Louisiana Administrative Code

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 and records not specifically stated in this Chapter, refer to Chapters 11 and 25 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 14:808 (October 1988), effective January 1, 1989, amended LR 29:2093 (October 2003), effective January 1, 2004, LR 38:1235 (May 2012), amended by the Department of Health, Board of Pharmacy, LR 46:582 (April 2020).

§1503. Definitions

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

CFR – Code of Federal Regulations.

Electronic drug record keeping system – 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.

Hospital Off-Site Satellite Pharmacy – a pharmacy located within a hospital licensed by the Louisiana Department of Health, or its successor, the location of which is physically separate from the location of the provider pharmacy.

Hospital Patient – a person receiving health care services within a hospital facility, or an animal receiving veterinary care within a veterinary teaching hospital owned or operated by a public university in this state.

Hospital Pharmacy – a pharmacy department permitted by the board and located in a hospital licensed pursuant to R.S. 40:2100 *et seq* or in a veterinary teaching hospital owned or operated by a public university in this state. For the purposes of this Chapter, a hospital pharmacy is one example of a primary care treatment modality pharmacy.

Password – a private identification that is created by a user to obtain access to an electronic drug record keeping system.

Personal identifier – 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

Positive identification –

1. has the same meaning as defined in Section 1119 of this Part, 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 the prescribing and administration of a drug, provided the pharmacist-in-charge has determined:
    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 the 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 all three provisions cited above in this definition are being fulfilled and reviewed; and
    e. appropriate policies and procedures are in place to address all four provisions cited above in this definition.
2. All of the above notwithstanding, however, positive identification as defined in Section 1119 of this Part shall always be used to document the:
    a. Dispensing, compounding, or prepackaging of a drug;
    b. Removal and possession of a controlled substance to administer to a patient; and
    c. Waste of a controlled substance.

Provider Pharmacy – a hospital pharmacy which provides administrative control, staffing as well as products and services to a hospital off-site satellite pharmacy.

Registered Patient – A person receiving health care services within a hospital facility, or an animal receiving veterinary care within a veterinary teaching hospital owned or operated by a public university in this state.

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, LR 33:1132 (June 2007), LR 39:1282 (May 2013), LR 40:2256 (November 2014), effective January 1, 2015, LR 41:2147 (October 2015), amended by the Department of Health, Board of Pharmacy, LR 46:583 (April 2020), LR 46:973 (June 2020).

§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 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 29:2093 (October 2003), effective January 1, 2004, LR 33:1132 (June 2007), amended by the Department of Health, Board of Pharmacy, LR 46:583 (April 2020).

§1507. Pharmacist-in-Charge

Repealed.

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

§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 be responsible for maintaining the following records:
        a. A record of all drugs procured, the quantity received, and the name, address and wholesale distributor license number of the person from whom the drugs were procured.
        b. All drug orders and records relating to the practice of pharmacy.
            i. 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 hospital patient to whom, or for whose use, the drug was dispensed; and
                (d) Positive identification of all pharmacists involved in the dispensing.
            ii. All other records relating to the practice of pharmacy other than dispensing shall include, but are not limited to:
                (a) The name of the hospital patient to whom, or for whose benefit, the activity was performed.
                (b) The nature of the pharmacy practice 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.

iii. Records of drugs dispensed to patients for use outside the hospital shall be maintained in compliance with Section 1123 of this Part.

c. A record of all drugs compounded or prepackaged for use only within the hospital, which shall include at least the following:
   i. Name of drug, strength, quantity, and dosage form;
   ii. Manufacturer's or distributor's control number (except for patient-specific sterile compounded preparations);
   iii. Manufacturer's or distributor's name, if a generic drug is used;
   iv. Pharmacy control number;
   v. Manufacturer's distributor's expiration date (except for patient-specific sterile compounded preparations);
   vi. Pharmacy's expiration date or beyond-use date;
   vii. Identification of the licensed person responsible for the compounding or prepackaging of the drug.

d. A record of the distribution of drugs to patient care areas and other areas of the hospital held for administration, which shall include at least the following:
   i. The name, strength, dosage form, and amount of the drug distributed;
   ii. The area receiving the drug;
   iii. The date distributed;
   iv. Identification of the individual receiving the drug if it is a controlled dangerous substance;
   v. The area of the hospital receiving the controlled dangerous substance 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 shall be maintained of all changes made to a drug record in an electronic drug recordkeeping system after a drug transaction has been made. The log shall contain at least, but is not limited, to the following:
   i. Date and time of the change;
   ii. Changes made;
   iii. Person making the change.

