

**Louisiana Administrative Code**  
**Title 46 – Professional and Occupational Standards**  
**Part LIII: Pharmacists**

So frequently we use the term institutional as another word for hospital, but it is not used that way here.

**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.

So can a community pharmacy fill medications for an institutional patient?

**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.

Think of this as an automated medication system that was covered in Chap 12, without the automation.

Can all of this information fit on a small label?

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.

So if you have a crash cart in your business, you better get a permit.

July 2008

Now this is interesting, so the PIC of the pharmacy that makes tons of EDKs for nursing homes must keep track of everyone....

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.

Key word here is dispensed, if the DATC only writes orders, no need for this permit.

### **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.

So this is a cost cutting measure, however I wonder if it is ever used.

Unlike other pharmacies where we put Lortabs with the cough medicine? Sarcasm.

They said penal.

So if you relabel it, how will you know that it had already been labeled for some else?

- 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).