Louisiana Administrative Code

Title 46 – Professional and Occupational Standards

Part LIII: Pharmacists

Chapter 18. Penal Pharmacy

§1801. Penal Pharmacy Permit

A. A penal pharmacy permit shall be required to operate a pharmacy located within a penal institution, to provide medications and pharmacy care for offenders residing in that institution or another penal institution owned and operated by that governmental organization. The pharmacy in the penal institution may also provide medications and pharmacy care to offenders assigned to that institution and residing at home or another housing location.

B. In the event a pharmacy located outside a penal institution intends to provide medications and pharmacy care on a contractual basis to offenders residing in, or assigned to, a penal institution, that pharmacy shall first obtain a penal pharmacy permit.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1226.3.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 38:1236 (May 2012).

§1803. Permit Application Procedures

A. Application for Initial Issuance of Permit
   1. The applicant for a penal pharmacy permit shall complete the application form supplied by the board and submit it with the required attachments and appropriate fees, as set forth in R.S. 37:1184, to the board.
   2. Once received by the board, an application for the permit shall expire one year thereafter. Fees attached to an expired application shall be forfeited by the applicant and deposited by the board.
   3. The board shall not process applications received by facsimile, or that are incomplete, or submitted with the incorrect fees.
   4. The applicant may be required to personally appear before the board or one of its committees prior to any decision on the permit application.
   5. The applicant shall be required to submit to the criminal history record check process used by the board, unless waived by the board.

B. Application for Renewal of Permit
   1. Without respect to the date of initial issuance, a penal pharmacy permit shall expire at midnight on December 31 of every year, unless surrendered, suspended, or revoked sooner in accordance with the Pharmacy Practice Act or these rules.
   2. A penal pharmacy shall not operate with an expired permit.
   3. The pharmacy shall complete the renewal application form supplied by the board and submit it with any required attachments and appropriate fees on or before the expiration date.
   4. The board shall not process applications received by facsimile, or that are incomplete, or submitted with the incorrect fees.

C. Application for Reinstatement of Expired Permit
   1. The applicant shall complete an application form for this specific purpose supplied by the board and submit it with any required attachments and appropriate fees to the board.
   2. The board shall not process applications received by facsimile, or that are incomplete, or submitted with the incorrect fees.
   3. An application for the reinstatement of a permit which has been expired:
      a. Less than one year may be approved by the board's administrative personnel.
      b. More than one year but less than five years may be approved by a member of the board charged with such duties.
      c. More than five years may only be approved by the full board following a hearing to determine whether the applicant is competent to operate the pharmacy and whether the reinstatement is in the public's best interest.
   4. Applications requiring a reinstatement hearing shall be accompanied by payment of the administrative hearing fee authorized by R.S. 37:1184.

D. Application for Reinstatement of Suspended or Revoked Permit
   1. The applicant shall complete an application form for this specific purpose supplied by the board and submit it with any required attachments and appropriate fees to the board.
   2. The board shall not process applications received by facsimile, or that are incomplete, or submitted with the incorrect fees.
   3. The application may only be approved by the full board following a hearing to determine whether the applicant is competent to operate the pharmacy and whether the reinstatement is in the public's best interest.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1226.3.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 38:1236 (May 2012).

§1805. Maintenance of Permit

A. A penal pharmacy permit is valid only for the entity to whom it is issued and shall not be subject to sale, assignment or other transfer, voluntary or involuntary, nor shall a permit be valid for any premises other than the business location for which it is issued.
B. The owner of the pharmacy shall appoint a Louisiana-licensed pharmacist as the pharmacist-in-charge of the permit. The owner of the pharmacy and the pharmacist-in-charge shall comply with the provisions of *§1105 – Pharmacist-in-Charge* of the board's rules.
C. A pharmacy contemplating permanent closure of its prescription department shall comply with the provisions of *§1133 – Pharmacy Closing Procedures* of the board's rules.
D. A pharmacy contemplating a change in ownership shall comply with the provisions of *§1135 – Pharmacy Change of Ownership Procedures* of the board's rules.
E. A pharmacy contemplating a change in location shall comply with the provisions of *§1137 – Pharmacy Change of Location Procedures* of the board's rules.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1226.3.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 38:1236 (May 2012).

§1807. Prescription Department Requirements

A. The prescription department of a penal pharmacy shall comply with the minimum specifications identified in *§1103 – Prescription Department Requirements* of the board's rules.
B. To ensure adequate access to medications and pharmacy care, the prescription department of a penal pharmacy shall be open for business a minimum of ten (10) hours per week, with said business hours posted at the pharmacy entrance.
C. A pharmacist shall be on duty at all times during regular operating hours of the pharmacy. When the pharmacy is closed, a pharmacist shall be available for emergency calls.
D. In the absence of a pharmacist, there shall be no access to the prescription department.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1226.3.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 38:1237 (May 2012).