B. Automated Medication Systems. A hospital pharmacy may use one or more automated medication systems in compliance with the provisions of Chapter 12 of this Part.
   1. When the pharmacy uses an electronic product verification process as described in Section 1217 of this Part, and in the absence of any subsequent human intervention in the automated drug product selection process, the pharmacist-in-charge may elect to forego manual checks of drug products selected in that manner, provided however, that such selection by the pharmacist-in-charge shall require an initial quality assurance validation followed by an ongoing quality review at intervals no greater than 90 days since the previous review, all conducted by a pharmacist.
   2. The pharmacist-in-charge remains accountable to the Board for the accuracy of all drug distribution activities.

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, amended LR 40:2257 (November 2014), effective January 1, 2015, LR 41:1488 (August 2015), amended by the Department of Health, Board of Pharmacy, LR 46:583 (April 2020).

§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.

§1512. Hospital Pharmacy Prepackaging

A. Prepackaging is the preparation of medication in a unit-of-use container by credentialed pharmacy personnel in a pharmacy prior to the receipt of a prescription or medical order for ultimate issuance by a pharmacist in Louisiana.

B. Labeling. The label on the prepackaged container shall contain the following minimum information:
   1. Drug name;
   2. Dosage form;
   3. Strength;
   4. Quantity dispensed when appropriate;
   5. Special storage requirements;
   6. A unique pharmacy prepackage lot number which shall correspond to the following:
      a. Name of manufacturer and/or distributor;
      b. Manufacturer's lot or batch number;
      c. Date of preparation; and
      d. Verifying pharmacist's initials.
   7. Expiration date, according to United States Pharmacopeia (USP) guidelines.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 38:1235 (May 2012).

§1513. Labeling

A. All drugs dispensed or compounded 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 date 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, LR 38:1235 (May 2012).

§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.
   1. Within a veterinary teaching hospital owned or operated by a public university in this state, the pharmacist-in-charge shall approve policies and procedures detailing the person(s) authorized to access the pharmacy after-hours.

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 30 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, amended by the Department of Health, Board of Pharmacy, LR 46:587 (April 2020).

§1519. Drug Returns; Drug Disposal

A. In a hospital with a permitted hospital pharmacy on site, drugs may be returned to the pharmacy for re-dispensing in accordance with good professional practice standards.
B. When a patient or his designee wishes to return previously dispensed prescription drugs to a pharmacy for disposal, the pharmacy shall inform the patient or his designee of the disposal mechanisms available to him. In the event the pharmacy elects to accept such previously dispensed products for disposal, the pharmacy shall comply with the following requirements:
   1. From the time of receipt of such products until the time of disposal, the pharmacy shall quarantine such products to keep them separate from its active dispensing stock and shall take appropriate security measures to prevent the theft or diversion of such products.
   2. The pharmacy shall comply with the provisions of 21 CFR §1317 or its successor for the pharmacy's disposal of controlled substances and other non-hazardous waste pharmaceuticals.
   3. The pharmacy shall comply with the provisions of 40 CFR §261 or its successor for the pharmacy's disposal of hazardous waste pharmaceuticals.

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, amended by the Department of Health, Board of Pharmacy, LR 46:973 (June 2020).

