preparation of parenteral medications.

(b) If intravenous admixtures are prepared within the Institutional Facility, the Institutional Pharmacy shall have adequate equipment, personnel, and space for such preparation. The compounding and labeling of intravenous admixtures, including all total parenteral nutrition, shall be performed by, or under, the direct supervision of a pharmacist; however, if twenty-four hour (24-hour) pharmacy service is not provided at the Institutional Facility, the PIC shall establish written policies and procedures to be followed in the preparation of intravenous admixtures when the Institutional Pharmacy is closed or in emergency situations.

(c) All admixtures shall be labeled with a distinctive supplementary label, indicating the name and amount of drug added, date and time of addition, expiration date, and rate of administration, and the name or identification code of the person adding the drug.

(d) The PIC shall be responsible for removing concentrated electrolytes (including, but not limited to, potassium chloride, potassium phosphate, sodium chloride greater than 0.9%) from patient care areas and limiting their access to pharmacists, if at all possible. If twenty-four hour (24-hour) on-call status for pharmacists is not available, the Institutional Facility must utilize the most trained professional available to process concentrated electrolytes. Training in the safe use of concentrated electrolytes should be conducted by the Institutional Pharmacy for non-pharmacist staff with access to concentrated electrolytes. Evidence of training will be documented and retrievable, and the Institutional Facility will have policies and procedures that detail this process. Premixed large volume intravenous solutions containing electrolytes and premixed potassium bolus doses will be used whenever possible.

Section 17. Practitioner's Orders.

(a) All orders for drugs shall be transmitted to the Institutional Pharmacy by electronic order entry, or by means of an order format that is capable of producing a direct copy or an electronically reproduced facsimile. A pharmacist shall review the

(b) External medications are stored separately from internal medications;

(c) Thermolabile drugs are stored at the proper temperature;

(d) There are no outdated or deteriorated drugs;

(e) All drugs are properly labeled;

(f) Emergency Drug Carts (crash carts) are adequate and in proper supply;

(g) Medication storage areas are locked when not in use, and only authorized individuals have access to these areas;

(h) Distribution and administration of controlled substances are properly and adequately documented;

(i) Telephone numbers of the regional poison control center and other emergency assistance organizations are posted;

(j) Metric-apothecaries' weight and measure conversion tables and charts are available; and

(k) Adequate pharmaceutical reference texts are at these areas.

Section 21. Medications brought into the institution by patients.

Whenever patients bring drugs into an Institutional Facility, such drugs shall not be administered unless they can be precisely identified; administration shall be pursuant to a practitioner's order. If such drugs are not to be administered, they shall be delivered to the Institutional Pharmacy, packaged, sealed, and returned to an adult (18 years or older) member of the patient's immediate family (spouse, unless legally separated; adult child; parent; grandparent; adult brother or sister; adult grandchild), the patient's legal guardian or conservator, or the patient's designated agent, or they shall be stored and returned to the patient upon discharge, only after advice is provided regarding continuing the returned medication.

Section 22. Controlled Drugs.

(a) All controlled substances issued by the Institutional Pharmacy to any Institutional Facility department, excluding those controlled substances for which the dispensing and record-keeping are maintained utilizing an automated drug dispensing device, shall be labeled and accompanied with control sheets (proof of use forms) that provide space for recording:

(i) The drug name, strength, and dosage form;

(ii) The date and time of administration;

(b) External medications are stored separately from internal medications;

(c) Thermolabile drugs are stored at the proper temperature;

(d) There are no outdated or deteriorated drugs;

(e) All drugs are properly labeled;

(f) Emergency Drug Carts (crash carts) are adequate and in proper supply;

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