§1809. Drug Distribution Control

A. The pharmacist-in-charge shall be responsible for the safe and efficient procurement, receipt, storage, distribution, control, accountability, and patient administration and management of all drugs used in the penal institution. The administration and staff of the institution shall cooperate with the pharmacist-in-charge in meeting drug control requirements in ordering and accounting for drugs.
   1. The pharmacist-in-charge shall maintain a written policy and procedure manual for the safe and efficient distribution of drug products and delivery of pharmacy care. A copy of the current version of the manual shall be available for board inspection upon request.
   2. The pharmacist-in-charge shall be responsible for making and keeping pharmacy records in compliance with the provisions of §1119 – 1129 of the board's rules.
   3. The procurement, storage, security, and recordkeeping of controlled substances shall be in compliance with the provisions of *Chapter 27 – Controlled Dangerous Substances* of the board's rules.

B. The pharmacy may utilize automated medication systems, but only in compliance with *Chapter 12 – Automated Medication Systems* of the board's rules.
C. The penal pharmacy located within a penal institution may utilize drug cabinets located outside the prescription department of that institution to provide access to a limited inventory of medications when the prescription department is closed.
   1. A drug cabinet is intended solely for the proper and safe storage of needed drugs when the pharmacy is closed, and such drugs shall be available for emergency use only by authorized institution personnel.
   2. The drug cabinet shall be a securely constructed and locked enclosure located outside the prescription department ensuring access by authorized personnel only.
   3. 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 stored therein. Medications shall be available in quantities sufficient only for immediate therapeutic needs.
   4. Medications stored in a drug cabinet shall bear a legible label with the following minimum information:
      a. Drug name, strength, and dosage form;
      b. Name of manufacturer or distributor and their lot or batch number;
      c. Expiration date, in compliance with the relevant standards from the United States Pharmacopeia (USP);
      d. For prepackaged medications, the pharmacy's lot number and initials of the pharmacist.
   5. Documented orders from the medical practitioner and proof of use records shall be provided when any medications are removed from the drug cabinet.
   6. The pharmacy shall inspect medications stored in a drug cabinet on a periodic basis, but no more than thirty days since the previous inspection.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1226.3.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 38:1237 (May 2012).

§1811. Definitions

A. As used in this Section, the following terms shall have the meaning ascribed to them in this Subsection:
   Emergency Drug Kit (EDK) – a container holding designated emergency drugs which may be required to meet the immediate therapeutic needs of an offender.
   Emergency Drugs – those drugs which may be required to meet the immediate therapeutic needs of an offender and which are not available from any other authorized source in sufficient time to prevent risk of harm to the offender because of a delay resulting from obtaining such medications from such other source.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1226.3.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 38:1237 (May 2012)

§1813 Emergency Drug Kit Permit

A. A penal pharmacy located outside a penal institution intending to use one more emergency drug kits within the penal institution shall first obtain an EDK permit from the board.
B. Application for Initial Issuance of Permit
   1. The penal pharmacy shall apply to the board for the permit.
   2. The applicant shall complete the application form supplied by the board and submit it with the required attachments and appropriate fees, as set forth in R.S. 37:1184, to the board.
   3. Once received by the board, an application for the permit shall expire one year thereafter. Fees attached to an expired application shall be forfeited by the applicant and deposited by the board.
   4. The board shall not process applications received by facsimile, or that are incomplete, or submitted with the incorrect fees.
C. Application for Renewal of Permit
   1. Without respect to the date of initial issuance, an EDK permit shall expire at midnight on June 30 of every year, unless relinquished, surrendered, suspended, or revoked sooner in accordance with the Pharmacy Practice Act or these rules.

2. An EDK shall not be maintained or used with an expired permit.
3. The penal pharmacy shall complete the renewal application form supplied by the board and submit it with any required attachments and appropriate fees on or before the expiration date.
4. The board shall not process applications received by facsimile, or that are incomplete, or submitted with the incorrect fees.

D. Application for Reinstatement of Expired Permit
1. The applicant shall complete an application form for this specific purpose supplied by the board and submit it with any required attachments and appropriate fees to the board.
2. The board shall not process applications received by facsimile, or that are incomplete, or submitted with the incorrect fees.
3. An application for the reinstatement of an EDK permit which has been expired:
   a. Less than one year may be approved by the board's administrative personnel.
   b. More than one year but less than five years may be approved by a member of the board charged with such duties.
   c. More than five years may only be approved by the full board following a hearing to determine whether the reinstatement of the permit is in the public's best interest.
4. Applications requiring a reinstatement hearing shall be accompanied by payment of the administrative hearing fee authorized by R.S. 37:1184.