§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 USC §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 USC §13(c), 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. Hospital Off-Site Satellite Pharmacy

A. Issuance and Maintenance of Permit
   1. A hospital pharmacy may establish a hospital off-site satellite pharmacy within a facility bearing the same hospital license number as the facility housing the provider pharmacy.
   2. The provider pharmacy, acting through its pharmacist-in-charge, shall make application for the satellite pharmacy permit using a form and process specified by the board.
   3. The applicant shall pay the fee for the initial issuance and renewal as specified in R.S. 37:1184.
   4. Once issued, the satellite pharmacy permit shall expire at midnight on December 31 of each year, unless suspended or revoked earlier by the board.
   5. The satellite pharmacy shall renew its permit using the form and process specified by the board.
   6. The operation of a hospital off-site satellite pharmacy without a pharmacy permit, or with an expired permit, shall constitute a violation of R.S. 37:1241(A)(12).
   7. In the event a provider pharmacy sustains a change of ownership sufficient to require a new pharmacy permit, the hospital off-site satellite pharmacy shall also obtain a new pharmacy permit.
   8. In the event a provider pharmacy closes permanently and surrenders its permit, the hospital off-site satellite pharmacy shall also close and surrender its permit.

B. General Requirements
   1. The hospital off-site satellite pharmacy shall be of sufficient size and shall contain sufficient fixtures, equipment and supplies commensurate with the scope of practice for that pharmacy, provided:
      a. The pharmacy shall be of sufficient size to allow for the safe and proper storage of prescription drugs and/or controlled substances;
      b. All areas where drugs and devices are stored shall be dry, well-lighted, well ventilated, and maintained in a clean and orderly condition, and more specifically, storage areas shall be maintained at temperatures which will ensure the integrity of drugs prior to their dispensing as stipulated by the United States Pharmacopeia (USP) and/or the manufacturer's or distributor's product labeling unless otherwise indicated by the board.
      c. The pharmacy shall be secured by either a physical barrier with suitable locks and/or an electronic barrier to detect entry at a time when the pharmacist is not present; and
      d. Prescription and other patient healthcare information shall be maintained in a manner that protects the integrity and confidentiality of such information.
   2. The pharmacist-in-charge of the provider pharmacy shall be responsible for all pharmacy operations involving the hospital off-site satellite pharmacy including supervision of pharmacy personnel.
   3. The hospital off-site satellite pharmacy shall have at least one licensed pharmacist on duty and physically present in the pharmacy at all times the hospital off-site satellite pharmacy is open for the transaction of business.
   4. The hospital off-site satellite pharmacy shall have a sufficient number of pharmacists on duty to operate the pharmacy competently, safely, and adequately to meet the needs of the patients of the pharmacy.
   5. When the hospital off-site satellite pharmacy is closed or there is no pharmacist on duty, other individuals shall not have access to the hospital off-site satellite pharmacy except for temporary absences as provided for in Chapter 11 of this Part.
   6. The provider pharmacy and the hospital off-site satellite pharmacy shall have:
      a. The same owner; and

b. Share a common electronic file or have the appropriate technology to allow access to sufficient information necessary or required to process a prescription or medical order.

7. The hospital off-site satellite pharmacy shall comply with the recordkeeping provisions identified in Chapter 11 of this Part.
8. The compounding of preparations in a hospital off-site satellite pharmacy shall be accomplished in compliance with the current federal standards applicable to such practices: USP Chapter 797, or its successor, for the compounding of sterile preparations, and USP Chapter 795, or its successor, for the compounding of non-sterile preparations.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 39:1283 (May 2013), amended by the Department of Health, Board of Pharmacy, LR 46:583 (April 2020).

§1527. Remote Access to Medical Orders

Repealed.

[Editor's Note: Contents transferred to Section 1145.]

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 41:2147 (October 2015), repealed by the Department of Health, Board of Pharmacy, LR 46:583 (April 2020).

§1529. Investigational Drugs

A. Where the hospital pharmacy is a participant in one or more investigational drug studies, the pharmacy may dispense investigational drug products as well as commercially available drug products to patients enrolled in a study, whether or not the patient is a registered patient of the hospital.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 46:575 (April 2020).

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