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 and records not specifically stated in this Chapter, refer to Chapter 11 of this Part.

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, amended by the Department of Health, Board of Pharmacy, LR 46:583 (April 2020).

§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.

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, amended by the Department of Health, Board of Pharmacy, LR 46:583 (April 2020).

§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 or penal institution, 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 this Part.
B. Pharmacies operated within a hospital shall be operated in accordance with Chapter 15 of this Part.
C. Pharmacies operated within a correctional center shall be operated in accordance with Chapter 18 of this Part.

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, LR 39:313 (February 2013), amended by the Department of Health, Board of Pharmacy, LR 46:584 (April 2020).

§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 readily retrievable 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.

E. Cancellation Prior to Renewal. In the event the facility or provider pharmacy elects to cancel the permit prior to the renewal date, the pharmacy shall relinquish the permit to the board office no later than 10 days following the date of cancellation.

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 by the Department of Health, Board of Pharmacy, LR 46:584 (April 2020).

§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 30 days, plus or minus five 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.

J. The placement of controlled dangerous substances in an EDK in non-federally registered long-term care facilities shall be deemed in compliance with the Comprehensive Drug Abuse Prevention and Control Act of 1970 provided that:

1. Controlled dangerous substances shall be stored in the EDK as deemed necessary and jointly approved by the pharmacist, medical director and the director of nursing services;
2. The source from which the controlled dangerous substances for EDKs are obtained shall be a pharmacy licensed by the board in possession of a valid DEA registration and Louisiana CDS license;
3. The number of different controlled dangerous substances in a single EDK shall be limited to a maximum of eight separate drug entities with not more than eight single-use containers of each drug entity;
4. The EDK containing controlled dangerous substances shall be closed with a tamper proof seal and kept in a located medication room, cart or closet;
5. Access to controlled dangerous substances stored in an EDK shall be limited to the pharmacist, a practitioner, the director of nursing services, or the registered nurse or licensed practical nurse on duty;
6. Controlled dangerous substances stored in an EDK shall be administered to a patient only by authorized personnel and only as expressly authorized by an individual practitioner and in compliance with the provisions of 21 CFR 1306.11 and 21 CFR 1306.21 or their successors;
7. A usage record shall be retained in the EDK for each separate drug included which shall be completed by the nursing staff when retrieving any controlled dangerous substance(s) from the EDK;
8. The pharmacist at the provider pharmacy shall receive and retain all completed usage records for a minimum of two years;
9. When the EDK is opened:
    a. The pharmacist shall be notified by the facility within 24 hours; and
    b. Shift counts shall be performed by the nursing staff on all controlled dangerous substances until the kit is resealed by the pharmacist.
10. Shift counts of the controlled dangerous substances contained in the EDK shall not be required when the EDK is sealed;
11. The pharmacist shall check the controlled dangerous substances in the EDK at least monthly and so document that check inside the kit.

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, amended LR 39:312 (February 2013), amended by the Department of Health, Board of Pharmacy, LR 46:584 (April 2020).

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 of this Part.

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, amended by the Department of Health, Board of Pharmacy, LR 46:584 (April 2020).

§1719. Definitions

A. As used in this Subchapter, the following terms shall have the meaning ascribed to them in this Section:

Administer or Administration – 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 – 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 – 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 – 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.

Patient or Client – 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 – 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, amended by the Department of Health, Board of Pharmacy, LR 46:584 (April 2020).

§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 this Part.

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, amended by the Department of Health, Board of Pharmacy, LR 46:584 (April 2020).

§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 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, amended by the Department of Health, Board of Pharmacy, LR 46:584 (April 2020).