E. Maintenance of Permit
1. EDK permits are specific to a penal institution and they are not transferable.
2. In the event multiple kits are required for a penal institution, a separate permit shall be required for each EDK.
3. The original EDK permit shall be displayed in the penal pharmacy supplying the EDK, and a copy of the permit shall be maintained in the room or area where the EDK is located.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1226.3.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 38:1237 (May 2012)

§1815 Emergency Drug Kit Requirements

A. The EDK shall be tamper-evident, shall be maintained in a secure enclosure located within the penal institution, and shall be available for emergency use by authorized personnel only.

B. The EDK shall be clearly labeled to indicate it is an emergency drug kit, and further, the attached exterior label shall identify the inventory of contents as well as contact information for the penal pharmacy responsible for maintaining the kit.

C. Medications stored in an EDK shall bear a label with the following minimum information:
1. Drug name;
2. Dosage form;
3. Drug strength;
4. Name of manufacturer and/or distributor;
5. Manufacturer's lot or batch number; and
6. Expiration date, according to relevant standards from the United States Pharmacopeia (USP).

D. The EDK shall be stored in a proper environment for the preservation of the drugs contained therein, in compliance with the relevant USP standards. In the event federal or state laws or rules require storage outside the EDK for one or more drugs in the EDK, documentation shall be maintained with the EDK properly identifying this special storage requirement and the drug(s) affected.

E. The penal institution and penal pharmacy shall maintain policies and procedures to implement and maintain these requirements. These policies and procedures may be maintained in written or electronic format and shall be available for review by the board or its agents.

F. When an authorized prescriber issues an order for the administration of a drug contained within the EDK, the order and proof of use shall be delivered in written or electronic format to the penal pharmacy; further, such records shall contain the following minimum information:
1. Name of offender;
2. Drug name, strength, and quantity;
3. Nature of the emergency;
4. Time and date of administration;
5. Name of prescriber authorizing the medication; and
6. Name of person administering the medication.

G. The penal pharmacy shall inspect the EDK periodically, but in no event more than thirty days after the previous inspection. Proper documentation of these inspections, EDK inventory, and all records of use shall be maintained by the penal pharmacy and available for review by the board or its agents.
H. The EDK shall be available for inspection by the board or its agents.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1226.3.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 38:1238 (May 2012)

1817. Drug Donations to Penal Pharmacies

A. A penal pharmacy may accept the donation of a prescription drug, except a controlled substance, previously dispensed to another patient provided the following procedures are satisfied:
   1. The physical transfer of the donated drug shall be accomplished by an individual authorized to do so by the penal pharmacy.
   2. An inventory list of the drugs being donated shall accompany the drugs received in the penal pharmacy; the list shall contain, at a minimum, the name and strength of the drug, the quantity received, and expiration date. The penal pharmacy receiving the donated drugs shall maintain this list as an acquisition record.
   3. The penal pharmacy shall not knowingly accept the donation of any expired drugs. In the event expired drugs are received by a penal pharmacy, the pharmacist-in-charge shall destroy them as required by law.
   4. The patient's name, prescription number, and any other identifying marks shall be obliterated from the packaging prior to its receipt in the penal pharmacy.
   5. The drug name, strength, and expiration date shall remain on the medication package or label.
B. The pharmacist-in-charge of the penal pharmacy receiving donated drugs shall be responsible for determination of suitability of the drug product for reuse.
   1. No product where integrity cannot be assured shall be accepted for re-dispensing by the pharmacist.
   2. A re-dispensed prescription medication shall be assigned the expiration date stated on the package.
   3. No product shall be re-dispensed more than one time.
C. Once accepted by the penal pharmacy, under no circumstances may the donated drugs be transferred to another location.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1226.3.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 38:1238 (May 2012).

§1819. Medication Use Procedures

A. The pharmacist shall review the practitioner's medical order or prescription prior to dispensing or otherwise provide access to the initial dose of the medication, except in cases of emergency.
B. All drugs dispensed by the pharmacy or held for administration to offenders at the institution shall be packaged in appropriate containers that comply with the relevant standards of the USP.
C. The compounding of drug preparations shall comply with the relevant standards of the USP, as well as the provisions of §2531 – 2537 of the board's rules.
D. All drugs dispensed by the pharmacy, intended for use within the penal institution, shall be labeled as to identify the offender's name and location as well as the drug name and strength. Further, compounded preparations shall include the expiration date or beyond-use date, initials of the preparer, and initials of the pharmacist performing the final check on the label.
E. Drugs dispensed by the penal pharmacy may be returned to that penal pharmacy for re-use, in accordance with good professional practice procedures, subject to the following limitation.
   1. Drugs returned to the penal pharmacy for re-use shall not be further distributed to another entity.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1226.3.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 38:1239 (May 2012).